EMD Serono and MD Anderson Cancer Center Enter Three-Year Strategic Collaboration

- First company to gain access to MD Anderson's APOLLO platform, with goal of accelerating research-driven patient care
- Collaboration to accelerate development of investigational oncology/immuno-oncology compounds

(2)

ROCKLAND, Mass., Jan. 9, 2017 /PRNewswire/ -- EMD Serono, the healthcare business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada, and The University of Texas MD Anderson Cancer Center today announced a three-year strategic collaboration, with the aim of more quickly advancing the development of investigational cancer therapies in four cancers – breast, colorectal, glioblastoma and leukemia.

"This collaboration illustrates our commitment to delivering meaningful value to patients by rapidly progressing our immuno-oncology pipeline, focusing on the identification of innovative biomarkers, together with our partner, the prestigious MD Anderson Cancer Center," said Belén

EMD Serono will be the first company to gain access to the Adaptive Patient-Oriented Longitudinal Learning and Optimization Platform (APOLLO) – MD Anderson's research platform that standardizes the long-term collection of patients' medical history and data derived from tissue samples in order to better understand the biology of cancer and accelerate research-driven patient care. The collaboration will encompass both biomarker-focused pre-clinical research and clinical trials in specific tumor types aimed at identifying biomarkers of response and resistance and developing a better understanding of the disease biology.

The collaboration will enhance the value of EMD Serono's future oncology/immuno-oncology pipeline, with a goal of multiple registrational studies in novel indications in the next two to three years. Data from APOLLO will be used to match a number of investigational compounds to select tumor types for potential development and collaboratively design biomarker-driven pre-clinical and clinical studies at MD Anderson evaluating the potential therapeutic effect of the compounds – alone or in combination.

APOLLO was developed by MD Anderson as part of its Moon Shots Program, an ambitious effort to reduce cancer deaths by more rapidly developing and implementing advances in prevention, early detection and treatment based on scientific discoveries.

"Our goal when establishing the APOLLO research platform was to enable innovative solutions such as this collaboration between academia and industry to help accelerate clinical advances for the benefit of all cancer patients," said Ronald DePinho, M.D., president, MD Anderson. "This joint effort supports our mission to end cancer by addressing some of the greatest challenges in oncology today."

Merck KGaA, Darmstadt, Germany is committed to exploring an array of targets, and taking creative scientific approaches to developing novel therapies for hard-to-treat cancers. The strength of Merck KGaA, Darmstadt, Germany's promising oncology development program and growing presence in the immunotherapy space demonstrates how the company is re-imagining the way cancer care is delivered.

About MD Anderson

The University of Texas MD Anderson Cancer Center in Houston ranks as one of the world's

MD Anderson is one of only 45 comprehensive cancer centers designated by the National Cancer Institute (NCI). MD Anderson is ranked No.1 for cancer care in U.S. News & World Report's "Best Hospitals" survey. It has ranked as one of the nation's top two hospitals since the survey began in 1990, and has ranked first for nine of the past 10 years. MD Anderson receives a cancer center support grant from the NCI of the National Institutes of Health (P30 CA016672).

About EMD Serono, Inc.

EMD Serono is the healthcare business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has 1,200 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.
www.emdserono.com

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2015, Merck KGaA, Darmstadt, Germany, generated sales of € 12.85 billion in 66 countries.

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Merck KGaA, Darmstadt, Germany, Licenses Four Oncology Research and Development Programs from Vertex and Becomes a Leader in DNA Damage and Repair

- Merck KGaA, Darmstadt, Germany licenses two promising clinical-stage programs targeting DNA damage and repair, and two novel pre-clinical programs
- All programs have first-in-class and best-in-class potential
- Vertex receives upfront payment of $230 million plus royalties on future sales

DARMSTADT, Germany, Jan. 11, 2017 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates its biopharmaceutical business in the US and Canada as EMD Serono, today announced that it has entered into a licensing agreement with Vertex Pharmaceuticals Incorporated, Boston, USA, for the worldwide development and commercialization of four promising research and development programs that represent novel approaches to the treatment of cancer.

"With this strategic deal, we significantly strengthen our oncology pipeline in two attractive areas where we have leading competence, DNA damage and repair and immuno-oncology—areas which also have promising therapeutic synergy," says Belén Garijo, CEO Healthcare and

opportunity to build on Vertex's rigorous science and advance these leading programs."

As part of the agreement, Merck KGaA, Darmstadt, Germany will license two clinical-stage programs targeting DNA damage and repair, along with two additional novel pre-clinical programs. Vertex will receive an upfront payment of $230 million, in addition to royalties on future net sales. Merck KGaA, Darmstadt, Germany will assume full responsibility for the development and commercialization of all the programs.

"The Vertex R&D team has produced a portfolio of first-in-class compounds with the potential to enhance the therapy of multiple cancers," said Jeffrey Leiden, Chairman, President and CEO of Vertex. "We are pleased to partner with Merck KGaA, Darmstadt, Germany, a leader in oncology with exciting complementary assets that will help fully realize the value of these unique compounds and accelerate the programs' potential benefits for patients."

The two clinical-stage programs represent first-in-class approaches to inhibit the DNA repair pathways that are fundamental to the survival and proliferation of certain cancers:

- An ataxia telangiectasia and Rad3 related (ATR) program comprised of two compounds, VX-970 and VX-803. VX-970 is being investigated broadly through 10 ongoing Phase 1 and Phase 2 trials across a variety of tumors and patient subtypes expected to be responsive to ATR inhibition based on biomarker data. Preliminary VX-970 clinical data were presented at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting and the 2016 American Association for Cancer Research (AACR) Annual Meeting. VX-803 is an orally dosed ATR inhibitor currently in Phase 1 trials evaluating escalating doses of VX-803 alone and in combination with chemotherapy.
- A DNA-dependent protein kinase (DNA-PK) inhibitor program including the clinical candidate VX-984. A Phase 1 trial is now evaluating escalating doses of VX-984 alone and in combination with pegylated liposomal doxorubicin in subjects with advanced solid tumors. Merck KGaA, Darmstadt, Germany will combine these assets with its existing DNA-PK assets into a single development program.

The pre-clinical programs include one immuno-oncology program against an attractive target with first-in-class potential, and a program against a completely novel target. For both of these programs, Vertex research has demonstrated efficacy in relevant pre-clinical models, including demonstration of combination potential with immune checkpoint inhibition for the immuno-oncology program. Merck KGaA, Darmstadt, Germany will continue to characterize the Vertex compounds in these programs with the goal of taking them forward into the clinic.

imagining the way cancer can be treated.

About Vertex

Vertex is a global biotechnology company that aims to discover, develop and commercialize innovative medicines so people with serious diseases can lead better lives. In addition to our clinical development programs focused on cystic fibrosis, Vertex has more than a dozen ongoing research programs aimed at other serious and life-threatening diseases.

Founded in 1989 in Cambridge, Mass., Vertex today has research and development sites and commercial offices in the United States, Europe, Canada and Australia. For seven years in a row, Science magazine has named Vertex one of its Top Employers in the life sciences. For additional information and the latest updates from the company, please visit www.vrtx.com.

About EMD Serono, Inc.

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SOURCE Merck KGaA, Darmstadt, Germany

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Merck KGaA, Darmstadt, Germany, and Palantir Launch New Healthcare Acceleration Partnership

- Collaboration of big data-driven initiatives
- Partners seek to revolutionize delivery of patient services

PALO ALTO, Calif. and DARMSTADT, Germany, Jan. 12, 2017 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced a partnership with Palantir Technologies, developer of the world's most sophisticated data integration and analysis software, at Palantir's headquarters in Palo Alto, California. The partnership will leverage Palantir's advanced data analytics capabilities to help Merck KGaA, Darmstadt, Germany, better and more rapidly develop and deliver medicines to patients, commercialize new products, and improve patient outcomes. Initially Merck KGaA, Darmstadt, Germany, will apply Palantir's technology to cancer treatment and patient services. Ultimately Merck KGaA, Darmstadt, Germany, plans to deploy Palantir's technology across all three of the company's business sectors Healthcare, Life Science and Performance Materials. Financial details were not disclosed.

"As a science and technology company, we are tackling the greatest challenges in healthcare, life science and performance materials. Now we are teaming up with Palantir since developing

Board and CEO of Merck KGaA, Darmstadt, Germany, during the announcement of this partnership on Thursday.

"At the heart of Palantir's mission is the desire to bring new tools to solve the world's most difficult problems," said Alexander Karp, founder and CEO of Palantir. "When something like cancer is killing 8.2 million people each year, we want to do everything we can to apply our technological expertise to the fight, alongside partners who have been there since the beginning. We are pleased to have found a partner that shares our values and vision."

The partnership will launch with three initiatives within the Healthcare business sector of Merck KGaA, Darmstadt, Germany.

- Medical Research & Drug Development: The partnership will increase precision of the drug development process by developing a collaborative data and analytics platform so that researchers of Merck KGaA, Darmstadt, Germany, can analyze real-world and bioinformatics data to understand the patients who may benefit most.
- Global Patient Intimacy: The partnership will improve the experience of patients using products of Merck KGaA, Darmstadt, Germany, by utilizing large-scale data sources to increase adherence and understand real-world drug efficacy.
- Global Supply Chain: The data and analytics platform of Merck KGaA, Darmstadt, Germany, and Palantir will improve supply chain forecasting and agility in order to provide medicines to patients around the world with maximum speed and reliability.

Biomedical research generates unprecedented volumes of rapidly evolving data every day. But accessing, learning from, and expanding on those assets has become a huge bottleneck in scientists' ability to bring new innovations from the bench to the bedside. Through their combined expertise, Merck KGaA, Darmstadt, Germany, and Palantir will aim to harness the power locked inside that data for the benefit of patients.

Palantir

Palantir Technologies is a leading data integration platform. Palantir's software products are currently deployed by financial institutions, NGO's, government agencies and other organizations to solve mission critical data driven problems in intelligence, defense, law enforcement, data protection, health care and global finance among other areas. Palantir's platofrm is built to manage sensitive information while giving institutions the tools to effectively protect privacy.

Merck KGaA, Darmstadt, Germany

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SOURCE Merck KGaA, Darmstadt, Germany

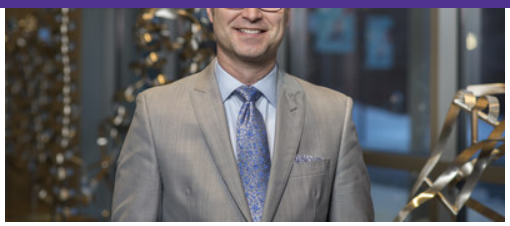
Richard R. Smith Joins EMD Serono as Senior Vice President and Head of US Fertility and Endocrinology

Smith brings more than 20 years of industry experience to the EMD Serono leadership team

(1)

ROCKLAND, Mass., Jan. 17, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced that Richard R. Smith has joined the company as Senior Vice President and Head of US Fertility and Endocrinology. In this role, Mr. Smith will oversee the Fertility and Endocrinology businesses in the U.S., including the U.S. Fertility Technologies division, which launched its first product last year with Gidget™, a hand-held witnessing system for the IVF laboratory that provides visual lab workflow management and support for traceability and audit reporting.

Mr. Smith joins EMD Serono from Novartis, where he was most recently Vice President and US Head of Sales & Operations of the Cardiovascular franchise. During his 18 years with Novartis, Mr. Smith held roles of increasing responsibility across the commercial business including Executive Director and Head of the organization's Transplant franchise as well as positions in



Managed Markets strategy, pricing and contracting for the Neuroscience franchise. He began his career at Novartis as a sales representative.

"We have a longstanding focus on providing comprehensive solutions in the areas of fertility and endocrinology care through innovative products as well as financial, educational and emotional support," said Gary Zieziula, President and Managing Director of EMD Serono. "Adding Richard's expertise, passion and industry knowledge to our strong and committed team will ensure that we are well-positioned to further meet the needs of patients and customers."

EMD Serono is a long-standing leader in commercializing biologic and specialty pharmaceuticals in fertility and endocrinology. EMD Serono's GONAL-*f*® [follitropin alfa for injection] is the world's first and most-widely prescribed recombinant human follicle stimulating hormone (r-hFSH). In 2016, EMD Serono celebrated the 20th anniversary of the U.S. Food and Drug Administration's approval of Serostim® [somatropin (rDNA origin) for injection]. Serostim® has been an important treatment for a subset of HIV positive patients affected by HIV Associated Wasting. EMD Serono also markets Saizen® [somatropin (rDNA origin) for injection] for the treatment of growth hormone deficiency.

Mr. Smith succeeds Craig Millian, who was recently appointed Senior Vice President, U.S. Neurology and Immunology.

Mr. Smith received his Bachelor of Science (BS) in Business Management from Carson-Newman College.

CONSUMER INDICATION and IMPORTANT RISK INFORMATION
GONAL-f® (follitropin alfa for injection) and GONAL-f® RFF (follitropin alfa for injection)
IMPORTANT INFORMATION ABOUT THE PROPER USE AND RISKS OF GONAL-f® (follitropin alfa for injection) and GONAL-f® RFF* (follitropin alfa for injection)

What are the uses of Gonal-f® (follitropin alfa for injection) and Gonal-f® RFF* (follitropin alfa for injection)?

a group of human reproductive hormones.

Gonal-f® Multi-Dose and Gonal-f® RFF are used in certain infertile women to help with ovulation (production and release of a mature egg) and pregnancy. Gonal-f® will not help women whose ovaries no longer work because of a condition called Primary Ovarian Failure. Gonal-f® may also be used in women who are in an Assisted Reproductive Technology (ART) program such as *in vitro* fertilization to help their ovaries make more eggs.

Gonal-f® Multi-Dose can also be prescribed to increase sperm production in men with a rare condition that affects sperm production.

Both products should be prescribed only by doctors specializing in infertility problems and their treatment.

Who should not use Gonal-f® and Gonal-f® RFF?

Gonal-f® Multi-Dose and Gonal-f® RFF should not be used in patients who are pregnant or think they might be pregnant, in patients with primary ovarian failure (the ovaries no longer produce eggs), or in patients with allergies to recombinant human FSH products or any other ingredients in the medication. Patients with cancer of the sex organs or brain, or with uncontrolled thyroid or adrenal disease, should not use Gonal-f® Multi-Dose or Gonal-f® RFF. Women with a history of abnormal bleeding from the uterus or vagina or with swollen, enlarged, or painful ovaries should speak to their doctor before starting treatment.

What are the possible side effects of Gonal-f® and Gonal-f® RFF?

The lowest dose expected to achieve the desired results should be used. A doctor should monitor a woman's response often to avoid overdose, which can lead to serious side effects, including blood clots. Women should contact their doctor if severe pain or bloating in the stomach or pelvic area, severe upset stomach, vomiting, or weight gain are experienced during treatment. These could be signs of a rare but serious condition known as Ovarian Hyperstimulation Syndrome, or OHSS, which can result in hospitalization.

Use of Gonal-f® Multi-Dose or Gonal-f® RFF by a woman can be associated with fertilization of more than 1 egg. This can lead to complications for the woman and the birth of 2 or more babies.

Multi-Dose were skin pimples, breast pain and growth, and tiredness. Injections may cause some discomfort.

Full prescribing information for Gonal-f® can be found at: http://www.emdserono.com/ms.country.us/en/images/Gonal-f_RFF_Redi-ject_PI_tcm115_140008.pdf?Version=

CONSUMER INDICATION and IMPORTANT RISK INFORMATION

What is SEROSTIM® (somatropin) for injection?

Serostim is an injectable prescription medicine used for the treatment of HIV-positive patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Treatment with antiretroviral therapy at the same time is necessary.

You should not take SEROSTIM if you have:

A critical illness from surgery, serious injuries, or a severe breathing problem, cancer or undergoing treatment for cancer, eye problems caused by diabetes, allergies to growth hormone.

What should I tell my doctor before using SEROSTIM?

If you have cancer or had cancer in the past. If you have diabetes, are at risk for getting diabetes, or have blood sugar levels that are higher than normal. New cases of type 2 diabetes have been reported in patients taking Serostim. If you are allergic to growth hormone, or other ingredients such as benzyl alcohol, sucrose, phosphoric acid, sodium hydroxide, or metacresol. If you are taking any other medicines (both prescription or over the counter), vitamins, or supplements because these medicines may affect each other. Your doctor may need to adjust the dose of Serostim or other medicines you are taking. If you are nursing, pregnant, or plan to become pregnant. It is not known if Serostim passes into your breast milk or could harm your unborn baby.

What are the most common side effects of SEROSTIM reported in clinical trials in patients treated for HIV-associated wasting or cachexia?

Swelling, especially in the hands or feet. Bone, muscle, and joint pain or stiffness. Tingling and numbness. Unusual skin sensations. Breast enlargement in men. Nausea. Extreme tiredness.

Other less common but serious side effects of SEROSTIM are:

Tumors or cancerous growths. High blood sugar (hyperglycemia/diabetes) which can include

allergic reactions that require immediate medical attention. Numbness and tingling in the hand or arm caused by a pinched nerve in the wrist. Injection site reactions (such as pain, numbness, redness, and swelling). Pain and tenderness in the abdomen, which could be a sign of a problem with the pancreas.

These are not all of the possible side effects. Let your doctor know about any side effects you experience.

How should you administer Serostim?

Patients and caregivers should be trained by a healthcare professional on how to mix and inject Serostim prior to use. Never share Serostim with another person, even if the needle is changed.Full prescribing information for Serostim® can be found at: http://www.emdserono.com/ms.country.us/en/images/Serostim_PI_tcm115_140011.pdf?Version=

CONSUMER INDICATION and IMPORTANT RISK INFORMATION

What is SAIZEN® (somatropin) for injection?

Saizen is a prescription medicine that is used to treat growth hormone deficiency (GHD) in:

1. Children with growth failure who produce low amounts of growth hormone.
2. Adults with GHD that started as a child or as an adult.

Saizen is an injectable form of a protein called growth hormone that is produced by your body.

Who should not take SAIZEN?

Saizen should not be used in children after the growth plates have closed. Saizen should not be used in children and adults with any of the following medical conditions because serious side effects can occur: A critical illness from surgery, serious injuries, or a severe breathing problem. Prader-Willi syndrome who are severely overweight or have a history of breathing problems including sleep apnea. Cancer or other tumors. Allergies to growth hormone. Eye problems caused by diabetes

What should patients tell their doctor before taking SAIZEN?

If you have or had cancer as a child. There is an increased risk of getting another tumor if you are a childhood cancer survivor. If you have diabetes, are at risk for getting diabetes, or have blood sugar levels that are higher than normal. New cases of type 2 diabetes have been reported in patients taking Saizen. If you are allergic to growth hormone, or other ingredients

because these medicines may affect each other. Your doctor may need to adjust the dose of Saizen or other medicines you are taking. If you are nursing, pregnant, or plan to become pregnant. It is not known if Saizen passes into your breast milk or could harm your unborn baby

Your doctor will perform certain tests before prescribing SAIZEN and will monitor progress during the course of treatment.

What are the most common side effects of SAIZEN reported in clinical trials in patients treated for GHD?
The most common side effects reported are:
An injection site reaction such as pain, numbness, redness, and swelling. Muscle and joint pain. Tingling and numbness. Unusual skin sensations. Headache. Adults also commonly report swelling associated with fluid retention especially in the legs, arms, and face.

Other less common but serious side effects of SAIZEN are:
Tumors or cancerous growths. High blood sugar (hyperglycemia/diabetes) which can include symptoms of increased thirst and urination, tiredness, trouble concentrating and weight loss. Headaches, changes in vision, nausea or vomiting which requires immediate medical attention. Serious allergic reactions that require immediate medical attention. Hip and knee pain or a limp in children, which can be a sign that the thigh bone and hip joint may have slipped out of place. Curvature of the spine or backbone in children (scoliosis). Pain and tenderness in the abdomen, which could be a sign of a problem with the pancreas

These are not all of the possible side effects. Let your doctor know about any side effects you may experience.

How should you administer SAIZEN?
Patients and caregivers should be trained by a healthcare professional on how to mix and inject Saizen prior to use. Children should always be supervised.

Full prescribing information for Saizen® can be found at:
http://www.emdserono.com/ms.country.us/en/images/Saizen_Ce_Pi_tcm115_140010.pdf?Version=

About EMD Serono, Inc.

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SOURCE EMD Serono

Merck KGaA, Darmstadt, Germany, Announces Research Collaboration with Domain Therapeutics in Immuno-Oncology

Companies to co-develop adenosine receptor antagonists, exploring their potential in immuno-oncology

Merck KGaA, Darmstadt, Germany, to gain worldwide rights for Domain Therapeutics' next generation of adenosine receptor antagonists, complementing Merck KGaA, Darmstadt, Germany's existing immuno-oncology pipeline

Darmstadt, Germany, January 23, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates its biopharmaceutical business in the US and Canada as EMD Serono, today announced it has entered into a collaboration and licensing agreement with Domain Therapeutics, Strasbourg, France, to explore the potential of adenosine inhibition in the development of novel immuno-oncology agents. This collaboration strengthens our combination strategy in immuno-oncology, and underscores Merck KGaA, Darmstadt, Germany's science-driven approach to discovering and developing novel compounds through both internal capabilities and external collaborations.

"This new generation of adenosine receptor antagonists are an important addition to our immuno-oncology pipeline," said Laszlo Radvanyi, Senior Vice President, Head of Research in Immuno-Oncology at the biopharma business of Merck KGaA, Darmstadt, Germany. "We plan

Adenosine receptor antagonists are small molecules thought to slow tumor progression and improve the response to combination immunotherapies by inhibiting adenosine – a compound generated by cancer cells that inhibits anti-tumor responses by binding to T cells.

The agreement will involve a close collaboration between Merck KGaA, Darmstadt, Germany, and Domain Therapeutics to develop and test new agents targeting key adenosine receptors. Merck KGaA, Darmstadt, Germany, will support research activities and gain worldwide rights to Domain Therapeutics' next generation of adenosine receptor inhibitors.

"With its growing portfolio of immuno-oncology agents, Merck KGaA, Darmstadt, Germany, is the ideal partner to develop our adenosine programs," said Pascal Neuville, CEO, Domain Therapeutics. "As a strong collaborator with a leading investigational checkpoint inhibitor, we are confident that through Merck KGaA, Darmstadt, Germany, our programs will progress rapidly."

Merck KGaA, Darmstadt, Germany, is committed to exploring an array of targets, and taking creative scientific approaches to developing novel therapies for hard-to-treat cancers. The strength of Merck KGaA, Darmstadt, Germany's promising oncology development program and growing presence in the immunotherapy space demonstrates how the company is re-imagining the way cancer care is delivered.

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North American Businesses of Merck KGaA, Darmstadt, Germany Certified as 2017 Top Employer

BOSTON and MISSISSAUGA, Ontario, Feb. 8, 2017 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates as EMD Serono, MilliporeSigma and EMD Performance Materials in the United States and Canada, today announced that its North American businesses have been certified by the Top Employers Institute for exceptional employee offerings.

In addition to North America, Merck KGaA, Darmstadt, Germany has also achieved Top Employer status in the following regions where it operates businesses: Asia Pacific, Europe, Latin America and the Middle East.

"Throughout our nearly 350 year history, attracting the best and brightest talent in key regions such as North America, has been a fundamental part of what we do as a successful global company. Whether one is seeking a career in the research lab, or on the manufacturing floor, the opportunities are boundless at MilliporeSigma, EMD Serono and EMD Performance Materials in this region and this recognition only reaffirms the potential for

"We are honored to receive this official certification as all of the businesses of Merck KGaA, Darmstadt, Germany are committed to empowering our talented employees to do their best work," said Gary Zieziula, President and Managing Director of EMD Serono and the spokesperson for the North American businesses for Merck KGaA, Darmstadt, Germany. "We are focused on continuing to foster a collaborative and creative environment so our employees can grow professionally and be inspired to further our mission of creating technologies that enhance the lives of people around the world."

The annual, international research undertaken by the Top Employers Institute recognizes leading employers around the world: those that provide excellent employee conditions, nurture and develop talent throughout all levels of the organization, and which strive to continuously optimize employment practices.

This recognition follows the Massachusetts-based businesses of Merck KGaA, Darmstadt, Germany—MilliporeSigma and EMD Serono —which were named to *The Boston Globe*'s annual "Top Places to Work" list in 2016. In addition, Merck KGaA, Darmstadt, Germany, ranked number 11 among the top 20 employers in the global biopharmaceutical industry by *Science* magazine, a leading peer-reviewed international scientific publication, also in 2016.

To achieve the Top Employers certification companies undergo a stringent research process in which they are assessed on criteria including talent strategy, workforce planning, leadership development and culture.

"Optimal employee conditions ensure that people can develop themselves personally and professionally," said David Plink, CEO of the Top Employers Institute. "Our comprehensive research concluded that Merck KGaA, Darmstadt, Germany provides an outstanding employment environment, and offers a wide range of creative initiatives, from secondary benefits and working conditions, to performance-management programs that are well thought out and truly aligned with the culture of their company."

To learn more about the Top Employers Institute and the Top Employers Certification, visit: www.top-employers.com.

About EMD Serono

care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has 1,200 employees in the U.S. with commercial, clinical and research operations based in the company's home state of Massachusetts and 100 employees in Canada with its Canadian headquarters in Mississauga, Ontario. www.emdserono.com www.emdserono.ca

About MilliporeSigma

The life science business of Merck KGaA, Darmstadt, Germany, which operates as MilliporeSigma in the U.S. and Canada, has 19,000 employees and 65 manufacturing sites worldwide, with a portfolio of more than 300,000 products enabling scientific discovery. Udit Batra is the global chief executive officer of MilliporeSigma.

Merck KGaA, Darmstadt, Germany completed its $17 billion acquisition of Sigma-Aldrich in November 2015, creating a leader in the $125 billion global life science industry. MilliporeSigma is a leading supplier in the life science industry. With products for protein research and cell biology as well as the manufacture of chemical-based and biopharmaceutical drugs, MilliporeSigma covers the full bioprocessing value chain. Its aim is to solve the toughest problems in the industry by collaborating with the global scientific community.

About EMD Performance Materials

EMD Performance Materials is the North America high-tech materials business of Merck KGaA, Darmstadt, Germany, comprising a portfolio of applications in fields such as consumer electronics, semiconductors, lighting, coatings, printing technology, plastics, and cosmetics.

Key products include display materials, LED materials for lighting as well as OLED materials for lighting and displays, functional materials for solar panels and energy solutions, effect pigments as well as active ingredients and fillers for cosmetics, food and pharmaceutical products, effect pigments and functional materials for coatings, printing and plastics and high-purity specialty chemical materials for the electronics and semiconductor industry. Today, the business has about 500 employees around the country with main operations in Philadelphia (PA). For more information, please visit www.emd-pm.com.

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2015, Merck KGaA, Darmstadt, Germany, generated sales of € 12.85 billion in 66 countries.

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Merck KGaA, Darmstadt, Germany, is one of the world's leading suppliers of effect pigments for the coatings, plastics, printing, cosmetic, food and pharmaceutical industries. Effect pigments underscore the emotional impact of color and are an important design element when creating surfaces with a special appearance or quality. Application possibilities range from cars to packaging and high-tech products up to building façades. In addition to decorative effect pigments, Merck KGaA, Darmstadt, Germany, offers pigments that also have functional applications such as heat-reflecting or anti-counterfeiting pigments.

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SOURCE Merck KGaA, Darmstadt, Germany

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Cladribine Tablets Significantly Reduced Brain Atrophy in Patients with Multiple Sclerosis

EXPLORE MORE

Post hoc analysis of Phase III CLARITY study data recently published in Multiple Sclerosis Journal showed statistically significant reduction in brain atrophy in patients on a short course of investigational Cladribine Tablets over two years compared with patients receiving placebo

These findings correlated with effects on clinical progression as measured by the EDSS scale, a method of quantifying disability in multiple sclerosis

Darmstadt, Germany, 9 February 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the publication of the results of a post hoc analysis of the Phase III CLARITY study in *Multiple Sclerosis Journal*. The post hoc analysis showed that Cladribine Tablets reduced the annualised rate of brain volume loss – also known as brain atrophy – compared with placebo in patients with relapsing remitting multiple sclerosis (RRMS).

In addition, the analysis found that patients with lower rates of brain atrophy showed the highest probability of remaining free from disability progression at two years.[1] This supports existing findings that increased brain volume loss over time is associated with worse clinical

"Evidence shows that brain atrophy in general accumulates throughout the course of multiple sclerosis and is associated with disability progression. This analysis is important because it confirms the link between reduced brain atrophy and reduced disability progression found in the CLARITY study," said Nicola De Stefano, lead author of the publication and Associate Professor of Neurology, Department of Medicine, Surgery and Neuroscience, University of Siena.

The CLARITY study was a two-year (96-week), randomised, double-blind, placebo-controlled Phase III study of Cladribine Tablets in 1,326 people with RRMS. The CLARITY study primary (rate of relapse at 96 weeks) and key secondary endpoints (proportion of patients who were relapse free and the time to sustained progression of disability) were met. These outcomes and safety results were published in *The New England Journal of Medicine*.

The brain atrophy analysis evaluated the effect of Cladribine tablets on brain volume loss (BVL) over 2 years in RMS and the association of BVL with confirmed disability progression in 1,025 (77.3%) of the patients in CLARITY. The mean percentage brain volume loss per year was significantly reduced in patients treated with Cladribine Tablets 3.5 mg/kg (–0.56%±0.68, p=0.010, n=336) and 5.25 mg/kg (–0.57%±0.72, p=0.019, n=351) compared with patients treated with placebo (–0.70%±0.79, n=338). The risk of disability progression was also significantly lower in patients treated with Cladribine Tablets 3.5 mg/kg (HR 0.63, 95% CI 0.438, 0.894; p=0.010) and 5.25 mg/kg (HR 0.58, 95% CI 0.406, 0.833; p=0.003) than in those treated with placebo. After adjusting for treatment group, percentage brain volume loss per year showed a significant correlation with the cumulative probability of disability progression in the overall study population (HR 0.67, 95% CI 0.571, 0.787; p<0.0001).

"These findings reinforce and expand on the consistent and positive effect of Cladribine Tablets in improving clinically relevant outcomes, such as reducing relapse rate and disability, and further our resolve to make this investigational therapy available for patients living with RRMS," said Steven Hildemann, MD, PhD, Global Chief Medical Officer and Head of Global Medical Affairs and Safety, Merck KGaA, Darmstadt, Germany.

CLARITY study design

The CLARITY study was a two-year (96-week), randomised, double-blind, placebo-controlled, international study. It randomised 1,326 patients with relapsing remitting MS according to the

placebo tablets (1:1:1 ratio).

The primary endpoint of the CLARITY study was the relapse rate over 96 weeks. Secondary endpoints included MRI endpoints, proportion of subjects relapse-free and disability progression at 96 weeks.

Lymphopenia was the most commonly reported adverse event (AE) in patients treated with Cladribine Tablets. The incidence of infections was 48.3% with Cladribine Tablets and 42.5% with placebo, with 99.1% and 99.0% rated mild-to-moderate by investigators.

About Cladribine Tablets

Cladribine Tablets is an investigational short-course oral therapy that selectively and periodically targets lymphocytes thought to be integral to the pathological process of MS. Cladribine Tablets is currently under clinical investigation and not yet approved for the treatment for any use in the United States, Canada and Europe. In July 2016, the European Medicines Agency (EMA) accepted for review the Marketing Authorisation Application (MAA) of Cladribine Tablets for the treatment of relapsing remitting multiple sclerosis.

The clinical development program for Cladribine Tablets includes:

- The CLARITY (CLAdRIbine Tablets Treating MS OrallY) study and its extension: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with RRMS and its two-year extension designed to provide data on the long-term safety and efficacy of extended administration of Cladribine Tablets for up to four years.
- The ORACLE MS (ORAl CLadribine in Early MS) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS).
- The ONWARD (Oral Cladribine Added ON To Interferon beta-1a in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled study designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy.
- PREMIERE (Prospective Observational Long-term Safety Registry of Multiple Sclerosis Patients Who Have Participated in Cladribine Clinical Studies) study: interim long-term

total, with follow-up in some patients exceeding eight years at completion.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately 2.3 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common. Although many treatments exist there is a need for an effective therapy without the risks associated with continuous immunosuppression and which reduces the need for frequent switches.

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FDA Accepts the Biologics License Application for Avelumab for the Treatment of Metastatic Urothelial Carcinoma for Priority Review

Second Biologics License Application accepted by the FDA for avelumab

Prognosis for urothelial carcinoma is currently poor, particularly when the disease has metastasized

Rockland, MA and New York, US, February 28, 2017 – EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, and Pfizer Inc. today announced that the US Food and Drug Administration (FDA) has accepted for Priority Review EMD Serono's Biologics License Application (BLA) for avelumab* as a treatment for patients with locally advanced or metastatic urothelial carcinoma (mUC) with disease progression on or after platinum-based therapy. The FDA has set a Prescription Drug User Fee Act (PDUFA) target action date of August 27, 2017, for avelumab in this indication.

"Taken together with last year's filing for metastatic Merkel cell carcinoma, this BLA acceptance confirms our rapid and continued progress in the clinical development of avelumab," said Luciano Rossetti, M.D., Executive Vice President, Global Head of Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany. "We continue to evaluate

treatment options for fighting their disease."

Despite advances in the treatment of UC, the prognosis for patients remains poor, particularly when the disease has metastasized. Bladder cancer makes up approximately 90% of urothelial cancers and is the sixth most common cancer in the US.1,2

"Advanced urothelial carcinoma remains a difficult-to-treat tumor, which is why we are developing a comprehensive clinical development program that involves Phase I and III trials designed to address this challenge," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology, Pfizer Global Product Development. "We're continuing to accelerate our urothelial carcinoma development program and look forward to continuing our dialogue with the FDA."

Avelumab is an investigational, fully human anti-PD-L1 antibody. The FDA's Priority Review status reduces the review time from 10 months to a goal of six months from the day of filing acceptance and is given to drugs that may offer major advances in treatment or may provide a treatment where no adequate therapy exists. In November 2016, the FDA accepted, and granted Priority Review status to, the BLA for avelumab for the treatment of patients with metastatic Merkel cell carcinoma.

The international clinical development program for avelumab, known as JAVELIN, involves at least 30 clinical programs, including nine Phase III trials, and more than 4,000 patients evaluated across more than 15 tumor types. In December 2015, Merck KGaA, Darmstadt, Germany, and Pfizer announced the initiation of a Phase III study (JAVELIN Bladder 100) of avelumab in the first-line setting as a maintenance treatment in patients with locally advanced or metastatic UC. This trial is currently enrolling patients.

*Avelumab is not approved for any indication in any market. This marks the second acceptance of an application by the FDA to review the investigational product, avelumab.

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https://www.cancer.org/cancer/bladder-cancer/about/key-statistics.html. Last Accessed: February 2017.

About Metastatic Urothelial Carcinoma

Urothelial Carcinoma includes several tumors originating from the cells lining the bladder, renal pelvis and urethra. While cancers outside of the bladder are relatively uncommon, accounting for an estimated 10% of cases, bladder cancer represents 90% of urothelial cancers and is the ninth most common cancer globally.1,3 Worldwide, approximately 400,000 new cases of bladder cancer are diagnosed and 150,000 deaths are attributed to this disease each year.3 The incidence and mortality of bladder cancer have remained unchanged over the past 25 years.3

About Avelumab

Avelumab is a fully human antibody specific for a protein found on tumor cells called PD-L1, or programmed death ligand-1. By inhibiting PD-L1 interactions, avelumab is thought to enable the activation of T-cells and the adaptive immune system. By retaining a native Fc-region, avelumab is thought to potentially engage the innate immune system and induce antibody-dependent cell-mediated cytotoxicity (ADCC). In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab. Common adverse reactions include fatigue, musculoskeletal pain, diarrhea, nausea peripheral edema, decreased appetite, and rash. Immune-mediated adverse reactions have also been reported.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other’s strengths and capabilities and further explore the therapeutic potential of avelumab, an investigational anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer’s PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

science and technology company – in the US and Canada focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has 1,200 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts. www.emdserono.com

About Merck KGaA, Darmstadt, Germany

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Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines, as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases

communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of February 28, 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about avelumab (MSB0010718C), including a potential indication for avelumab for the treatment of metastatic urothelial carcinoma (the "Potential Indication"), Pfizer's and Merck, KGaA, Darmstadt, Germany's immuno-oncology alliance involving anti-PD-L1 and anti-PD-1 therapies, and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in other jurisdictions for the Potential Indication and whether and when drug applications may be filed in any jurisdictions for any other potential indications for avelumab, combination therapies or other product candidates; whether and when the BLA for the Potential Indication, the BLA and EU marketing authorization application for avelumab for the treatment of metastatic Merkel cell carcinoma or any such other applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of avelumab, combination therapies or other product candidates; and competitive developments.

including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com

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EMD Serono to Present Real-World Data Analyses at the Annual Pacific Coast Reproductive Society Meeting

EXPLORE MORE

(1)

ROCKLAND, Mass., March 22, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced two new real-world data analyses will be presented during the poster presentation session at the 65th Annual Pacific Coast Reproductive Society (PCRS) Meeting in Indian Wells, California on March 24th.

The results being presented are based on analyses of a real-world database collected from July 2009 to December 2015 containing data from 15 fertility clinics across the United States. Patients analyzed were from all 50 US states. One presentation evaluates the impact of single embryo transfer (eSET) versus double embryo transfer (DET) on live birth rates and multiple rates. The second presentation examines

"Analysis of real-world data can provide important information on clinical and laboratory trends and associated outcomes," said Mary Mahony, PhD, Vice President, Fertility and Endocrinology, EMD Serono. "Our partnership with some of the largest fertility centers in the United States has allowed us to gather relevant real-world data that we feel provides important insights for healthcare providers and the infertility community as we seek to improve patient outcomes as well as the patient experience."

EMD Serono will also host a booth at the PCRS Meeting that will feature information about the company's Fertility Technologies division, which launched its first product last year with Gidget™, a hand-held witnessing system for the IVF laboratory that provides visual lab workflow management and support for traceability and audit reporting, as well as EMD Serono's GONAL-*f*® [follitropin alfa for injection], which is the world's first and most-widely prescribed recombinant human follicle stimulating hormone (r-hFSH).

Additional meeting information and full abstracts are available on the PCRS meeting website.

Poster Presentation Information:

- **(Poster# 11) Weighing The Impact of eSET Versus DET On Live Birth Rates And Associated Multiple Rates For 38,020 Day 5/6 Transfers In A Large Real-World Database.** Friday, March 24, 2017 6:00 – 6:45 p.m. PST. Location: Exhibit Hall.
- **(Poster#62) Treatment Decision Trends in The Infertility Patient Journey from 78,958 Cycles in a Real-World Database: Impact of Age, Diagnosis, and Year of Treatment.** Friday, March 24, 2017 6:45 – 7:30 p.m. PST. Location: Exhibit Hall.

CONSUMER INDICATION and IMPORTANT RISK INFORMATION
GONAL-f® (follitropin alfa for injection) and GONAL-f® RFF (follitropin alfa for injection)
IMPORTANT INFORMATION ABOUT THE PROPER USE AND RISKS OF GONAL-f® (follitropin alfa for injection) and GONAL-f® RFF* (follitropin alfa for injection)

What are the uses of Gonal-f® (follitropin alfa for injection) and Gonal-f® RFF* (follitropin alfa for injection)?
Gonal-f® Multi-Dose and Gonal-f® RFF are 2 products that contain follitropin alfa, which is

Gonal-f® Multi-Dose and Gonal-f® RFF are used in certain infertile women to help with ovulation (production and release of a mature egg) and pregnancy. Gonal-f® will not help women whose ovaries no longer work because of a condition called Primary Ovarian Failure. Gonal-f® may also be used in women who are in an Assisted Reproductive Technology (ART) program such as *in vitro* fertilization to help their ovaries make more eggs.

Gonal-f® Multi-Dose can also be prescribed to increase sperm production in men with a rare condition that affects sperm production.

Both products should be prescribed only by doctors specializing in infertility problems and their treatment.

Who should not use Gonal-f® and Gonal-f® RFF?

Gonal-f® Multi-Dose and Gonal-f® RFF should not be used in patients who are pregnant or think they might be pregnant, in patients with primary ovarian failure (the ovaries no longer produce eggs), or in patients with allergies to recombinant human FSH products or any other ingredients in the medication. Patients with cancer of the sex organs or brain, or with uncontrolled thyroid or adrenal disease, should not use Gonal-f® Multi-Dose or Gonal-f® RFF. Women with a history of abnormal bleeding from the uterus or vagina or with swollen, enlarged, or painful ovaries should speak to their doctor before starting treatment.

What are the possible side effects of Gonal-f® and Gonal-f® RFF?

The lowest dose expected to achieve the desired results should be used. A doctor should monitor a woman's response often to avoid overdose, which can lead to serious side effects, including blood clots. Women should contact their doctor if severe pain or bloating in the stomach or pelvic area, severe upset stomach, vomiting, or weight gain are experienced during treatment. These could be signs of a rare but serious condition known as Ovarian Hyperstimulation Syndrome, or OHSS, which can result in hospitalization.

Use of Gonal-f® Multi-Dose or Gonal-f® RFF by a woman can be associated with fertilization of more than 1 egg. This can lead to complications for the woman and the birth of 2 or more babies.

The most common side effects reported by women were headache, ovarian cysts, upset stomach, and sinus infection. The most common side effects reported by men taking Gonal-f®

http://www.emdserono.com/ms.country.us/en/images/Gonal-f_RFF_Redi-ject_PI_tcm115_140008.pdf?Version=

About EMD Serono, Inc.

EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada - a leading science and technology company - focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has 1,200 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts. www.emdserono.com

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FDA Grants Approval for BAVENCIO® (avelumab), the First Immunotherapy Approved for Metastatic Merkel Cell Carcinoma

- Only FDA-approved treatment for metastatic Merkel cell carcinoma, a rare and aggressive skin cancer

- First indication for BAVENCIO, a human anti-PD-L1 antibody

ROCKLAND, Mass. and NEW YORK, March 23, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US and Canada, and Pfizer Inc. (NYSE: PFE) today announced that the US Food and Drug Administration (FDA) has approved BAVENCIO® (avelumab) Injection 20 mg/mL, for intravenous use, for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC). This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[1] BAVENCIO was developed, reviewed and approved through the FDA's Breakthrough Therapy Designation and Priority Review programs.

Experience the interactive Multimedia News Release here:
https://www.multivu.com/players/English/8058251-emd-serono-pfizer-bavencio-fda-approval/

BAVENCIO, a human anti-PD-L1 antibody, is the first FDA-approved therapy for patients with mMCC.[2] Metastatic MCC is a rare and aggressive skin cancer, with fewer than half of patients surviving more than one year and fewer than 20% surviving beyond five years.[3]

"At the heart of this FDA approval is our drive to make a meaningful difference for patients with hard-to-treat cancers like metastatic Merkel cell carcinoma," said Belén Garijo, CEO Healthcare and Member of the Executive Board of Merck KGaA, Darmstadt, Germany. "BAVENCIO's journey has included years of hard work – from the scientists who discovered this molecule in our labs, to our alliance with Pfizer and to the study participants and investigators worldwide. We are grateful to all who have made it possible for us to bring this important new treatment option to patients."

"Today is a significant milestone for people fighting metastatic Merkel cell carcinoma, who until now have not had any options beyond chemotherapy," said Albert Bourla, Group President, Pfizer Innovative Health. "This approval demonstrates the power of collaboration to accelerate meaningful new choices for cancer patients."

"Merkel cell carcinoma is rarer than some of the more well-known skin cancers, however, it's very aggressive and the proportion of people who die from MCC is much higher than that of people with melanoma," said Deborah S. Sarnoff, MD, President of the Skin Cancer Foundation. "With this approval, I believe there is new hope for people and their families touched by this rare form of skin cancer."

The efficacy and safety of BAVENCIO was demonstrated in the JAVELIN Merkel 200 trial, an open-label, single-arm, multi-center study conducted in 88 patients with histologically confirmed metastatic MCC whose disease had progressed on or after chemotherapy administered for distant metastatic disease. Sixty-five percent of patients were reported to have had one prior anti-cancer therapy for metastatic MCC and 35% had two or more prior therapies. The major efficacy outcome measures were confirmed overall response rate (ORR) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by a blinded independent central review committee (IRC) and IRC-assessed duration of response.

The overall response rate (ORR) was 33% (95% confidence interval [CI]: 23.3–43.8%)

with 86% of responses lasting for at least six months (n=25).[1] Forty-five percent of responses lasted at least 12 months (n=13).[1] Duration of response ranged from 2.8 to over 23.3 months.

The warnings and precautions for BAVENCIO include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, and other adverse reactions), infusion-related reactions and embryo-fetal toxicity. The most common adverse reactions (reported in at least 20% of patients) included fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), infusion-related reactions (22%), rash (22%), decreased appetite (20%) and peripheral edema (20%).[1] For more information, please see Important Safety Information for BAVENCIO below.

BAVENCIO is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, BAVENCIO is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T-cells, exposing them to anti-tumor responses.[1] BAVENCIO has been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro.[1]

BAVENCIO is available for order now.

The alliance is committed to providing industry-leading patient access and reimbursement support through its CoverOne™ program. This program provides a spectrum of patient access and reimbursement support services intended to help patients receive appropriate access to BAVENCIO in the United States. CoverOne may be reached by phone at 844-8COVER1 (844-826-8371) or online at www.CoverOne.com.

About JAVELIN Merkel 200

The efficacy and safety of BAVENCIO was demonstrated in the JAVELIN Merkel 200 trial, an open-label, single-arm, multi-center study conducted in 88 patients with histologically confirmed metastatic MCC whose disease had progressed on or after chemotherapy administered for distant metastatic disease. Sixty-five percent of patients were reported to have had one prior anti-cancer therapy for metastatic MCC and 35% had two or more prior therapies. The major efficacy outcome measures were confirmed overall response rate (ORR) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by a blinded independent central review committee (IRC) and IRC-assessed duration of response.

anti-PD-1, anti-PD-L1 or anti-CTLA-4 antibodies; CNS metastases; infection with HIV, hepatitis B or hepatitis C; or ECOG performance score greater than or equal to two. Patients received BAVENCIO 10 mg/kg as an intravenous infusion over 60 minutes every two weeks until disease progression or unacceptable toxicity.

The international clinical development program for avelumab, known as JAVELIN, involves at least 30 clinical programs, including nine Phase III trials, and more than 4,000 patients across more than 15 tumor types. In October 2016, the alliance announced the European Medicines Agency accepted the Marketing Authorisation Application for avelumab for the proposed indication of metastatic MCC.

For full prescribing information and medication guide for BAVENCIO, please see www.BAVENCIO.com or the FDA website.

IMPORTANT SAFETY INFORMATION and INDICATION

BAVENCIO can cause **immune-mediated pneumonitis**, including fatal cases. Monitor patients for signs and symptoms of pneumonitis and evaluate suspected cases with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold BAVENCIO for moderate (Grade 2) and permanently discontinue for severe (Grade 3), life-threatening (Grade 4), or recurrent moderate (Grade 2) pneumonitis. Pneumonitis occurred in 1.2% (21/1738) of patients, including one (0.1%) patient with Grade 5, one (0.1%) with Grade 4, and five (0.3%) with Grade 3.

BAVENCIO can cause **immune-mediated hepatitis**, including fatal cases. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater hepatitis. Withhold BAVENCIO for moderate (Grade 2) immune-mediated hepatitis until resolution and permanently discontinue for severe (Grade 3) or life-threatening (Grade 4) immune-mediated hepatitis. Immune-mediated hepatitis was reported in 0.9% (16/1738) of patients, including two (0.1%) patients with Grade 5 and 11 (0.6 %) with Grade 3.

BAVENCIO can cause **immune-mediated colitis**. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold BAVENCIO until resolution for moderate or severe (Grade 2 or 3) colitis and permanently discontinue for life-threatening (Grade 4) or recurrent (Grade 3) colitis upon re-initiation of BAVENCIO. Im

BAVENCIO can cause **immune-mediated endocrinopathies**, including adrenal insufficiency, thyroid disorders, and type 1 diabetes mellitus.

Monitor patients for signs and symptoms of **adrenal insufficiency** during and after treatment and administer corticosteroids as appropriate. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Adrenal insufficiency was reported in 0.5% (8/1738) of patients, including one (0.1%) with Grade 3.

Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation. Manage hypothyroidism with hormone replacement therapy and hyperthyroidism with medical management. Withhold BAVENCIO for severe (Grade 3) or life threatening (Grade 4) thyroid disorders. Thyroid disorders including hypothyroidism, hyperthyroidism, and thyroiditis were reported in 6% (98/1738) of patients, including three (0.2%) with Grade 3.

Type 1 diabetes mellitus, including diabetic ketoacidosis: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Withhold BAVENCIO and administer anti-hyperglycemics or insulin in patients with severe or life-threatening (Grade 3 or greater) hyperglycemia and resume treatment when metabolic control is achieved. Type 1 diabetes mellitus without an alternative etiology occurred in 0.1% (2/1738) of patients, including two cases of Grade 3 hyperglycemia.

BAVENCIO can cause **immune-mediated nephritis and renal dysfunction**. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater nephritis. Withhold BAVENCIO for moderate (Grade 2) or severe (Grade 3) nephritis until resolution to Grade 1 or lower. Permanently discontinue BAVENCIO for life-threatening (Grade 4) nephritis. Immune-mediated nephritis occurred in 0.1% (1/1738) of patients.

BAVENCIO can result in **other severe and fatal immune-mediated adverse reactions** involving any organ system during treatment or after treatment discontinuation. For suspected immune-mediated adverse reactions evaluate to confirm or rule out an immune-mediated adverse reaction and to exclude other causes. Depending on the severity of the adverse reaction, withhold or permanently discontinue BAVENCIO, administer high-dose corticosteroids, and initiate hormone replacement therapy if appropriate. Resume BAVENCIO when the immune-mediated adverse reaction remains at Grade 1 or lower following a corticosteroid taper. Permanently discontinue BAVENCIO for any severe (Grade 3) immune-mediated

The following clinically significant immune-mediated adverse reactions occurred in less than 1% of 1738 patients treated with BAVENCIO: myocarditis with fatal cases, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, and systemic inflammatory response.

BAVENCIO can cause severe (Grade 3) or life-threatening (Grade 4) **infusion-related reactions**. Patients should be premedicated with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent doses based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for mild (Grade 1) or moderate (Grade 2) infusion-related reactions. Permanently discontinue BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Infusion-related reactions occurred in 25% (439/1738) of patients, including three (0.2%) patients with Grade 4 and nine (0.5%) with Grade 3.

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least one month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least one month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

The most common adverse reactions (all grades, greater than or equal to 20%) in patients with metastatic MCC were fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), infusion-related reactions (22%), rash (22%), decreased appetite (20%), and peripheral edema (20%). The most common adverse reaction requiring dose interruption was anemia.

Selected treatment-emergent laboratory abnormalities (all grades, greater than or equal to 20%) in patients with metastatic MCC were lymphopenia (49%), anemia (35%), increased aspartate aminotransferase (34%), thrombocytopenia (27%). and increased alanine aminotransferase (20%). **Selected treatment-emergent Grade 3-4 laboratory abnormalities** (greater than or equal to 2%) were lymphopenia (19%), anemia (9%), hyperglycemia (7%), increased alanine aminotransferase (5%), and increased lipase (4

INDICATION

BAVENCIO is indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see full Prescribing Information and Medication Guide.

About BAVENCIO® (avelumab)

BAVENCIO is a human programmed death ligand-1 (PD-L1) blocking antibody indicated in the US for the treatment of adults and pediatric patients 12 years of age and older with metastatic Merkel cell carcinoma.[1] This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

BAVENCIO is not approved in any market outside the US.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

About EMD Serono, Inc.

EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany – a leading science and technology company – in the US and Canada, focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business h…

the company's home state of Massachusetts.
www.emdserono.com

About Merck KGaA, Darmstadt, Germany

All Merck KGaA, Darmstadt, Germany Press Releases are distributed by e-mail at the same time they become available on the Merck KGaA, Darmstadt, Germany Website. Please go to www.emdgroup.com/subscribe to register online, change your selection or discontinue this service.

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of €15.0 billion in 66 countries.

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About Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook

Pfizer Disclosure Notice

The information contained in this release is as of March 23, 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about BAVENCIO (avelumab), including an indication in the US for BAVENCIO for the treatment of metastatic Merkel cell carcinoma (the Indication), Pfizer's and Merck KGaA, Darmstadt, Germany's immuno-oncology alliance involving anti-PD-L1 and anti-PD-1 therapies, and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of BAVENCIO; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any other jurisdictions for the Indication or in any jurisdictions for any other potential indications for BAVENCIO, combination therapies or other product candidates; whether and when any such applications (including the pending application for the Indication in the EU) may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of BAVENCIO, combination therapies or other product candidates; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

1. BAVENCIO Prescribing Information. Rockland, MA: EMD Serono Inc.; 2017.
2. National Institutes of Health, U.S. National Library of Medicine, Daily Med. Available at https://dailymed.nlm.nih.gov/dailymed/advanced-search.cfm. Accessed March 22, 2017.
3. Lemos B, Storer B, Iyer J, et al. Pathologic Nodal Evaluation Improves Prognostic Accuracy in Merkel Cell Carcinoma: Analysis of 5,823 Cases as the Basis of the First Consensus Staging System for this Cancer. Journal of the American Academy of Dermatology. 2010;63(5):751–761.

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Merck KGaA, Darmstadt, Germany Advances R&D Strategy through Unique Development Model with Avillion for Anti IL-17 A/F Nanobody®

- Agreement employs collaboration model that will create new options for Merck KGaA, Darmstadt, Germany to accelerate pipeline output in a risk-sharing manner
- Merck KGaA, Darmstadt, Germany's immunology asset anti IL-17 A/F Nanobody® to be developed by Avillion for plaque psoriasis and commercialized by Merck KGaA, Darmstadt, Germany

DARMSTADT, Germany, March 30, 2017 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced a development agreement with Avillion, a UK-based company focused on increasing R&D output through innovative models, for anti IL-17 A/F Nanobody®.

Merck KGaA, Darmstadt, Germany's Anti IL-17 A/F Nanobody® is an investigational therapy which has completed Phase I development, and is expected to begin Phase II in plaque psoriasis in 2017. In a collaboration model that is recently emerging in the biopharma industry, Avillion, which is amongst the pioneers of such models, will be responsible for developing anti IL-17 A/F Nanobody® from Phase II through Phase III. Avillion will also finance the clinical

assets through novel innovation models.

"The collaboration announced today with Avillion will allow us to optimally deliver on the potential of IL-17, a compound which could address several areas of unmet need for patients today," said Belén Garijo, member of the Executive Board of Merck and CEO Healthcare. "In parallel, we have several highly promising priority clinical assets in our pipeline, all of which we must continue to drive in-house. By partnering appropriately, not only can we maintain the internal focus on our R&D innovation strategy, but also maximize other opportunities that emerge from our pipeline."

Anti IL-17 A/F Nanobody® is an investigational therapy that has the potential to treat inflammatory diseases. Due to the small size and unique structure of Nanobodies®, they could be an ideal building block for a new generation of novel biological drugs.

"We are delighted to embark on this new clinical development project with Merck KGaA, Darmstadt, Germany and its innovative nanobody candidate," said Allison Jeynes-Ellis, MD, Chief Executive Officer of Avillion. "This agreement is a further endorsement of our innovative business model. We are very encouraged that our collaborative approach to advancing the development of clinical candidates and boosting our partners' R&D productivity is gaining such awareness in the biopharma industry."

Merck KGaA, Darmstadt, Germany acquired full, exclusive rights to anti IL-17 A/F Nanobody® through a global development and commercialization license from Ablynx in 2013.

Both Merck KGaA, Darmstadt, Germany and Avillion agreed to not disclose the terms of the deal.

About Anti IL-17 A/F Nanobody®

Anti IL-17 A/F Nanobody® is an investigational bi-specific half-life extended nanobody that is thought to neutralise both IL-17A and IL-17F with the potential to treat inflammatory diseases.

About Avillion

Avillion LLP is a drug development company with an innovative business model focusing on the clinical co-development and regulatory approval of late stage pharmaceutical products. Avillion offers a compelling opportunity to partner late-stage therapeutic projects for approval in the US and EU and to accelerate their availability to the market. Our objective is to enable our partners

100% of the clinical and regulatory risk, while advancing the development of these late-stage assets in return for milestone payments on the commercialisation of successfully developed products.

Avillion was founded in 2012 in London, UK, and is backed by Abingworth, Clarus Ventures and Royalty Pharma.

All Merck KGaA, Darmstadt, Germany, press releases are distributed by e-mail at the same time they become available on the EMD Group Website. In case you are a resident of the USA or Canada please go to www.emdgroup.com/subscribe to register again for your online subscription of this service as our newly introduced geo-targeting requires new links in the email. You may later change your selection or discontinue this service.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.

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SOURCE Merck KGaA, Darmstadt, Germany

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EMD Serono and Merck KGaA, Darmstadt, Germany to Present Rebif® (interferon beta-1a) and Investigational Cladribine Tablets Data at AAN 2017

- Breadth of data and activities underscore company's long-standing commitment to enhancing care for people with MS

ROCKLAND, Mass., April 21, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, will present data at the American Academy of Neurology (AAN) 69th Annual Meeting, taking place from April 22-28, 2017, in Boston, Mass. EMD Serono and Merck KGaA, Darmstadt, Germany will present 15 abstracts on multiple sclerosis (MS), including studies evaluating Rebif® (interferon beta-1a) and investigational Cladribine Tablets.

"Rebif has a well-established safety profile supported by more than 20 years of accrued clinical trial and patient experience, and the information from the studies and analyses we are presenting at AAN deepens our understanding of this RRMS therapy," said Dr. Kathleen Hawker, Vice President, Neurology and Immunology US, EMD Serono.

which may be integral to the pathological process of MS. Cladribine Tablets is currently under clinical investigation and not yet approved for the treatment for any use in the United States, Canada or elsewhere. In July 2016, the European Medicines Agency (EMA) accepted for review the Marketing Authorisation Application (MAA) of Cladribine Tablets for the treatment of adult patients with RRMS.

"We have an unwavering focus on delivering innovation to patients in need, and our presentations this week at AAN, a leading neurology conference, further validate the promise of Cladribine Tablets as a potential RRMS treatment option," said Luciano Rossetti, Head of Global R&D for the biopharma business of Merck KGaA, Darmstadt, Germany.

Attendees can learn more about EMD Serono's programs, pipeline and activities in neurology by visiting our medical booth #473. Booth activities include a $25,000 charitable donation presentation to Can DO MS on April 25 at 3 p.m. ET, as well as "I'm Facing MS" simulation stations that will translate users' experiences with different MS impairments into artwork.

AAN Brain Health Fair

EMD Serono will have an exhibition at the AAN Brain Health Fair on April 21 from 10 a.m. – 4 p.m. ET, where attendees can gain first-hand experience about what it's like to have MS through virtual reality and other activities.

The following abstracts were accepted for presentation at the AAN 2017 Annual Meeting:

Rebif (interferon beta-1a) Presentations			
Title	**Lead Author**	**Abstract/ Poster #**	**Presentation Date/Time/Session**
Cholecalciferol Supplementation in Relapsing Multiple Sclerosis Patients Treated with Subcutaneous Interferon Beta-1a: A Randomized Controlled Trial	W. Camu	004	April 27, 2017, 4:06 p.m. Oral Presentation Session S44: MS Risk Factors and Modifications

Relapsing-Remitting Multiple Sclerosis Receiving Subcutaneous Interferon ß-1a (scIFNβ-1a)			Oral Presentation Session S44: MS Risk
Treatment with Interferon Reduces the Appearance of Lesions in Clinically Relevant White Matter (WM) Tracts in Patients with Clinically Isolated Syndrome (CIS)	M. Battaglini	340	April 28, 2017, 4:00 – 5:30 p.m. Poster Session P6
Effect of Early Versus Delayed Treatment (DT) with Subcutaneous IFN ß-1a (scIFNß-1a) on Radiological Activity Free (RAF) or Clinical Activity Free (CAF) Status in Patients with Clinically Isolated Syndrome (CIS): A Post-hoc Analysis of REFLEXION	M. Freedman	358	April 28, 2017, 4:00 – 5:30 p.m. Poster Session P6
Clinical Efficacy of Interferon ß-1a Subcutaneously Three Times Weekly According to Baseline Radiological Characteristics: Post Hoc Analyses of PRISMS Data	F. Nelson	343	April 28, 2017, 4:00 – 5:30 p.m. Poster Session P6
Efficacy of Interferon ß-1a Subcutaneously Three Times Weekly According to Baseline EDSS/Duration, EDSS, and MSSS Sub-groups: Post Hoc Analysis of PRISMS Data	E. Williamson	329	April 28, 2017, 4:00 – 5:30 p.m. Poster Session P6

Title	Lead Author	Abstract/ Poster #	Presentation Date/Time/Session
Cladribine Tablets in the Treatment of Patients with Multiple Sclerosis (MS): An Integrated Analysis of Safety from the MS Clinical Development Program	S. Cook	394	April 27, 2017, 5:30 – 7:00 p.m. Poster Session P5
Absolute Lymphocyte Count Recovery in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS) Treated with Cladribine Tablets 3.5 mg/kg in CLARITY and CLARITY Extension	P. Soelberg-Sorensen	379	April 27, 2017, 5:30 – 7:00 p.m. Poster Session P5
Cladribine Tablets in the ORACLE-MS Study Open-label Maintenance Period: Analysis of Efficacy in Patients after Conversion to Clinically Definite Multiple Sclerosis (CDMS)	G. Comi	349	April 28, 2017, 4:00 – 5:30 p.m. Poster Session P6
Defining High Disease Activity (HDA) in Patients with Relapsing Multiple Sclerosis (RMS) Receiving Placebo in the CLARITY Study	G. Giovannoni	351	April 28, 2017, 4:00 – 5:30 p.m. Poster Session P6
Durable Efficacy of Cladribine Tablets in Patients with Multiple Sclerosis: Analysis of Relapse Rates and Relapse-free Patients in the CLARITY and CLARITY Extension Studies	G. Giovannoni	353	April 28, 2017, 4:00 – 5:30 p.m. Poster Session P6

Subgroups of Patients with Relapsing Multiple Sclerosis (RMS) in the CLARITY Study			Poster Session P6

Additional Company-Sponsored Presentations

Title	Lead Author	Abstract/ Poster #	Presentation Date/Time/Session
Multiple Sclerosis Relapse Rates, Before, During, and After Pregnancy: A US Retrospective Claims Database Analysis	A. Phillips	361	April 23, 2017, 4:00 – 5:30 p.m. Poster Session P1
Pregnancy Complications of Women With and Without Multiple Sclerosis in a Large US Claims Database	M.K. Houtchens	110	April 24, 2017, 8:30 a.m. – 7:00 p.m. Poster Session P2
Does Patients' Experience of Care Differ by Level of Adherence in Multiple Sclerosis?	J. Smrtka	337	April 25, 2017, 5:30 – 7:00 p.m. Poster Session P3

About Rebif® (interferon beta-1a)

Rebif (interferon beta-1a) is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS. The efficacy and safety of Rebif in controlled clinical trials beyond 2-years has not been established.

Important Safety Information

Rebif is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation.

reported to occur with increased frequency in patients receiving interferon compounds, including Rebif.

Severe liver injury, including some cases of hepatic failure requiring liver transplantation, has been reported rarely in patients taking Rebif. The potential for liver injury should be considered when used in combination with other products associated with liver injury. Monitor liver function tests and patients for signs and symptoms of hepatic injury. Consider discontinuing Rebif if hepatic injury occurs.

Anaphylaxis and other allergic reactions (some severe) have been reported as a rare complication of Rebif. Discontinue Rebif if anaphylaxis occurs.

In controlled clinical trials, injection site reactions occurred more frequently in Rebif-treated patients than in placebo-treated and Avonex-treated patients. Injection site reactions including injection site pain, erythema, edema, cellulitis, abscess, and necrosis have been reported in the postmarketing setting. Do not administer Rebif into affected area until fully healed; if multiple lesions occur, discontinue Rebif until skin lesions are healed.

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif-treated patients than in placebo-treated patients. Patients should be monitored for symptoms or signs of decreased blood counts. Monitoring of complete blood and differential white blood cell counts is also recommended.

Cases of thrombotic microangiopathy (TMA), some fatal, have been reported with interferon beta products, including Rebif, up to several weeks or years after starting therapy. Discontinue Rebif if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.

Caution should be exercised when administering Rebif to patients with pre-existing seizure disorders. Seizures have been temporally associated with the use of beta interferons, including Rebif, in clinical trials and in postmarketing reports.

The most common side effects with Rebif are injection-site disorders, headaches, influenza-like symptoms, abdominal pain, depression, elevated liver enzymes, and hematologic

There are no adequate and well-controlled studies in pregnant women. Rebif should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Rebif full prescribing information is available at http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=

About Cladribine Tablets

Cladribine Tablets is an investigational short-course oral therapy that is thought to selectively and periodically target lymphocytes, which maybe integral to the pathological process of MS. Cladribine Tablets is currently under clinical investigation and not yet approved for the treatment for any use in the United States, Canada and Europe. In July 2016, the European Medicines Agency (EMA) accepted for review the Marketing Authorisation Application (MAA) of Cladribine Tablets for the treatment of relapsing remitting multiple sclerosis.

The clinical development program for Cladribine Tablets includes:

- The CLARITY (CLAdRIbine Tablets Treating MS OrallY) study and its extension: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with RRMS and its two-year extension designed to provide data on the long-term safety and efficacy of extended administration of Cladribine Tablets for up to four years.
- The ORACLE MS (ORAl CLadribine in Early MS) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS).
- The ONWARD (Oral Cladribine Added to Interferon beta-1a in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled study designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy.
- PREMIERE (Prospective Observational Long-term Safety Registry of Multiple Sclerosis Patients Who Have Participated in Cladribine Clinical Studies) study: interim long-term follow-up data from the prospective registry, PREMIERE, to evaluate the safety and efficacy of Cladribine Tablets. The follow-up will consist of over 10,000 patient years of exposure in total, with follow-up in some patients exceeding eight years at completion.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is

the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About EMD Serono, Inc.

EMD Serono is the North America biopharma business of Merck KGaA, Darmstadt, Germany - a leading science and technology company - focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has more than 1,100 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

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SOURCE EMD Serono

Investigational Cladribine Tablets Data Show Greater Treatment Effect in Relapsing MS Patients at a Higher Risk of Disease Progression

- Subgroup analysis shows >80% reduction in the risk of disability progression with Cladribine Tablets vs placebo

ROCKLAND, Mass., April 28, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, announced the presentation of new analyses of efficacy and safety data for investigational Cladribine Tablets in poster presentations at the Annual Meeting of the American Academy of Neurology (AAN), taking place April 22 – 28, 2017, in Boston, Massachusetts.

The findings from a retrospective subgroup analysis of the Phase III CLARITY trial in 289 patients with high disease activity* demonstrated statistically significant reduction in the risk of disability progression and relapse with Cladribine Tablets at a dose of 3.5mg/kg (n=140) compared with placebo (n=149) in relapsing multiple sclerosis (MS) patients who were either treatment naïve or had prior disease modifying drug (DMD) exposure.

the CLARITY studies and Chair of Neurology, Barts and The London School of Medicine and Dentistry. "These data are important since they indicate that patients in the high disease activity subgroup treated with Cladribine Tablets showed a greater response than that seen in the overall CLARITY trial population."

The analysis demonstrated that treatment with Cladribine Tablets 3.5 mg/kg was associated with a larger reduction in the risk of 6-month confirmed EDSS progression in patients with high disease activity (82%; P=0.0001) than observed in the overall CLARITY population (47%; P=0.0016) vs placebo. Additionally, data showed that Cladribine Tablets reduced the relative risk of annualised relapse rate in patients with high disease activity (67%; P<0.0001) compared with the overall CLARITY population (58%; P=<0.0001). The study found that relapse and treatment history as well as MRI characteristics can help to identify patients who are at increased risk of experiencing relapses and disability progression.

"Cladribine Tablets is thought to selectively target the adaptive immune response in MS, and may be able to address a medical need in those patients already at higher risk of disability progression or relapses," said Luciano Rossetti, Head of Global R&D for the biopharma business of Merck KGaA, Darmstadt, Germany.

A safety analysis of patients given Cladribine Tablets for 20 days over two years in either CLARITY or CLARITY Extension showed that, following the 10-day dosing period in treatment year 1, median lymphocyte counts were reduced to a low of 1.00×10^9/L. However, by the end of treatment year 1 and 2, median lymphocyte counts had recovered to within the normal range. In the 2-year CLARITY study, the most commonly reported adverse event (AE) in patients treated with Cladribine Tablets was lymphopenia. The incidence of infections was 48.3% with Cladribine Tablets and 42.5% with placebo, with 99.1% and 99.0% respectively rated mild-to-moderate by investigators.

*Higher risk of disease progression and/or high disease activity is defined as patients with ≥ 1 relapse during the year prior to study entry while on DMD therapy AND ≥ 1 T1 Gd+ or ≥ 9 T2 lesions plus patients with ≥ 2 relapses during the year prior to study entry, regardless of prior use of DMD.

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About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately 2.3 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

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immuno-oncology and immunology as R&D focus areas. Today, the business has more than 1,100 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

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SOURCE EMD Serono

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13th Annual EMD Serono Specialty Digest™ Details Utilization and Clinical Management Trends

- Digest Launches at 2017 Asembia Specialty Pharmacy Summit

(1)

ROCKLAND, Mass., May 1, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced the launch of the 13th edition of the EMD Serono Specialty Digest™ at the Asembia Specialty Pharmacy Summit in Las Vegas, NV. The Digest is an annual industry resource that provides market data on health plans' management of specialty pharmaceuticals and identifies common trends occurring across plans. The Digest is available to those who request a copy at http://www.specialtydigest.emdserono.com.

"The healthcare industry is continuing to evolve at a rapid pace and this year's Specialty Digest once again seeks to identify the current trends in managed care and provide insights into the challenges and opportunities that exist to improve access to patient care," said Scott Filosi, Senior Vice President, Market Access & Customer Solutions, EMD Serono. "It is our hope that the Digest will serve as a foundation to initiate important conversations about potential barriers

The 13th edition EMD Serono Specialty Digest outlines the results of a survey of 58 commercial health plans representing 173 million covered lives in 2016. This year, the Digest has a heightened focus on emerging opportunities and challenges presented by the introduction of additional biosimilars to the marketplace, as well as management strategies and opportunities in oncology care.

"Now on its thirteenth year, the EMD Serono Specialty Digest has been a leading source for insights on specialty pharmacy perspectives from managed care decision makers," said Kevin Host, President and COO, Pharmaceutical Strategies Group, who oversaw the development of the Digest. "This year we've seen a shift as health plans have indicated that 'ensuring clinically appropriate use' has now risen above 'managing oncology drugs' as their top challenge. I am confident that this year's report and those to come will continue to provide an invaluable measure of specialty drug management trends."

Eighty-three percent of respondents ranked ensuring clinical use among their top five challenges, with managing oncology drugs and determining the value of specialty drugs ranking second at 79%. This suggests that health plans are moving to a more mature management stage, moving beyond 'value' and a single therapeutic area to the clinical management of specialty drugs as a whole. Other topics addressed in the survey include utilization and clinical management, reimbursement methods and competitiveness, benefit design, and emerging challenges and opportunities.

Originally developed in 2004 to serve as a reference and benchmarking tool for managed care decision makers, the EMD Serono Specialty Digest has been accessed and used annually by thousands of stakeholders, including health plans, pharmacy benefit managers, employers, specialty pharmacies, and pharmaceutical companies.

Findings are available in the full text of the EMD Serono Specialty Digest, at http://www.specialtydigest.emdserono.com

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therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has 1,200 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

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SOURCE EMD Serono

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FDA Grants BAVENCIO® (avelumab) Approval for a Common Type of Advanced Bladder Cancer

- Second approval for BAVENCIO in less than two months
- Advanced urothelial carcinoma is an aggressive disease with a high rate of recurrence

(3)

ROCKLAND, Mass. and NEW YORK, May 9, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, and Pfizer Inc. (NYSE: PFE) today announced that the US Food and Drug Administration (FDA) has approved BAVENCIO® (avelumab) Injection for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. BAVENCIO was previously granted accelerated approval from the FDA for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC). These indications are approved under accelerated approval based on tumor response and duration of response.

"This approval for BAVENCIO in patients with locally advanced or metastatic urothelial carcinoma exemplifies our unwavering commitment to finding new treatments for the most challenging cancers," said Luciano Rossetti, M.D., Executive Vice President, Global Head of Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany. "Coming just a few weeks after the approval for metastatic Merkel cell carcinoma, we continue to demonstrate our ability to accelerate access to innovative medicines for patients in need."

"This approval builds on the ongoing clinical development program for BAVENCIO in urothelial carcinoma and reinforces our commitment to providing new medicines to patients with difficult-to-treat cancers," said Liz Barrett, Global President, Pfizer Oncology. "By drawing on the strength of the alliance, as well as Pfizer's deep experience in genitourinary cancers, we believe BAVENCIO will be an important treatment option, and we hope it will help to improve outcomes for these patients."

Bladder cancer makes up approximately 90% of urothelial carcinomas and is the sixth most common cancer in the US.[2,3] When the disease has metastasized, the five-year survival rate is approximately 5%.[4] Despite advances in the treatment of locally advanced or metastatic urothelial carcinoma, the prognosis for patients remains poor and more treatment options are needed.[2]

"Once urothelial carcinoma progresses after treatment with chemotherapy, the five-year survival rate is alarmingly low," said Dr. Andrea Apolo, National Cancer Institute, Bethesda, MD, US. "Until recently, there had been limited innovation in urothelial carcinoma, and this approval gives us another treatment to help battle this aggressive disease."

The efficacy and safety of BAVENCIO was demonstrated in the urothelial carcinoma cohorts (N=242) of the JAVELIN Solid Tumor trial, a Phase I, open-label, single-arm, multicenter study of BAVENCIO in the treatment of various solid tumors. The urothelial carcinoma cohorts enrolled patients with locally advanced or metastatic urothelial carcinoma with disease progression on or after platinum-containing chemotherapy or who had disease progression within 12 months of treatment with a platinum-containing neoadjuvant or adjuvant chemotherapy regimen. These data will be presented at an upcoming medical congress.

adverse reactions), infusion-related reactions and embryo-fetal toxicity. The most common adverse reactions (reported in at least 20% of patients) in patients with locally advanced or metastatic urothelial carcinoma were fatigue (41%), infusion-related reaction (30%), musculoskeletal pain (25%), nausea (24%), decreased appetite/hypophagia (21%) and urinary tract infection (21%).[1] For more information, please see Important Safety Information for BAVENCIO below.

BAVENCIO is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, BAVENCIO is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T cells, exposing them to anti-tumor responses.[1] BAVENCIO has also been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro.[1]

The alliance is committed to providing industry-leading patient access and reimbursement support through its CoverOne™ program. This program provides a spectrum of patient access and reimbursement support services intended to help patients receive appropriate access to BAVENCIO in the United States. CoverOne may be reached by phone at 844-8COVER1 (844-826-8371) or online at www.CoverOne.com.

About Urothelial Carcinoma Cohorts in JAVELIN Solid Tumor Trial

The efficacy and safety of BAVENCIO was demonstrated in the urothelial carcinoma cohorts of the JAVELIN Solid Tumor trial, a Phase I, open-label, single-arm, multicenter study that included 242 patients with locally advanced or metastatic urothelial carcinoma with disease progression on or after platinum- containing chemotherapy or who had disease progression within 12 months of treatment with a platinum-containing neoadjuvant or adjuvant chemotherapy regimen who were treated with BAVENCIO.

Patients with active or a history of central nervous system metastasis; other malignancies within the last five years; an organ transplant; conditions requiring therapeutic immune suppression; or active infection with HIV, hepatitis B or C were excluded. Patients with autoimmune disease, other than type 1 diabetes, vitiligo, psoriasis, or thyroid disease that did not require immunosuppressive treatment, were excluded. Patients were included regardless of their PD-L1 status. Patients received BAVENCIO at a dose of 10 mg/kg intravenously over 60 minutes every two weeks until disease progression or unacceptable toxicity. Tumor response assessments were performed every six weeks, as assessed by an Independent Endpoint Review Committee (IERC) using Response Evaluation Criteria in Solid Tumors (RECIST) v1.1. Efficacy

13 weeks and 6 months at the time of data cut-off.

Out of the total 226 patients evaluable for efficacy, 44% had non-bladder urothelial carcinoma, including 23% of patients with upper tract disease; 83% of patients had visceral metastases; 34% of patients had liver metastases. Nine patients (4%) had disease progression following prior platinum-containing neoadjuvant or adjuvant therapy only. Forty-seven percent of patients only received prior cisplatin-based regimens, 32% received only prior carboplatin-based regimens, and 20% received both cisplatin and carboplatin-based regimens.

The international clinical development program for avelumab, known as JAVELIN, involves more than 30 clinical programs, including nine Phase III trials, and more than 5,200 patients across more than 15 tumor types.

In December 2015, Merck KGaA, Darmstadt, Germany and Pfizer announced the initiation of a Phase III multicenter, multinational, randomized, open-label, parallel-arm study (JAVELIN Bladder 100) of BAVENCIO plus best supportive care versus best supportive care alone as a maintenance treatment in patients with locally advanced or metastatic urothelial carcinoma whose disease did not progress after completion of first-line platinum-containing chemotherapy. This trial is currently enrolling patients.

For more information about JAVELIN trials, please visit www.clinicaltrials.gov.

For full prescribing information and medication guide for BAVENCIO, please see www.BAVENCIO.com.

IMPORTANT SAFETY INFORMATION and INDICATIONS

BAVENCIO can cause **immune-mediated pneumonitis**, including fatal cases. Monitor patients for signs and symptoms of pneumonitis and evaluate suspected cases with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold BAVENCIO for moderate (Grade 2) and permanently discontinue for severe (Grade 3), life-threatening (Grade 4), or recurrent moderate (Grade 2) pneumonitis. Pneumonitis occurred in 1.2% (21/1738) of patients, including one (0.1%) patient with Grade 5, one (0.1%) with Grade 4, and five (0.3%) with Grade 3.

Grade 2 or greater hepatitis. Withhold BAVENCIO for moderate (Grade 2) immune-mediated hepatitis until resolution and permanently discontinue for severe (Grade 3) or life-threatening (Grade 4) immune-mediated hepatitis. Immune-mediated hepatitis was reported in 0.9% (16/1738) of patients, including two (0.1%) patients with Grade 5 and 11 (0.6%) with Grade 3.

BAVENCIO can cause **immune-mediated colitis**. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold BAVENCIO until resolution for moderate or severe (Grade 2 or 3) colitis and permanently discontinue for life-threatening (Grade 4) or recurrent (Grade 3) colitis upon re-initiation of BAVENCIO. Immune-mediated colitis occurred in 1.5% (26/1738) of patients, including seven (0.4%) with Grade 3.

BAVENCIO can cause **immune-mediated endocrinopathies**, including adrenal insufficiency, thyroid disorders, and type 1 diabetes mellitus.

Monitor patients for signs and symptoms of **adrenal insufficiency** during and after treatment, and administer corticosteroids as appropriate. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Adrenal insufficiency was reported in 0.5% (8/1738) of patients, including one (0.1%) with Grade 3.

Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation. Manage hypothyroidism with hormone replacement therapy and hyperthyroidism with medical management. Withhold BAVENCIO for severe (Grade 3) or life- threatening (Grade 4) thyroid disorders. Thyroid disorders including hypothyroidism, hyperthyroidism, and thyroiditis were reported in 6% (98/1738) of patients, including three (0.2%) with Grade 3.

Type 1 diabetes mellitus including diabetic ketoacidosis: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Withhold BAVENCIO and administer anti-hyperglycemics or insulin in patients with severe or life-threatening (Grade ≥ 3) hyperglycemia, and resume treatment when metabolic control is achieved. Type 1 diabetes mellitus without an alternative etiology occurred in 0.1% (2/1738) of patients, including two cases of Grade 3 hyperglycemia.

BAVENCIO can cause **immune-mediated nephritis and renal dysfunction**. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer

BAVENCIO for life-threatening (Grade 4) nephritis. Immune-mediated nephritis occurred in 0.1% (1/1738) of patients.

BAVENCIO can result in **other severe and fatal immune-mediated adverse reactions** involving any organ system during treatment or after treatment discontinuation. For suspected immune-mediated adverse reactions, evaluate to confirm or rule out an immune-mediated adverse reaction and to exclude other causes. Depending on the severity of the adverse reaction, withhold or permanently discontinue BAVENCIO, administer high-dose corticosteroids, and initiate hormone replacement therapy if appropriate. Resume BAVENCIO when the immune-mediated adverse reaction remains at Grade 1 or lower following a corticosteroid taper. Permanently discontinue BAVENCIO for any severe (Grade 3) immune-mediated adverse reaction that recurs and for any life-threatening (Grade 4) immune-mediated adverse reaction. The following clinically significant immune-mediated adverse reactions occurred in less than 1% of 1738 patients treated with BAVENCIO: myocarditis with fatal cases, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, and systemic inflammatory response.

BAVENCIO can cause severe (Grade 3) or life-threatening (Grade 4) **infusion-related reactions**. Patients should be premedicated with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent doses based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for mild (Grade 1) or moderate (Grade 2) infusion-related reactions. Permanently discontinue BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Infusion-related reactions occurred in 25% (439/1738) of patients, including three (0.2%) patients with Grade 4 and nine (0.5%) with Grade 3.

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least 1 month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least 1 month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

(23%), nausea (22%), infusion-related reaction (22%), rash (22%), decreased appetite (20%), and peripheral edema (20%).

Selected treatment-emergent laboratory abnormalities (all grades, ≥ 20%) in patients with **metastatic MCC** were lymphopenia (49%), anemia (35%), increased aspartate aminotransferase (34%), thrombocytopenia (27%), and increased alanine aminotransferase (20%).

The most common adverse reactions (all grades, ≥ 20%) in patients with **locally advanced or metastatic urothelial cancer (UC)** were fatigue (41%), infusion-related reaction (30%), musculoskeletal pain (25%), nausea (24%), decreased appetite/hypophagia (21%) and urinary tract infection (21%).

Selected laboratory abnormalities (grades 3-4, ≥ 3%) in patients with **locally advanced or metastatic UC** were hyponatremia (16%), gamma-glutamyltransferase increased (12%), lymphopenia (11%), hyperglycemia (9%), increased alkaline phosphatase (7%), anemia (6%), increased lipase (6%), hyperkalemia (3%), and increased aspartate aminotransferase (3%).

INDICATIONS

BAVENCIO is indicated for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (MCC).

BAVENCIO is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

These indications are approved under accelerated approval based on tumor response and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see full Prescribing Information and Medication Guide.

Avelumab has not yet been approved for any indication in any market outside of the US. As announced on October 31, 2016, the European Medicines Agency (EMA) has validated for

About BAVENCIO® (avelumab)

BAVENCIO is a human programmed death ligand-1 (PD-L1) blocking antibody indicated in the US for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy, as well as for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma.[1] These indications are approved under accelerated approval based on tumor response and duration of response. Continued approval for these indications is contingent upon verification and description of clinical benefit in confirmatory trials.

BAVENCIO is not approved for any indication in any market outside the US.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

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they become available on the Merck KGaA, Darmstadt, Germany Website. Please go to www.emdgroup.com/subscribe to register online, change your selection or discontinue this service.

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of €15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the "Merck" name and brand except in the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of May 9, 2017. Pfizer assumes no obligation to

This release contains forward-looking information about BAVENCIO (avelumab), the alliance between Merck KGaA, Darmstadt, Germany and Pfizer involving anti-PD-L1 and anti-PD-1 therapies, and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of BAVENCIO; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any other jurisdictions for the Indication or in any jurisdictions for any other potential indications for BAVENCIO, combination therapies or other product candidates; whether and when any such applications (including the pending application for BAVENCIO for metastatic Merkel cell carcinoma in the EU) may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of BAVENCIO, combination therapies or other product candidates; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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Merck KGaA, Darmstadt, Germany, and Pfizer to Present Data Highlighting Potential of Avelumab in Challenging Cancers at ASCO 2017

A total of 13 abstracts across seven hard-to-treat cancers highlight the progress of avelumab as a monotherapy and potential novel combination treatment option

New data in metastatic Merkel cell carcinoma and previously treated metastatic urothelial carcinoma, following recent US FDA accelerated approvals

Darmstadt, Germany, and New York, US, May 17, 2017 – Merck KGaA, Darmstadt, Germany, and Pfizer today announced that 13 avelumab* abstracts across seven challenging tumor types will be featured at the 53rd American Society of Clinical Oncology (ASCO) Annual Meeting held June 2–6, 2017 in Chicago, IL. Key presentations include data for avelumab in first-line metastatic Merkel cell carcinoma (mMCC) and in previously treated metastatic urothelial carcinoma (UC), as well as results from the Phase Ib trial investigating avelumab in combination with the tyrosine kinase inhibitor axitinib, in advanced renal cell carcinoma (RCC).

Rossetti, M.D., Executive Vice President, Global Head of Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono. "We're particularly excited to share the latest avelumab data in both metastatic Merkel cell carcinoma in the first-line setting and previously treated metastatic urothelial carcinoma with the cancer community."

"Our data at ASCO this year underscore the potential of avelumab as a monotherapy treatment, as well as part of combination regimens," said Chris Boshoff, M.D., PhD, Senior Vice President and Head of Immuno-Oncology, Early Development, Translational Oncology, Pfizer Global Product Development. "Now with accelerated approvals in two indications for avelumab in the US, we are entering the next chapter of our clinical development program to provide meaningful new treatment options for patients who need them most."

Highlights of avelumab data at ASCO 2017 include the following:

- Preliminary data from the ongoing JAVELIN Merkel 200 trial, an open-label, multicenter study conducted in first-line mMCC investigating avelumab in patients who had no prior systemic treatment for mMCC, will be presented for the first time at a medical congress.
- Data from a pooled analysis of two metastatic UC cohorts of the JAVELIN Solid Tumor trial, a Phase Ib, open-label, single-arm, multicenter study of avelumab in the treatment of various solid tumors, will be presented.
- An oral presentation of results from the JAVELIN Renal 100 trial, a Phase Ib, open-label study evaluating the clinical activity and safety of the combination of avelumab and axitinib for the first-line treatment of advanced RCC.
- Beyond mMCC, metastatic UC and RCC, the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer will also showcase avelumab abstracts in non-small cell lung cancer, metastatic castrate-resistant prostate cancer, locally advanced squamous cell carcinoma of the head and neck and relapsed or refractory diffuse large B-cell lymphoma, as well as updated safety data in solid tumors.

The alliance's rapidly accelerating JAVELIN clinical development program now involves at least 30 clinical programs, including nine Phase III trials, and more than 5,200 patients across more than 15 tumor types. Results from JAVELIN program trials have supported two FDA accelerated approvals in 2017.

A list of accepted avelumab abstracts is included below. The abstracts are also available on the ASCO website.

Title	Lead Author	Abstract ID / Poster No.	Presentation Date / Time	Sessions
ORAL PRESENTATIONS				
Renal Cell Carcinoma (JAVELIN Renal 100) First-line avelumab + axitinib therapy in patients with advanced renal cell carcinoma: results from a phase 1b trial	Choueiri TK	4504	Monday, June 5 8:00-11:00 a.m.	Genitourinary (Nonprostate) Cancer
POSTER SESSIONS				

Head and Neck Cancer (TiP) (JAVELIN Head and Neck 100) JAVELIN Head and Neck 100: a phase 3 trial of avelumab in combination with chemoradiotherapy (CRT) vs CRT for 1st-line treatment of locally advanced squamous cell carcinoma of the head and neck (LA SCCHN)	Lee NY	TPS6093	Monday, June 5 1:15-4:45 p.m.	Head and Neck Cancer
Lymphoma (TiP) (JAVELIN DLBCL) Phase 1b/3 study of avelumab-based combination regimens in patients (pts) with relapsed or refractory diffuse large B-cell lymphoma (R/R DLBCL)	Chen R	TPS7575	Monday, June 5 8:00-11:30 a.m.	Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia

Merkel Cell Carcinoma (JAVELIN Merkel 200) First-line avelumab treatment in patients with metastatic Merkel cell carcinoma: preliminary data from an ongoing study	D'Angelo SP	9530	Saturday, June 3 1:15-4:45 p.m.	Melanoma/Skin Cancers
Merkel Cell Carcinoma (JAVELIN Merkel 200) Exploratory biomarker analysis in patients with chemotherapy-refractory metastatic Merkel cell carcinoma treated with avelumab	Shapiro I	9557	Saturday, June 3 1:15-4:45 p.m.	Melanoma/Skin Cancers

Non-Small Cell Lung Cancer (JAVELIN Solid Tumor) Exposure– response and PD- L1 expression analysis of second-line avelumab in patients with advanced NSCLC: data from the JAVELIN Solid Tumor trial	Gulley JL	9086	Saturday, June 3 8:00-11:30 a.m.	Lung Cancer—Non-Small Cell Metastatic
Pan-Tumor (JAVELIN Solid Tumor) Safety profile of avelumab in patients with advanced solid tumors: a JAVELIN pooled analysis of phase 1 and 2 data	Kelly K	3059	Monday, June 5 8:00-11:30 a.m.	Developmental Therapeutics—Immunotherapy

Prostate Cancer (JAVELIN Solid Tumor) Avelumab in metastatic castration-resistant prostate cancer (mCRPC)	Fakhrejahani F	5037	Monday, June 5 1:15-4:45 PM	Genitourinary (Prostate) Cancer
Renal Cell Carcinoma (JAVELIN Renal 101) Avelumab plus axitinib vs sunitinib as first-line treatment of advanced renal cell carcinoma: phase 3 study (JAVELIN Renal 101)	Choueiri TK	TPS4594	Sunday, June 4 8:00-11:30 a.m.	Genitourinary (Nonprostate)

Urothelial Carcinoma (JAVELIN Solid Tumor) Updated efficacy and safety of avelumab in metastatic urothelial carcinoma: pooled analysis from 2 cohorts of the phase 1b JAVELIN Solid Tumor study	Apolo AB	4528	Sunday, June 4 8:00-11:30 a.m.	Genitourinary (Nonprostate) Cancer
PUBLICATIONS				
Merkel Cell Carcinoma (JAVELIN Merkel 200) Non-progression during avelumab treatment is associated with clinically relevant improvements in health-related quality of life in patients with Merkel cell carcinoma	Bharmal M	e21070		

Merkel Cell Carcinoma (JAVELIN Merkel 200) Patient experiences with avelumab vs chemotherapy for treating Merkel cell carcinoma: results from protocol-specified qualitative research	Kaufman HL	e21065		
Non-Small Cell Lung Cancer (JAVELIN Solid Tumor) Comparative study of two PD-L1 expression assays in patients with non-small cell lung cancer (NSCLC)	Feng Z	e20581		

*Avelumab is under clinical investigation for treatment of NSCLC, RCC, DLBCL, SSCHN and mCRPC and has not been demonstrated to be safe and effective for these indications. There is no guarantee that avelumab will be approved for NSCLC, RCC, DLBCL, SSCHN and mCRPC by any health authority worldwide.

About Avelumab

Avelumab is a human antibody specific for a protein called PD-L1, or programmed death ligand-

protection against white blood cells, such as T-cells, exposing them to anti-tumor responses. Avelumab has been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro. In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co- develop and co-commercialize avelumab.

Indications

The US Food and Drug Administration (FDA) granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) metastatic Merkel cell carcinoma (mMCC) in adults and pediatric patients 12 years and older and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials. Avelumab is not approved for any indication in any market outside the US.

Important Safety Information

The warnings and precautions for BAVENCIO include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction and other adverse reactions), infusion-related reactions and embryo-fetal toxicity.

Common adverse reactions (reported in at least 20% of patients) in patients treated with avelumab include fatigue, musculoskeletal pain, diarrhea, nausea, infusion- related reaction, peripheral edema, decreased appetite/hypophagia, urinary tract infection and rash.

For full prescribing information and medication guide for BAVENCIO, please see www.BAVENCIO.com.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other’s strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer’s PD-1 antibody. The alliance is

cancer.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of €15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, operates as EMD Serono, MilliporeSigma and EMD Performance Materials in the United States and Canada.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

update forward-looking statements contained in this release as the result of new information or future events or developments.

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EMD Serono to Present Data Highlighting Investigational Cladribine Tablets at CMSC 2017

- Company to present eight abstracts evaluating the efficacy and safety of Cladribine Tablets for the treatment of relapsing multiple sclerosis
- Oral presentation to highlight efficacy results from the CLARITY and CLARITY EXTENSION studies

ROCKLAND, Mass., May 25, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, today announced 14 presentations, including eight sets of data on Cladribine Tablets, an investigational, oral, small molecule being developed for the treatment of relapsing multiple sclerosis (MS) at the 31st Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC), taking place from May 24-27, 2017, in New Orleans, LA.

"Our ongoing research underscores the company's commitment to developing new therapeutic options for patients with MS," said Dr. Joseph Leveque, Chief Medical Officer, EMD Serono. "Data presented at CMSC add to the body of research evaluating the efficacy and safety of Cladribine Tablets as a potential treatment option for patients with relapsing MS."

CLARITY and CLARITY EXTENSION studies.[1] The data demonstrate a statistically significant reduction in the annualized relapse rate at 96 weeks in both Cladribine Tablets groups, as compared with the placebo group (0.14 in the Cladribine Tablets 3.5-mg/kg group and 0.15 in the Cladribine Tablets 5.25-mg/kg group, vs 0.33 in the placebo group), for relative reductions of 57.6% and 54.5%, respectively ($p<0.001$ for both comparisons). Additionally, the proportion of patients with no new T1 Gd+ lesions was 73.0% to 89.9% respectively for the treatment groups (in CLARITY EXTENSION).

In the 2-year CLARITY study, the most commonly reported adverse event (AE) in patients treated with Cladribine Tablets was lymphopenia. The incidence of infections was 48.3% with Cladribine Tablets and 42.5% with placebo, with 99.1% and 99.0% respectively rated mild-to-moderate by investigators.

In CLARITY, patients were randomized to receive either Cladribine Tablets (3.5 or 5.25mg/kg) or placebo over two years. In the two-year extension, patients who received placebo in the double-blind phase, were re-randomized to receive Cladribine Tablets (3.5mg/kg). Patients who received Cladribine Tablets at either dose in the double-blind phase were re-randomized 2:1 to Cladribine Tablets 3.5mg/kg or placebo for years 3 and 4.

"We compared the results from two 2-year studies to further understand the duration of efficacy of Cladribine Tablets," said Dr. Kottil Rammohan, an investigator in the CLARITY studies and Professor of Neurology – Clinical, and the Director of the Multiple Sclerosis Center at the University of Miami. "It's important that we saw similar results replicated in the CLARITY EXTENSION trial, which further supports the overall efficacy profile of Cladribine Tablets. Rates of clinical and MRI disease activity-free status were consistent with Cladribine Tablets across all subsets of MS patients for the duration in both trials."

Additionally, a separate study, the ORACLE-MS study, investigated the effect of Cladribine Tablets 3.5 mg/kg of bodyweight or 5.25 mg/kg on conversion to clinically definite multiple sclerosis. Data showed that annualized relapse rates in the open-label period were lower in patients originally randomized to receive either dose of Cladribine Tablets compared with placebo (0.14 in the Cladribine Tablets 3.5-mg/kg group and 0.24 in the Cladribine Tablets 5.25-mg/kg group, vs. 0.42 in the placebo group.[2]

to Cladribine Tablets 5.25/mg/kg, 4.0% in patients previously exposed to Cladribine Tablets 3.5 mg/kg, and 3.3% in patients previously exposed to placebo.

Cladribine Tablets is currently under clinical investigation and not yet approved for the treatment for any use in the United States, Canada, Europe or elsewhere.

***I'm Facing MS*: Interactive Booth**

EMD Serono has an interactive and innovative medical booth at CMSC. Attendees can learn more about EMD Serono's programs, pipeline and activities in neurology by visiting booth #701. EMD Serono has created an interactive experience for attendees*, I'M Facing MS*, which simulates changes in balance, fatigue, and vision that patients with MS experience. For every participant in the *I'M Facing MS* activity, EMD Serono will give a donation to the CMSC Foundation. On Thursday, May 25 at 5 p.m. CT we will present a $10,000 donation to the CMSC Foundation.

Teamworks Program: A Virtual Team Addressing Patient Inquiries

The CMSC, with support from EMD Serono, will launch an educational video series at this year's annual meeting. The videos are multi-purpose and are designed help the MS community prepare for doctor's appointments, gain knowledge when they are in between appointments, or aid physicians in providing education to their patients. The series will feature answers to patients' common questions and concerns, surrounding topics such as the symptoms that they are experiencing.

The following abstracts were accepted for presentation at the CSMC 2017 Annual Meeting:

Title	**Lead Author**	**Abstract/ Poster #**	**Presentation Date/Time**
Cladribine Tablets Presentations			
Benefits of Cladribine Tablets in patients with multiple sclerosis free from clinical and radiological indicators of disease activity in the CLARITY EXTENSION study	G. Giovannoni	Presentation No. DX04	**Disease Management, Imaging and Therapeutics category**

			p.m. CDT
Cladribine in the treatment of patients with multiple sclerosis: an integrated analysis of infections in association with severe lymphopenia	S. Cook	Poster No. DX68	**Disease Modifying Therapy Category** May 25, 2017, 6:15 – 8:15 p.m. CDT
Cladribine Tablets in the treatment of patients with multiple sclerosis: an integrated analysis of safety from the multiple sclerosis clinical development program		Poster No. DX69	
Cladribine Tablets in the ORACLE-MS study open-label maintenance period: analysis of efficacy in patients after conversion to clinically definite multiple sclerosis (CDMS)	G. Comi	Poster No. DX34	**Disease Modifying Therapy Category** May 25, 2017, 6:15 – 8:15 p.m. CDT
Reduction of lymphopenia by Cladribine Tablets under re-treatment guidelines: a long-term follow-up analysis of patients in the ORACLE-MS study	T. Leist	Poster No. DX41	**Disease Modifying Therapy Category** May 25, 2017, 6:15 – 8:15 p.m. CDT
Durable efficacy of Cladribine Tablets in patients with multiple sclerosis: analysis of relapse rates and relapse-free patients in the CLARITY and CLARITY Extension studies	G. Giovannoni	Poster No. DX30	
Benefits of Cladribine Tablets on no evidence of disease activity (NEDA) status in patients with multiple		Poster No. DX31	

Benefits of Cladribine Tablets on magnetic resonance imaging (MRI) outcomes in patients with multiple sclerosis: analysis of pooled data from the CLARITY and ONWARD studies		Poster No. DX32	
Benefits of Cladribine Tablets on relapse rates and disability progression in patients with multiple sclerosis: analysis of pooled data from the CLARITY and ONWARD studies		Poster No. DX33	

Rebif® (interferon beta-1a) Presentations

Title	**Lead Author**	**Abstract/Poster #**	**Presentation Date/Time**
Post Hoc Analysis of PRISMS Study: Efficacy of Interferon beta-1a Subcutaneously Three Times Weekly According to Baseline EDSS/Duration, EDSS, and MSSS Subgroups	R. Berkovich	Poster No. DX58	**Disease Modifying Therapy category** May 25, 2017, 6:15 – 8:15 p.m. CDT
Post Hoc Analyses of PRISMS Study: Clinical Efficacy of Interferon beta-1a Subcutaneously Three Times Weekly According to Baseline Radiological Activity	A. Reder	Poster No. DX14	

Additional Company-Sponsored Presentations

Title	**Lead Author**	**Abstract/Poster #**	**Presentation Date/Time**
Rates of Comorbidities in Patients with	K. Kresa-Reahl	Poster No. DX71	**Disease**

Analysis			**category** May 25, 2017, 6:15 – 8:15 p.m. CDT
Disease-Modifying Drug Treatment before, during, and after Pregnancy in Women with Multiple Sclerosis and a Live Birth	MK Houtchens	Poster No. DX11	
Time to Initiation of Disease-Modifying Drugs after a Live Birth in Women with Multiple Sclerosis	MK Houtchens	Poster No. DX12	

About Cladribine Tablets

Cladribine Tablets is an investigational short-course oral therapy that is thought to selectively and periodically target lymphocytes thought to be integral to the pathological process of MS. Cladribine Tablets is currently under clinical investigation and not yet approved for the treatment for any use in the United States, Canada and Europe. In July 2016, the European Medicines Agency (EMA) accepted for review the Marketing Authorisation Application (MAA) of Cladribine Tablets for the treatment of relapsing remitting multiple sclerosis.

The clinical development program for Cladribine Tablets includes:

- CLARITY (CLAdRIbine Tablets Treating MS OrallY) study and its extension: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with RRMS and its two-year extension designed to provide data on the long-term safety and efficacy of extended administration of Cladribine Tablets for up to four years.
- ORACLE MS (ORAl CLadribine in Early MS) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS).
- ONWARD (Oral Cladribine Added ON To Interferon beta-1a in Patients with Active Relapsing Disease) study: a Phase II placebo-controlled study designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy.
- PREMIERE (Prospective Observational Long-term Safety Registry of Multiple Sclerosis Patients Who Have Participated in Cladribine Clinical Studies) study: interim long-term

total, with follow-up in some patients exceeding eight years at completion.

About Rebif® (interferon beta-1a)

Rebif (interferon beta-1a) is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS. The efficacy and safety of Rebif in controlled clinical trials beyond 2-years has not been established.

Important Safety Information

Rebif is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation.

Rebif should be used with caution in patients with depression, a condition that is common in people with multiple sclerosis. Depression, suicidal ideation, and suicide attempts have been reported to occur with increased frequency in patients receiving interferon compounds, including Rebif.

Severe liver injury, including some cases of hepatic failure requiring liver transplantation, has been reported rarely in patients taking Rebif. The potential for liver injury should be considered when used in combination with other products associated with liver injury. Monitor liver function tests and patients for signs and symptoms of hepatic injury. Consider discontinuing Rebif if hepatic injury occurs.

Anaphylaxis and other allergic reactions (some severe) have been reported as a rare complication of Rebif. Discontinue Rebif if anaphylaxis occurs.

In controlled clinical trials, injection site reactions occurred more frequently in Rebif-treated patients than in placebo-treated and Avonex-treated patients. Injection site reactions including injection site pain, erythema, edema, cellulitis, abscess, and necrosis have been reported in the postmarketing setting. Do not administer Rebif into affected area until fully healed; if multiple lesions occur, discontinue Rebif until skin lesions are healed.

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif-treated patients than in placebo-treated

Cases of thrombotic microangiopathy (TMA), some fatal, have been reported with interferon beta products, including Rebif, up to several weeks or years after starting therapy. Discontinue Rebif if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.

Caution should be exercised when administering Rebif to patients with pre-existing seizure disorders. Seizures have been temporally associated with the use of beta interferons, including Rebif, in clinical trials and in postmarketing reports.

The most common side effects with Rebif are injection-site disorders, headaches, influenza-like symptoms, abdominal pain, depression, elevated liver enzymes, and hematologic abnormalities.
There are no adequate and well-controlled studies in pregnant women. Rebif should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Rebif full prescribing information is available at
http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=

About Multiple Sclerosis
Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately 2.3 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About EMD Serono, Inc.
EMD Serono is the North America biopharma business of Merck KGaA, Darmstadt, Germany - a leading science and technology company - focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has more than 1,100 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

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Consortium of Multiple Sclerosis Centers. May 26, 2017; New Orleans, Louisiana.

[2] Comi G, et al. Cladribine Tablets in the ORACLE-MS study open-label maintenance period: analysis of efficacy in patients after conversion to clinically definite multiple sclerosis (CDMS). Consortium of Multiple Sclerosis Centers. May 25, 2017; New Orleans, Louisiana.

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EMD Serono Honors World MS Day by Launching Care Partner Survey with IACO

- Largest global MS care partner survey with International Alliance of Carer Organizations (IACO) will help identify unmet needs

- Preliminary research indicates most MS care partners are between the ages of 18-34

ROCKLAND, Mass., May 31, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, honors World MS Day 2017 by announcing a collaboration with the International Alliance of Carer Organizations (IACO) to launch the most comprehensive multiple sclerosis (MS) care partner survey to date.

The survey is being launched in response to preliminary findings from research commissioned by Merck KGaA, Darmstadt, Germany, which indicate that while 18 to 34-year-olds make up the largest group of MS care partners, the impact of caregiving during the prime of their lives and the challenges faced by this group are poorly understood. The global survey aims to provide a deep understanding of these unmet needs as a first step towards developing better resources and solutions for MS care partners in the future.

lives, building careers or families for example," said Rick Greene, Executive Advisor, International Alliance of Carer Organizations. "The findings from the research highlight the stark reality that faces many care partners in MS – anxiety, depression and pain being just a few. Therefore, in collaboration with Merck KGaA, Darmstadt, Germany, we are announcing a large-scale survey that will help us to build a comprehensive picture of the problems facing MS care partners and, importantly, look to develop solutions to address these needs."

Preliminary findings from research commissioned by Merck KGaA, Darmstadt, Germany showed the following:

- Highest number of care partners were aged 18-34 (41% of males and 39% of females in this group)
  - The US had a higher percentage of care partners aged 18-34 (46% for male and 45% for female care partners vs. 35% male and 33% female care partners within Europe)

- Family members caring for a mother with MS generated the majority of social media conversations related to MS caregiving, reflecting the prevalence of younger care partners in MS
- Problems identified among care partners included anxiety, depression, insomnia and pain, along with concerns about the financial impact of MS for families.

"There are more than 2.3 million people with MS worldwide and between 350,000 and 500,000 people in the United States. MS affects their quality of life and that of caregivers, family and friends" said Peer Baneke, CEO of the MS International Federation. "This year's World MS Day campaign encourages anyone affected by MS to share their tips for managing the challenges of #LifeWithMS."

The global care partner survey, which is being launched on World MS Day and will be fielded in the following months, will uncover insights from care partners from the US, Europe, and Canada. Results from the survey will be announced in the next 12 months along with recommendations on how support can be shaped to address the needs of MS care partners, including younger care partners.

"EMD Serono is committed to improving understanding of the needs of MS patients and care partners to help inform our programs and initiatives," said Dr. Joseph Leveque, Chief Medical Officer, EMD Serono. "The global survey will help us identify new ways to support those affected by MS, including the families and friends of those with this overwhelming condition."

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About World MS Day 2017

World MS Day is officially marked on the last Wednesday of May. Events and campaigns take place throughout the month of May. It brings the global MS community together to share stories, raise awareness and campaign with and for everyone affected by multiple sclerosis.

In 2009, the MS International Federation (MSIF) MS International Federation (MSIF) and its members initiated the first World MS Day. Campaigns are rolled out globally which focus on a different theme each year. The theme for World MS Day 2017 is 'Life with MS'.

About the International Alliance of Carer Organizations (IACO)

Incorporated in 2012, the International Alliance of Carer Organizations (IACO) serves as an umbrella organization that provides cohesive direction, facilitates information sharing, and actively advocates for carers at an international level. IACO provides research, awareness and education regarding family carers on a global scale. By bringing visibility and an understanding of the growing numbers of carers worldwide, IACO facilities international collaboration by bringing together countries from around the globe that advocate for family carers.

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About Merck KGaA, Darmstadt, Germany

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or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2015, Merck KGaA, Darmstadt, Germany, generated sales of € 12.85 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. The company holds the global rights to the "Merck" name and brand except in the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

Merck KGaA, Darmstadt, Germany, is one of the world's leading suppliers of effect pigments for the coatings, plastics, printing, cosmetic, food and pharmaceutical industries. Effect pigments underscore the emotional impact of color and are an important design element when creating surfaces with a special appearance or quality. Application possibilities range from cars to packaging and high-tech products up to building façades. In addition to decorative effect pigments, Merck KGaA, Darmstadt, Germany, offers pigments that also have functional applications such as heat-reflecting or anti-counterfeiting pigments.

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Merck KGaA, Darmstadt, Germany, Strengthens Immuno-Oncology Portfolio through Expansion of F-star Collaboration including LAG-3/PD-L1 Bispecific Antibody

- New strategic collaboration to develop and commercialize bispecific immuno-oncology antibodies, including LAG-3/PD-L1 asset FS118

- Potential for Merck KGaA, Darmstadt, Germany, to rapidly expand its immuno-oncology portfolio, supporting the goal to be a leader in this area of research

DARMSTADT, Germany, June 4, 2017 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates its biopharmaceutical business as EMD Serono in the U.S. and Canada, today announced a new strategic collaboration with biopharmaceutical company F-star, Cambridge, UK, for the development and commercialization of five bispecific immuno-oncology antibodies. Beyond these five bispecific antibodies, Merck KGaA, Darmstadt, Germany, will have further rights to replace, as well as to add to these antibodies using F-star's bispecific antibody platform. This collaboration will further strengthen Merck KGaA, Darmstadt, Germany's immuno-oncology pipeline and underscores the commitment to discovering and developing breakthrough cancer therapies that make a meaningful difference to patients' lives.

Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany. "This deal complements our internal capabilities in immuno-oncology and positions us as a potential leader in this important area of research."

Under these agreements and upon delivery of pre-defined data packages, Merck KGaA, Darmstadt, Germany, has the option to acquire five of F-star's bispecific programs. This option includes exclusive development and commercialization rights to F-star's preclinical lead asset FS118, which is designed to block LAG-3 (Lymphocyte-Activation Gene 3) and PD-L1 (Programmed Death-Ligand 1), two pathways commonly used by cancer cells to evade the immune system. In addition, F-star will grant Merck KGaA, Darmstadt, Germany, exclusive development and commercial rights to four novel bispecific antibodies of Merck KGaA, Darmstadt, Germany's choosing from F-star's bispecific antibody platform. These bispecific antibodies target specific pathways to augment the anti-tumor immune response. In return, Merck KGaA, Darmstadt, Germany, will pay up to €115 million in upfront, R&D funding and milestone payments in the first 2 years, and may make further payments upon exercising its option and based on milestones.

Merck KGaA Darmstadt, Germany, already has a bifunctional antibody in its pipeline, M7824. Currently in Phase I, M7824 is believed to combine two mechanisms in one molecule to fight cancer. The addition of assets from F-star's bispecific antibody platform enrich and complement Merck KGaA, Darmstadt, Germany's existing in-house technologies investigating molecules that offer the potential advantage of taking a dual approach to tackling cancer. Discovered in-house, M7824 is an investigational immunotherapy designed to simultaneously block two immuno-inhibitory pathways (PD-L1 and TGF-β) that are commonly used by cancer cells to evade the immune system.

"This immuno-oncology collaboration expands our strong relationship with Merck KGaA, Darmstadt, Germany, and is a further validation of the potential of F-star's bispecific antibody platform," said John Haurum, CEO of F-star. "Our vision is to transform the treatment of cancer. This is the objective of partnering our lead asset FS118 and other next-generation immuno-oncology compounds with Merck KGaA, Darmstadt, Germany."

Merck KGaA, Darmstadt, Germany, is committed to exploring an array of targets, and taking creative scientific approaches to developing novel therapies for hard-to-treat cancers. With the belief that rational combination is the key to the future of new and more efficacious treatment

immunotherapies from its own or external portfolios. The strength of Merck KGaA, Darmstadt, Germany's promising oncology development program and growing presence in the field of immuno-oncology demonstrates how the company is re-imagining the way cancer care is delivered.

For further information and press materials on Merck KGaA, Darmstadt, Germany's activities in oncology, please visit http://www.emdgroup.com/emd/media/media_center_oncology.html

All Merck KGaA, Darmstadt, Germany, press releases are distributed by e-mail at the same time they become available on the EMD Group Website. In case you are a resident of the USA or Canada please go to www.emdgroup.com/subscribe to register again for your online subscription of this service as our newly introduced geo-targeting requires new links in the email. You may later change your selection or discontinue this service.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.

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SOURCE Merck KGaA, Darmstadt, Germany

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Merck KGaA, Darmstadt, Germany, Biopharma Innovation Cup 2017

- Winning team receives €20,000 for innovative project proposal on the role of Natural Killer cells in cancer immunology
- Overall, more than 1,400 applications from 60 countries
- Next year's 350th anniversary edition will also cover topics from Life Science and Performance materials

(1)

DARMSTADT, Germany, July 6, 2017 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the winners of its seventh Biopharma Innovation Cup. The winning team received €20,000 for its innovative idea around the role of Natural Killer (NK) cells in cancer immunology.

The Biopharma Innovation Cup is designed to support the professional development of post-graduate students and to foster innovation from a promising new generation of academic talent. It showcases Merck KGaA, Darmstadt, Germany's deep commitment to leverage innovation, curiosity and collaboration. With more than 1,400 applications from 60

researchers and managers in the biopharma field on developing business plans. For 6 days, bright minds came together at the Innovation Camp near Frankfurt, Germany, and jointly developed novel ideas into innovative project plans for drug discovery.

The winning team "Immuno-Oncology" inspired the audience with their outstanding project proposal on how to translate NK cell biology into a drug discovery project.

The team consisted of:

- Alex Kertser (Weizmann Institute of Science, Israel)
- Franklin Zhong (A*STAR, Singapore)
- Kelly Moynihan (MIT, USA)
- Patrik Andersson (Karolinska Institute, Sweden)
- Simone Mori (The Scripps Research Institute, USA)
- Arne Sutter (team coach)

As runner-up receiving €5,000, the team "Medicinal Chemistry" was chosen with an innovative proposal on DNA-encoded libraries.

The team consisted of:

- Adam McCallum (Georgia Institute of Technology, USA)
- Anna Rydzik (LMU Munich, Germany)
- Josua Jordi (Harvard, USA)
- Rüdiger Borrmann (ETH Zürich, Switzerland)
- Wilian Cortopassi (UCSF, USA)
- Henning Böttcher (team coach)

The initiative has won several innovation awards over the years, including the Edison Award 2017, Stevie Gold Award 2017, German Industry Innovation Award 2015 and the German Idea Award 2014. More detailed information on the Biopharma Innovation Cup can be found at Biopharma Open Innovation Portal.

"The Biopharma Innovation Cup is getting increasingly popular at innovation hotspots all over the world from year to year. We are happy to offer young talents this development opportunity," said Dr Ulrich Betz, Vice President of Innovation & Entrepreneurship Incubator at

On the occasion of their 350th anniversary in 2018, Merck KGaA, Darmstadt, Germany, will conduct a special anniversary edition of the Innovation Cup, covering topics in Life Science and Performance Materials in addition to Healthcare. Applications to participate in the 2018 edition of the cup can be submitted starting October 01, 2017.

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Investigational Cladribine Tablets Demonstrates Sustained Disease Control over 4 Years with Maximum of 20 Days Oral Treatment

- CLARITY Extension data published in the MS Journal shows 75% of patients who received 2 annual short courses of Cladribine Tablets remained relapse free over four years

- The majority of patients who experienced Grade 3 lymphopenia in Years 1 and 2 recovered to Grade 0-1 by the end of the study

ROCKLAND, Mass., Sept. 5, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, today announced the publication of the results of the CLARITY Extension study in the *Multiple Sclerosis Journal*. The trial, an extension of the Phase III CLARITY study, demonstrated that treatment of patients with relapsing remitting multiple sclerosis (RRMS) with Cladribine Tablets, an investigational short-course oral therapy for two years, followed by two years of treatment with placebo, had clinical benefits similar to those seen with four years of treatment with Cladribine Tablets, with a low risk of severe lymphopenia.

including annualised relapse rate (ARR) and confirmed 3-month Expanded Disability Status Scale (EDSS) progression. The proportion of patients who remained relapse-free at the end of four years was similar to the patients who received Cladribine Tablets 3.5 mg/kg in CLARITY followed by placebo in CLARITY Extension (75.6%), and those who received Cladribine Tablets 3.5 mg/kg in both studies (81.2%). The proportion of patients who remained free of 3-month EDSS progression was also similar between the treatment groups (72.4% vs 77.4%).

"Today's publication further strengthens the evidence for the use of Cladribine Tablets in MS, demonstrating significant, durable benefits in patients not receiving active treatment after the two short courses," said Prof. Gavin Giovannoni, a lead investigator in the CLARITY studies and Chair of Neurology, Barts and The London School of Medicine and Dentistry. "The data from this publication and other recent articles suggest that Cladribine Tablets selectively targets the adaptive immune system, particularly the b cell compartment, and therefore allows the immune system to reconstitute while still preventing MS disease activity in the majority of treated patients."

The safety outcomes were comparable to those seen in CLARITY; adverse event rates were similar in patients who received Cladribine Tablets in CLARITY followed by placebo in CLARITY Extension, and those who received Cladribine Tablets in both studies. In CLARITY, patients with active relapsing–remitting multiple sclerosis were randomized to placebo or 1 of 2 cumulative doses of Cladribine Tablets (3.5 or 5.25 mg/kg body weight) for 2 years. In CLARITY Extension, patients were administered placebo or a cumulative dose of Cladribine Tablets 3.5 mg/kg body weight. In patients who received Cladribine Tablets 3.5 mg/kg in CLARITY and placebo in CLARITY Extension, the majority of those who experienced Grade ≥ 3 lymphopenia recovered to Grade 0-1 by the completion of CLARITY Extension. Most AEs were classified as mild or moderate. In the patient group receiving placebo in CLARITY Extension following Cladribine Tablets 3.5 mg/kg in CLARITY, 3.1% of patients discontinued because of AEs. The most frequent AE in patients receiving Cladribine Tablets in the CLARITY Extension study was lymphopenia. The majority of lymphopenia events were classified as mild or moderate, and the majority of patients who experienced lymphopenia Grade ≥3 actually experienced Grade 3 only. In CLARITY Extension, herpes zoster infections were most frequent in patients receiving the highest cumulative dose of Cladribine Tablets (4.8%), however the incidence of herpes zoster in all other treatment groups was similar irrespective of cumulative dose (1.1–2.0%).

Serono. "At EMD Serono we are very excited about the difference Cladribine Tablets could make in the lives of patients with this debilitating condition."

In August, the European Commission (EC) granted Marketing Authorization of the investigational therapy, Cladribine Tablets, marketed as MAVENCLAD® in the EU, for the treatment of adults with highly active relapsing MS.* Merck KGaA, Darmstadt, Germany plans additional filings for regulatory approval in other countries, including the United States.

* Defined as: patients with 1 relapse during the previous year and ≥ 1 T1 Gd+ lesion or ≥ 9 T2 lesions while on therapy with other DMDs; OR patients with ≥ 2 or more relapses in the previous year, whether on DMD treatment or not.

CLARITY Extension Study Design

The CLARITY Extension study involved 806 patients out of 1,184 patients from the CLARITY study, allowing assessment of the effects of 2 years' additional treatment with Cladribine Tablets beyond the 2-year CLARITY regimen. Patients who received Cladribine Tablets 3.5 mg/kg or 5.25 mg/kg in the CLARITY study were randomised to receive either Cladribine Tablets 3.5 mg/kg or placebo in CLARITY Extension, and patients who received placebo in the original CLARITY study received Cladribine Tablets 3.5 mg/kg in CLARITY Extension.

About Cladribine Tablets

Cladribine Tablets is an investigational short-course oral therapy that selectively and periodically targets lymphocytes thought to be integral to the pathological process of relapsing MS (RMS). Cladribine Tablets is currently under clinical investigation and not yet approved for the treatment for any use in the United States and Canada. In August 2017, the European Commission (EC) granted marketing authorization for Cladribine Tablets, marketed as MAVENCLAD® in the European Union (EU), for the treatment of relapsing forms of multiple sclerosis (RMS) in the 28 countries of the EU in addition to Norway, Liechtenstein and Iceland.

The clinical development program for Cladribine Tablets includes:

- The CLARITY (Cladribine Tablets Treating MS Orally) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with RRMS.
- The CLARITY Extension study: a four-year Phase III placebo-controlled study following on from the CLARITY study, designed to evaluate the safety and efficacy of Cladribine Tablets

controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS).

- The ONWARD (Oral Cladribine Added ON To Interferon beta-1a in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled study designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy.
- PREMIERE (Prospective Observational Long-term Safety Registry of Multiple Sclerosis Patients Who Have Participated in Cladribine Clinical Studies) study: interim long-term follow-up data from the prospective registry, PREMIERE, to evaluate the safety and efficacy of Cladribine Tablets. This includes more than 10,000 patient years of data with over 2,700 patients included in the clinical trial program, and more than 10 years of observation in some patients.

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European Commission Approves Bavencio (Avelumab) for Metastatic Merkel Cell Carcinoma

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- First approved immunotherapy for rare and aggressive skin cancer in the European Union, with initial launches planned in Germany and the UK
- Builds on Bavencio's previous accelerated approvals in the US and recent approval in Switzerland
- Approval based on data from Javelin Merkel 200 study including durable tumor response rate and duration of response

Darmstadt, Germany, and New York, US, September 21, 2017 – Merck KGaA, Darmstadt, Germany and Pfizer Inc. (NYSE: PFE) today announced that the European Commission (EC) has granted marketing authorization for BAVENCIO® (avelumab) as a monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma (mMCC), a rare and aggressive skin cancer.[1] BAVENCIO will have marketing authorization in the 28 countries of the European Union (EU) in addition to Norway, Liechtenstein and Iceland. BAVENCIO is expected to become commercially available to patients in Europe by prescription within the coming months, with initial launches in Germany and UK expected as early as October 2017.

"The EC's decision is significant for BAVENCIO and, more importantly, for European patients living with this very challenging skin cancer," said Luciano Rossetti, M.D., Executive Vice

Pfizer continues to demonstrate the power of working together, and we are grateful to everyone who has helped to bring the first and only approved immunotherapy for mMCC to European patients."

"This European approval further establishes our continued momentum, building on the accelerated approvals BAVENCIO received in the US earlier this year," said Liz Barrett, Global President, Pfizer Oncology. "Importantly, we are now one step closer to our goal of making BAVENCIO available to patients around the world."

Approximately 2,500 Europeans are affected by MCC each year, with metastatic disease diagnosed in 5–12% of patients with MCC. Fewer than 20% of patients with metastatic MCC survive beyond 5 years. [2-6]

"Merkel cell carcinoma is a particularly aggressive form of skin cancer with very poor outcomes, especially for those with metastatic disease," said Dirk Schadendorf, MD, Director of Dermatology, University Hospital Essen, Germany. "This approval is a meaningful development for patients and their families suffering from this devastating disease."

The EC approval is based on data from JAVELIN Merkel 200, an international, multicenter, single-arm, open-label, Phase II study; with two parts:[1]

- Part A included 88 patients with mMCC whose disease had progressed after at least one chemotherapy treatment. The objective response rate was 33%, with 11% of patients experiencing a complete response and 22% of patients experiencing a partial response. At the time of analysis, tumor responses were durable, with 93% of responses lasting at least 6 months (n=25) and 71% of responses lasting at least 12 months (n=13). Duration of response (DOR) ranged from 2.8 to more than 24.9 months.
- Part B, at the time of the data cut-off, included 39 patients with histologically confirmed mMCC who were treatment-naïve to systemic therapy in the metastatic setting. The objective response rate was 62%, with 14% of patients experiencing a complete response (CR) and 48% of patients experiencing a partial response (PR). Sixty-seven percent of patients experienced a progression-free survival (PFS) rate of 3 months.

The safety of avelumab has been evaluated in 1,738 patients with solid tumours including metastatic MCC (N=88) receiving 10 mg/kg every 2 weeks of avelumab in clinical studies.[1]

diarrhea (18.9%), decreased appetite (18.4%), constipation (18.4%), infusion-related reactions (17.1%), weight decreased (16.6%), and vomiting (16.2%). The most common Grade ≥ 3 adverse reactions were anaemia (6.0%), dyspnoea (3.9%), and abdominal pain (3.0%). Serious adverse reactions were immune-related adverse reactions and infusion-related reaction.

The EC's decision follows the US Food and Drug Administration's (FDA) accelerated approval* for BAVENCIO earlier this year for the treatment of mMCC and patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy. BAVENCIO was also granted marketing authorization by Swissmedic on September 05, 2017, in Switzerland for the treatment of patients with mMCC, whose disease has progressed after at least one chemotherapy treatment.

The clinical development program for BAVENCIO, known as JAVELIN, involves at least 30 clinical programs and more than 6,300 patients evaluated across more than 15 different tumor types. In addition to mMCC, these cancers include breast, gastric/gastro-esophageal junction, head and neck, Hodgkin's lymphoma, emelanoma, mesothelioma, non-small cell lung, ovarian, renal cell carcinoma and urothelial carcinoma.

About Metastatic Merkel Cell Carcinoma

Metastatic MCC is a rare and aggressive disease in which cancer cells form in the top layer of the skin, close to nerve endings.[7-8] MCC, which is also known as neuroendocrine carcinoma of the skin or trabecular cancer, often starts in those areas of skin that are most often exposed to the sun, including the head and neck, and arms.[8,10] Risk factors for MCC include sun exposure and infection with Merkel cell polyomavirus. Caucasian males older than 50 are at increased risk.[8,10] MCC is often misdiagnosed as other skin cancers and grows at an exponential rate on chronically sun-damaged skin.[11-14] Current treatment options for MCC in Europe include surgery, radiation and chemotherapy.[15] Treatment for metastatic or Stage IV MCC is generally palliative.[16]

About JAVELIN Merkel 200

The efficacy and safety of BAVENCIO was demonstrated in the JAVELIN Merkel 200 trial, a Phase II, open-label, single-arm, multicenter study, split into two parts:[1]

- Part A was conducted in 88 patients with histologically confirmed mMCC whose disease had progressed on or after chemotherapy administered for distant metastatic disease, with life expectancy of more than 3 months, and a minimum follow-up of 18 months. Overall in Part

were confirmed best overall response (BOR) and DOR, according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, as assessed by a blinded independent endpoint review committee (IERC).

- Part B, at the time of the data cut-off, included 39 patients with histologically confirmed mMCC who were treatment-naïve to systemic therapy, 29 of whom had at least 13 weeks of follow-up. Enrollment in Part B of the study is ongoing and is planned to include 112 treatment-naïve patients. For Part B, the major efficacy outcome measure is durable response, defined as objective response (CR or PR) with a duration of at least 6 months; secondary outcome measures include BOR, DOR, PFS and overall survival (OS).

The trial excluded patients with active or a history of central nervous system metastasis, prior treatment with anti-PD-1, anti-PD-L1, or anti-CTLA-4 antibodies, active or a history of autoimmune disease, a history of other malignancies within the last 5 years, organ transplant, and conditions requiring therapeutic immune suppression or active infection with HIV, or hepatitis B or C. Patients received BAVENCIO 10 mg/kg as an intravenous infusion over 60 minutes every 2 weeks until disease progression or unacceptable toxicity.

About BAVENCIO

BAVENCIO® (avelumab) is a human antibody specific for a protein called PD-L1, or programmed death ligand-1. BAVENCIO is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, BAVENCIO is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T cells, exposing them to anti-tumor responses. BAVENCIO has been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro. In November 2014, Merck KGaA, Darmstadt, Germany and Pfizer announced a strategic alliance to co-develop and co-commercialize BAVENCIO.

***Indications in the US[16]**

The US Food and Drug Administration (FDA) granted accelerated approval for BAVENCIO for the treatment of (i) mMCC in adults and pediatric patients 12 years and older and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications were approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

for signs and symptoms of pneumonitis and evaluate suspected cases with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold BAVENCIO for moderate (Grade 2) and permanently discontinue for severe (Grade 3), life-threatening (Grade 4), or recurrent moderate (Grade 2) pneumonitis. Pneumonitis occurred in 1.2% (21/1738) of patients, including one (0.1%) patient with Grade 5, one (0.1%) with Grade 4, and five (0.3%) with Grade

3.

BAVENCIO can cause **immune-mediated hepatitis**, including fatal cases. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater hepatitis. Withhold BAVENCIO for moderate (Grade 2) immune-mediated hepatitis until resolution and permanently discontinue for severe (Grade 3) or life-threatening (Grade 4) immune-mediated hepatitis. Immune-mediated hepatitis was reported in 0.9% (16/1738) of patients, including two (0.1%) patients with Grade 5 and 11 (0.6 %) with Grade 3.

BAVENCIO can cause **immune-mediated colitis**. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold BAVENCIO until resolution for moderate or severe (Grade 2 or 3) colitis and permanently discontinue for life-threatening (Grade 4) or recurrent (Grade 3) colitis upon re-initiation of BAVENCIO. Immune-mediated colitis occurred in 1.5% (26/1738) of patients, including seven (0.4%) with Grade 3.

BAVENCIO can cause **immune-mediated endocrinopathies**, including adrenal insufficiency, thyroid disorders, and type 1 diabetes mellitus.

Monitor patients for signs and symptoms of **adrenal insufficiency** during and after treatment and administer corticosteroids as appropriate. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Adrenal insufficiency was reported in 0.5% (8/1738) of patients, including one (0.1%) with Grade 3.

Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation. Manage hypothyroidism with hormone replacement therapy and hyperthyroidism with medical management. Withhold BAVENCIO for severe (Grade 3) or life threatening (Grade 4) thyroid disorders. Thyroid disorders including hypothyroidism,

Type 1 diabetes mellitus, including diabetic ketoacidosis: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Withhold BAVENCIO and administer antihyperglycemics or insulin in patients with severe or lifethreatening (Grade 3 equal to or greater) hyperglycemia and resume treatment when metabolic control is achieved. Type 1 diabetes mellitus without an alternative etiology occurred in 0.1% (2/1738) of patients, including two cases of Grade 3 hyperglycemia.

BAVENCIO can cause **immune-mediated nephritis and renal dysfunction**. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater nephritis. Withhold BAVENCIO for moderate (Grade 2) or severe (Grade 3) nephritis until resolution to Grade 1 or lower. Permanently discontinue BAVENCIO for life-threatening (Grade 4) nephritis. Immune-mediated nephritis occurred in 0.1% (1/1738) of patients.

BAVENCIO can result in **other severe and fatal immune-mediated adverse reactions** involving any organ system during treatment or after treatment discontinuation. For suspected immune-mediated adverse reactions evaluate to confirm or rule out an immune-mediated adverse reaction and to exclude other causes. Depending on the severity of the adverse reaction, withhold or permanently discontinue BAVENCIO, administer high-dose corticosteroids, and initiate hormone replacement therapy if appropriate. Resume BAVENCIO when the immune-mediated adverse reaction remains at Grade 1 or lower following a corticosteroid taper. Permanently discontinue BAVENCIO for any severe (Grade 3) immune-mediated adverse reaction that recurs and for any life-threatening (Grade 4) immune-mediated adverse reaction. The following clinically significant immune-mediated adverse reactions occurred in less than 1% of 1738 patients treated with BAVENCIO: myocarditis with fatal cases, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, and systemic inflammatory response.

BAVENCIO can cause severe (Grade 3) or life-threatening (Grade 4) **infusionrelated reactions**. Patients should be premedicated with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent doses based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for mild (Grade

reactions occurred in 25% (439/1738) of patients, including three (0.2%) patients with Grade 4 and nine (0.5%) with Grade 3.

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least one month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least one month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

The most common adverse reactions (all grades, greater than or equal to 20%) in patients with **metastatic Merkel cell carcinoma (MCC)** were fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), infusion-related reactions (22%), rash (22%), decreased appetite (20%), and peripheral edema (20%).

Selected treatment-emergent laboratory abnormalities (all grades, greater than or equal to 20%) in patients with **metastatic MCC** were lymphopenia (49%), anemia (35%), increased aspartate aminotransferase (34%), thrombocytopenia (27%). and increased alanine aminotransferase (20%).

The most common adverse reactions (all grades greater than or equal to 20%) in patients with **locally advanced or metastatic urothelial carcinoma (UC)** were fatigue (41%), infusion-related reaction (30%), musculoskeletal pain (25%), nausea (24%), decreased appetite/hypophagia (21%) and urinary tract infection (21%).

Selected laboratory abnormalities (grades 3-4, greater than or equal to 3%) inpatients with **locally advanced or metastatic UC** were hyponatremia (16%), increased gamma-glutamyltransferase (12%), lymphopenia (11%), hyperglycemia (9%), increased alkaline phosphatatse (7%), anemia (6%), increased lipase (6%), hyperkalemia (3%), and increased aspartate aminotransferase (3%).

Please see full US Prescribing Information and Medication Guide available at www.BAVENCIO.com.

global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

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About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of €15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, operates as EMD Serono, MilliporeSigma and EMD Performance Materials in the United States and Canada.

Pfizer Inc.: Working together for a healthier world®
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines, as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative

world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of September 21, 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about BAVENCIO (avelumab), including a new indication in the EU as a monotherapy for the treatment of adult patients with metastatic Merkel cell carcinoma the Merck KGaA, Darmstadt, Germany-Pfizer Alliance involving anti-PD-L1 and anti-PD-1 therapies, and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of BAVENCIO; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when any other drug applications may be filed in any jurisdictions for potential indications for BAVENCIO, combination therapies or other product candidates; whether and when regulatory authorities in any other jurisdictions where applications are pending or may be submitted for BAVENCIO, combination therapies or other product candidates may approve any such applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of BAVENCIO, combination therapies or other product candidates; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and in its subsequent reports on Form 10-

all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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SITEMAP

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Merck KGaA, Darmstadt, Germany Launches Global Initiative to Recognize and Support the Pivotal Role of Unpaid Caregivers

EXPLORE MORE

- New findings address the emotional, financial and health implications of being an unpaid caregiver

- 42% of unpaid caregivers surveyed report putting the health of the person they are caring for above their own; more than half report their physical health has suffered

- Leading organizations come together to raise caregiver challenges as a public health priority

DARMSTADT, Germany, Oct. 5, 2017 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany today launched Embracing Carers™, a global initiative to recognize and raise awareness of the crucial role of unpaid caregivers. At the International Carers Conference in Adelaide, Australia, Merck KGaA, Darmstadt, Germany unveiled the findings of the Embracing Carers™ International Survey which concludes that a strong need for increased support to caregivers exists globally. Since caregivers are people who provide unpaid assistance to someone in need, their own needs are often overlooked.

global public health priority. Not enough services and programs exist today to help caregivers address their own health and well-being and it's our aim to champion caregiver support and become a long-standing partner for the caregiver community. Merck KGaA, Darmstadt, Germany's responsibility and commitment to helping patients live longer, more fulfilled lives, stretch beyond medical innovation for patients."

Advised by leading caregiver organizations from around the world, Embracing Carers™ is a multi-dimensional initiative to fill the need for better support and recognition of caregivers. As its first steps, Embracing Carers™ has undertaken to:

1. **Support** the caregiver infrastructure by making possible the International Alliance of Carer Organizations' (IACO) Carer Toolkit, providing countries without a caregiver infrastructure the information to develop a national caregiver organization.
2. **Convene** caregiver organizations from across the world to serve as strategic advisors in increasing support and recognition of caregivers.
3. **Develop** calls to action to broaden stakeholder engagement, increase global awareness of challenges, drive legislative action and engage with healthcare systems.

The survey[1], which questioned 3,516 unpaid caregivers across seven countries (Australia, France, Germany, Italy, Spain, United Kingdom, United States), revealed a strong need for increased support to caregivers. In fact, more than half (55%) of unpaid caregivers feel that their physical health has suffered as a result of their caregiver duties and 54% of unpaid caregivers don't often have time to book or attend medical appointments for themselves.

Co-created with the Embracing Carers™ strategic advisors, the Embracing Carers™ Carers Report: *Embracing the Critical Role of Carers Around the World* was also presented at the conference. The report concluded that caring for a loved one is an activity that cuts across most demographic groups, including age, race, educational attainment and household income.

"The Embracing Carers™ International Survey and Carers Report clearly demonstrates the need for more action to be conducted on an international level to address the challenges that family caregivers face when caring for a family member or friend," said Rick Greene, Executive Advisor, International Alliance of Carer Organizations. "The coming together of industry and advocacy results in greater expertise, resources and support for caregivers within healthcare systems wherever they live."

Caregiving, International Alliance of Carer Organizations (IACO) and Shanghai Roots & Shoots, China.

For more information on Embracing Carers™, the International Survey or Carers Report, visit our website at www.embracingcarers.com.

About the Embracing Carers™ strategic advisors

Caregiver Action Network
US-based Caregiver Action Network (CAN) serves a broad spectrum of family caregivers ranging from the parents of children with special needs, to the families and friends of wounded soldiers; from a young couple dealing with a diagnosis of MS, to adult children caring for parents with Alzheimer's disease. CAN (the National Family Caregivers Association) is a non-profit organization providing education, peer support, and resources to family caregivers across the country free of charge.

Carers Australia
Carers Australia is the national peak body representing Australia's carers, advocating on behalf of Australia's carers to influence policies and services at a national level. It works collaboratively with partners and its member organisations, the Network of state and territory Carers Associations, to deliver a range of essential national carer services.

Carers UK
Established in 1965, Carers UK is the UK's only national membership charity for carers, offering a supportive community and leading a movement for change. Its mission is to make life better for carers, through giving expert advice, information and support; connecting carers so no-one has to care alone; campaigning together for lasting change; and innovating to find new ways to reach and support carers.

Carers Worldwide
Carers Worldwide develops and promotes cost effective, sustainable and easily replicable methods of providing support to carers in low and middle income countries. In partnership with local agencies, it aims to enable service providers, policy makers and other stakeholders to recognise and respond to the needs of carers in the developing world, ensuring balance and equal value is given to the needs of the carer and the person receiving care.

to advance the recognition of informal care acting on behalf of all carers, former carers, and their organizations, irrespective of their age or the particular health need of the person they caring for. Eurocarers brings together carers' organisations as well as relevant universities & research institutes to ensure that care is valued and unpaid care is recognised as central to the sustainability of health and long term care systems.

National Alliance for Caregiving

Established in 1996, the National Alliance for Caregiving is a non-profit coalition of national organizations focusing on advancing family caregiving through research, innovation, and advocacy. Based in the United States, the Alliance conducts research, does policy analysis, develops national best-practice programs, and works to increase public awareness of family caregiving issues.

International Alliance of Carer Organizations (IACO)

Incorporated in 2012, the International Alliance of Carer Organizations (IACO) serves as an umbrella organization that provides cohesive direction, facilitates information sharing, and actively advocates for carers at an international level. IACO aims to investigate and address issues of international family caregiving with the intent of increasing public awareness of the needs of the family caregiver on a global scale.

Shanghai Roots & Shoots, China

The Shanghai branch of Roots & Shoots was founded as a volunteer organization in November, 1999. Five years later, in November, 2004, Roots & Shoots was granted a Non-Profit Organization status by the Shanghai Municipality Government. The program aims to foster respect and compassion for all living things, to promote understanding of all cultures and beliefs, and to empower and inspire individuals to take action to make a positive difference in our world.

About the Embracing Carers™ International Survey

The Embracing Carers™ online survey was conducted by Censuswide on behalf of Merck KGaA, Darmstadt, Germany. It questioned 3,516 unpaid carers aged 18-75 years including 2,106 respondents aged 35-55 in Australia, France, Germany, Italy, Spain, UK and the US between 27 July and 8 August, 2017.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the „Merck" name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

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SOURCE Merck KGaA, Darmstadt, Germany

Pursuing Novel Pathways in Immunology: Merck KGaA, Darmstadt, Germany Presents New Clinical Data at 2017 ACR/ARHP Annual Meeting

- Company to present 11 abstracts and highlight momentum of its clinical programs in systemic lupus erythematosus (SLE), osteoarthritis (OA), rheumatoid arthritis (RA) and fibrotic diseases

- Late-breaking Phase II data provide insights into potential disease- modifying properties of sprifermin in patients with knee OA

- Oral presentation of atacicept Phase II data analysis provides insights into its possible use for SLE patients with high disease activity

(1)

DARMSTADT, Germany, Oct. 20, 2017 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates its healthcare business in the U.S. and Canada as EMD Serono, today announced 11 abstracts are scheduled for presentation in oral and poster sessions, including one late-breaker, at the 2017 American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting to be held November 3-8, 2017 in San Diego, CA, U.S. This data reflects the company's

Noteworthy data includes a late-breaking abstract on FORWARD, a five-year Phase II study of sprifermin in OA of the knee, providing insights into its potential disease-modifying properties.

Additional data includes an oral presentation on the investigational agent atacicept in a subset of patients with high disease activity based on a post-hoc analysis of ADDRESS II, a 24-week, randomized, placebo-controlled Phase IIb study.

"We are committed to discovering and delivering transformative treatments to significantly improve the lives of people living with chronic progressive diseases," said Luciano Rossetti, Executive Vice President, Global Head of Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany. "Our approach has led to the discovery of novel pathways that modulate the immune system in more targeted ways, based on preclinical models. We're proud to showcase the progress we've made as we continue to explore the potential of these compounds that may eventually alter treatment paradigms."

Other data of note include an updated safety analysis of ADDRESS II and its long-term extension study; an exposure-response and exposure-safety modeling analysis of ADDRESS II and the Phase II APRIL-SLE study; an in-vitro study of abituzumab for potential use in fibrotic diseases (or fibrosis); and a pharmacodynamics (PD) modeling study of evobrutinib, one of the first Bruton's Tyrosine Kinase Inhibitors to be studied as a potential treatment in autoimmune diseases, with potential for eventual use in RA and SLE. All agents are investigational and have not been proven safe or effective, and are not registered in any market.

Accepted key abstracts at the 2017 ACR/ARHP Annual Meeting include:

Title	**Presenting Author**	**Abstract Number**	**Presentation Date/Time**	**Session Type/Title**
Sprifermin				
Efficacy and Safety of Intra-	M Hochberg	1L	Tuesday,	ACR Late-

Osteoarthritis: Results of the 2-Year Primary Analysis from a 5-Year Randomised, Placebo-Controlled, Phase II Study			6:00 PM PT	Session
Clinical Relevance of Structural Measures in Knee Osteoarthritis: Baseline Values and Change from Baseline Discriminate Patients Subsequently Receiving Knee Replacement	C Kwoh	1207	Monday, November 6, 9:00 AM – 11:00 AM PT	ACR Poster Session B: Osteoarthritis – Clinical Aspects Poster I: Clinical Trials and Interventions
Two-Year Changes in Knee Osteoarthritis Symptoms: Comparing Clinical Relevance of Patient-Reported Outcomes By Anchoring to Knee Replacement	C Kwoh	2183	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Osteoarthritis – Clinical Aspects Poster II: Observational and Epidemiological Studies
Atacicept				
Attainment of Low Disease Activity By Patients with Systemic Lupus Erythematosus (SLE) Starting with High Disease Activity in a 24-Week, Randomized, Placebo-Controlled, Phase IIb Study of Atacicept (ADDRESS II)	J Merrill	889	Sunday, November 5, 2:30 PM – 4:00 PM PT	ACR Concurrent Abstract Session – Oral Presentation: Systemic Lupus Erythematosus

				Treatment I: Novel and Current Therapies
Safety Profile in SLE Patients Treated with Atacicept in a Phase IIb Study (ADDRESS II) and Its Extension Study	J Merrill	2585	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Systemic Lupus Erythematosus – Clinical Aspects and Treatment Poster III: Therapeutics and Clinical Trial Design
Exposure-Response Modeling and Exposure-Safety Modeling Analyses in Two Phase II Studies of Atacicept in SLE	O Papasouliotis	2586	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Systemic Lupus Erythematosus – Clinical Aspects and Treatment Poster III: Therapeutics and Clinical Trial Design
QuantiFERON Testing in a Clinical Trial of Systemic Lupus Erythematosus: TB or Not TB	N Goel	2610	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Systemic Lupus

				Aspects and Treatment Poster III: Therapeutics and Clinical Trial Design
Abituzumab				
The αV Integrin Inhibitor Abituzumab Inhibits Myofibroblast Differentiation	E Samy	774	Sunday, November 5, 9:00 AM – 11:00 AM PT	ACR Poster Session A: Systemic Sclerosis, Fibrosing Syndromes and Raynaud's – Pathogenesis, Animal Models and Genetics Poster I
Evobrutinib				
Pharmacodynamic Modeling of BTK Occupancy Versus Efficacy in RA and SLE Models Using the Novel Specific BTK Inhibitor Evobrutinib	P Haselmayer	2565	Tuesday, November 7, 9:00 AM – 11:00 AM PT	ACR Poster Session C: Systemic Lupus Erythematosus – Animal Models Poster
Discovery Products				
A novel role for galectin-3	S Okitsu	25	Sunday,	ACR Poster

			11:00 AM PT	and Targets in Autoimmune Disease Poster
Assessing interferon regulatory factor 5 (IRF5) function in human primary immune cells with cell-penetrating peptides	G Chen	1060	Monday, November 6, 9:00 AM – 11:00 AM PT	ACR Poster Session B: Innate Immunity and Rheumatic Disease Poster II

For more information about the data to be presented, please visit the ACR/ARHP website. Also, visit the EMD Serono booth at this year's Annual Meeting to learn more about the company's commitment to advancing innovation in immunological diseases.

About Atacicept

Atacicept is in clinical development to investigate its potential as a treatment for systemic lupus erythematosus (SLE). It is a recombinant fusion protein which targets the cytokines APRIL and BlyS, two members of the tumor necrosis factor family that regulates B-cell maturation, function and survival and autoantibody production associated with certain autoimmune diseases such as SLE. Atacicept has been shown in animal models to affect several stages of B-cell development and may inhibit the survival of cells responsible for making antibodies. It is currently in Phase II studies.

About Sprifermin

Sprifermin is in clinical development to investigate its potential as a treatment for osteoarthritis (OA) in the knee. It is a truncated recombinant human FGF-18 protein thought to induce chondrocyte proliferation and increased extra-cellular matrix (ECM) production, with the potential of promoting cartilage growth and repair. Sprifermin is currently in Phase II studies.

About Abituzumab

Abituzumab is in clinical development to investigate its potential as a treatment for fibrotic diseases (or fibrosis). It is a recombinant de-immunized humanized IgG2 monoclonal antibody (mAb) that inhibits all subtypes of αv integrins. Abituzumab is designed to block integrin-

About Evobrutinib

Evobrutinib (M2951) is in clinical development to investigate its potential as a treatment for multiple sclerosis (MS), rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE). It is an oral, highly selective inhibitor of Bruton's Tyrosine Kinase (BTK) which is important in the development and functioning of various immune cells including B lymphocytes and macrophages. Evobrutinib is designed to inhibit primary B cell responses such as proliferation and antibody and cytokine release, without directly affecting T cells. BTK inhibition is thought to suppress autoantibody-producing cells, which preclinical research suggests may be therapeutically useful in certain autoimmune diseases. Evobrutinib is currently in Phase II studies.

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.

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neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has more than 1,100 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.
http://www.emdserono.com

ACR Abstract #
Atacicept: 889, 2585, 2586, 2610; Sprifermin: 1207, 2183, 1L; Abituzumab: 774; Evobrutinib: 2565; Discovery Products: 25, 1060

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SOURCE Merck KGaA, Darmstadt, Germany

EMD Serono Appoints Robert Truckenmiller to Senior Vice President of Market Access & Customer Solutions

ROCKLAND, Mass., Oct. 23, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the U.S. and Canada, today announced the appointment of Robert Truckenmiller as Senior Vice President, Market Access & Customer Solutions. In this role, Mr. Truckenmiller will oversee the development of U.S. market access strategy and implementation, as well as payer contracting and reimbursement strategies, to enable patient access to EMD Serono medications.

Mr. Truckenmiller joined EMD Serono in July 2016 as Vice President, Market Access & Customer Solutions, where he implemented new processes and procedures to optimize development and operations of all EMD Serono contracted business.

"Rob has demonstrated tremendous knowledge of the payer landscape, offering strategic insights and creating processes to ensure patients receive the medications they need," said Gary Zieziula, President and Managing Director of EMD Serono.

Prior to EMD Serono, Mr. Truckenmiller served as Vice President and Head of U.S. Market Access & Pricing at UCB, where he led a large team in developing a market access strategy that successfully improved overall patient access to UCB brands. He spent eleven years at UCB, taking on roles of increasing responsibility across market access and brand marketing. Additionally, Rob has more than 15 years of experience in the biopharmaceutical industry in various sales and marketing roles at companies such as Johnson & Johnson and DaVita Kidney Care.

Mr. Truckenmiller succeeds Scott Filosi, who was recently appointed to a new position within Merck KGaA, Darmstadt, Germany, as the Head of Global Market Access & Pricing.

Mr. Truckenmiller holds an undergraduate degree in Marketing and an MBA in Finance and Financial Management Services from University of Central Florida - College of Business Administration.

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EMD Performance Materials.

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SOURCE EMD Serono

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EMD Serono And Lupus Foundation Of America Launch Initiative To Improve Future Of Lupus Care

- The ALPHA Project aims to identify critical gaps and solutions for people with lupus, a disease affecting 1.5 million Americans

- Insights-driven collaboration paves path for timely and accurate diagnosis, greater access to care and improved treatment options

ROCKLAND, Mass., Nov. 1, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, and the Lupus Foundation of America (Foundation) today announced collaboration on The ALPHA Project: **A**ddressing **L**upus **P**illars for **H**ealth **A**dvancement, a global initiative to drive advancement in lupus research and care. This multi-phase initiative will seek to achieve better and timelier diagnosis, expand access to expert care, and improve treatment options for those living with this complex and unpredictable disease.

Lupus is a chronic autoimmune disease in which the body's immune system can attack and damage skin, joints, and internal organs. The Foundation estimates that 1.5 million Americans[1] have a form of lupus and as many as 16,000 new cases are reported each year.[2] In addition, lupus impacts at least 5 million people worldwide.

Global Head of R&D for EMD Serono. "We are proud to partner with the Lupus Foundation of America and support their unyielding resolution to advance lupus research and treatment. At EMD Serono, we are committed to identifying innovative solutions to help people with chronic, under-served conditions like lupus and are resolute in our search for ways to improve patient care."

Many unknowns remain about how to best care for people affected. The impact of lupus varies by individual, making it difficult to diagnose, treat and manage. Simple tests that allow clinicians to reliably identify lupus, as well as track and predict disease progression and related organ damage, are lacking.[3] The patient journey is often characterized by multiple visits, tests, and referrals over months – even years – prior to diagnosis.[4] On average, it takes nearly six years for people with lupus to be diagnosed from the time they first notice their lupus symptom.[5] Many others likely remain undiagnosed. Late diagnosis, poor access to care, less effective treatments, and poor adherence to therapeutic regimens may increase the damaging effects of lupus, causing more complications, and an increased risk of death.[6]

The ALPHA Project's goal is to enhance care for people with this difficult-to-treat disease. The initiative will consist of two parts: building a comprehensive picture of the challenges faced by individuals with lupus and developing actionable solutions to address these needs. This includes building a steering committee of leaders in the field of lupus, conducting qualitative research on the lupus patient journey to identify knowledge gaps in diagnosis and treatment, issuing a public report of the findings, and developing a roadmap to address these gaps.

The ALPHA Project will also build upon the National Public Health Agenda for Lupus, a first of its kind approach guiding lupus policy, planning, advocacy, and action initiatives. The National Public Health Agenda for Lupus was published in 2015 by the Lupus Foundation of America in partnership with the National Association of Chronic Disease Directors (NACDD) and the Centers for Disease Control and Prevention (CDC).

"Lupus is a highly complex and debilitating disease that has no cures. It is our hope that this project will lead to consensus positions and research directions agreed to by the international experts in lupus," said Sandra C. Raymond, CEO of the Lupus Foundation of America. "We are pleased to collaborate with EMD Serono on this important work that will translate science into new treatments and better tools to manage lupus with an eye directly on helping the patient as soon as possible."

Lupus is a chronic inflammatory disease that occurs when the body's immune system attacks its own tissues and organs. Inflammation caused by lupus can affect many different body systems — including the joints, skin, kidneys, blood cells, brain, heart and lungs.[7] Systemic lupus erythematosus (SLE) is the most common form of lupus and accounts for approximately 70% of all cases.[8] SLE can be mild or severe, and can cause serious complications involving major organ systems, including kidney failure, memory problems, stroke, seizures, behavioral changes, and heart attack.[9] Lupus impacts an estimated 1.5 million Americans and at least 5 million people worldwide.[10]

About the Lupus Foundation of America

The Lupus Foundation of America is the only national force devoted to solving the mystery of lupus, one of the world's cruelest, most unpredictable and devastating diseases, while giving caring support to those who suffer from its brutal impact. Through a comprehensive program of research, education, and advocacy, we lead the fight to improve the quality of life for all people affected by lupus. Learn more about the Lupus Foundation of America at **lupus.org**.

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[1] Lupus facts and statistics. The Lupus Foundation of America. http://resources.lupus.org/entry/facts-and-statistics. Accessed September 6, 2017.

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SOURCE EMD Serono

New Survey Reveals Physical, Mental and Financial Challenges Faced by Caregivers in the United States

- Findings revealed at launch of Embracing Carers™, a global initiative to raise the awareness of the crucial role of caregivers

- International survey spans seven countries and provides perspective on caregiver challenges around the globe

ROCKLAND, Mass., Nov. 6, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the US and Canada, announced the results of the Embracing Carers™ international survey highlighting the often-overlooked needs of unpaid caregivers. The survey[1], released as part of a multi-year initiative by the company, uncovered that nearly half (49%) of unpaid caregivers surveyed have feelings of depression.

US survey key findings include:

- Nearly half (45%) of unpaid caregivers surveyed feel that their physical health has suffered as a result of their caregiver duties.
- Nearly half (45%) of unpaid caregivers surveyed don't often have time to book or attend medical appointments for themselves.

- Almost half (47%) of female unpaid surveyed caregivers do not feel supported at all by the local community and a third (33%) of unpaid caregivers do not feel supported at all by their local health system and just 40% of unpaid caregivers feel supported by their employer in their role as a caregiver.

The challenge of caregiving is exacerbated by the lack of support that many caregivers say they receive.

"Millions of caregivers within the US play a pivotal role in the lives of patients. Embracing Carers™ aims to support the health and well-being of caregivers to seek help and resources to address the financial, emotional and physical pressures of caregiving," said Gary Zieziula, President and Managing Director, EMD Serono. "EMD Serono is working with caregiver thought leaders to help elevate caregiving as a public health priority within the US and around the world as part of our company's overall commitment to patients."

Embracing Carers™ Initiative Launched

To address the need for caregiver support, Merck KGaA, Darmstadt, Germany and EMD Serono launched Embracing Carers™ under advisement of leading caregiver organizations from both the US and around the world including the Caregiver Action Network (CAN), Carers Australia, Carers UK, Carers Worldwide, Eurocarers, National Alliance for Caregiving, International Alliance of Carer Organizations (IACO) and Shanghai Roots & Shoots, China.

"We have been encouraged by the findings of the Embracing Carers™ International Survey, particularly the results showing that nearly half of caregivers in the US are feeling some kind of physical strain – this aligns with findings from our own studies into caregiver challenges," said Grace Whiting, Chief Operating Officer, National Alliance for Caregiving. "The NAC is delighted to be a part of Embracing Carers™ movement helping to support caregivers. This initiative is very meaningful to us and the work we are doing in the United States."

Embracing the Critical Role of Caregivers Around the World

In addition to the survey, Embracing Carers™ published the, *Carers Report: Embracing the Critical Role of Carers Around the World*. Co-created with the Embracing Carers™ strategic advisors, the *Carers Report* concluded that a greater understanding of the issues facing caregivers needs to translate into action. Only through working with the global community of

greatly need and deserve.

"Data from the Embracing Carers™ International Survey clearly shows that we still need to provide the recognition that caregivers deserve and the significant support they need," said Lisa Winstel, Chief Operating Officer, Caregiver Action Network (CAN). "We welcome the launch of Embracing Carers™, which aligns with National Family Caregivers Month, as we all work together to get needed resources to caregivers and ultimately improve their lives, in the US and around the world."

For more information on Embracing Carers™, the International Survey or Carers Report, visit www.embracingcarers.com.

About the Embracing Carers™ International Survey

The Embracing Carers™ online survey was conducted by Censuswide on behalf of Merck KGaA, Darmstadt, Germany. It questioned 3,516 unpaid caregivers aged 18-75 years including 2,106 respondents aged 35-55 in Australia, France, Germany, Italy, Spain, UK and the US between July 27 and August 8, 2017.

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EMD Serono Receives FDA Approval for New GONAL-f® RFF Redi-ject® Pen

- Redesigned pen injector developed based on insights of healthcare professionals and fertility patients

ROCKLAND, Mass., Nov. 13, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, received approval for a redesigned version of GONAL-*f*® RFF* Redi-ject® (follitropin alfa injection) pen injector from the U.S. Food and Drug Administration (FDA). Originally approved in 2013, the new pen injector was reported to be easy to learn and easy to use in a simulated-use study including 86 women with infertility and 30 fertility nurses.[1]

"As a committed fertility treatment partner, we aspire to develop user-friendly treatment options for patients," said Richard R. Smith, Senior Vice President and Head of US Fertility and Endocrinology at EMD Serono. "The best drivers for innovation come from the insights of people using our products, which is why feedback from patients and healthcare professionals was critical in redesigning the pen injector features."

foundation as the only fertility drug pen injector that does not require mixing or loading, the new pen offers a larger display window for dose readability.

GONAL-*f*® RFF Redi-ject® (follitropin alfa injection) was first approved for use by the FDA on October 17, 2013 and is available in three sizes: 300 IU, 450 IU and 900 IU. GONAL-*f*® (follitropin alfa for injection) vials were first approved for use by the FDA in September 1997.

Supporting the one in eight couples in the U.S. suffering from infertility is a key focus for EMD Serono,[2] and the redesigned version of the GONAL-*f*® RFF Redi-ject® pen is one example of EMD Serono's ongoing dedication to the fertility community.

For more information about the new GONAL-*f*® RFF Redi-ject® pen injector, please call Fertility Lifelines at 1-866-538-7879.

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About GONAL-*f*® RFF Redi-ject® (follitropin alfa injection)

GONAL-*f*® RFF Redi-ject® (follitropin alfa injection) is indicated for induction of ovulation and pregnancy in oligo-anovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure and development of multiple follicles in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle. Prior to treatment, complete an evaluation of female and male partners to determine infertility diagnosis. Primary ovarian failure should be excluded.

GONAL-*f*® RFF Redi-ject® is contraindicated in women who exhibit: Hypersensitivity to rhFSH preparations or excipients, high levels of FSH indicating primary gonadal failure, pregnancy (Pregnancy Category X), uncontrolled non-gonadal endocrinopathies (thyroid, adrenal, pituitary disorders), sex hormone dependent tumors of the reproductive tract and accessory organs, tumors of pituitary gland or hypothalamus, abnormal uterine bleeding, ovarian cyst or enlargement of undetermined origin, not due to polycystic ovary syndrome.

The lowest effective dose should be used given risk of abnormal ovarian enlargement and Ovarian Hyperstimulation Syndrome (OHSS).

Thromboembolic events both in association with, and separate from OHSS have been reported in women treated with gonadotropins and can be serious. Women with generally recognized risk factors for thrombosis, such as personal or family history, severe obesity, or thrombophilia, may have an increased risk of venous or arterial thromboembolic events, during or following treatment with gonadotropins.

Ovarian torsion has been reported after treatment with gonadotropins.

Serious pulmonary conditions (e.g., atelectasis, acute respiratory distress syndrome and exacerbation of asthma) have been reported in women treated with gonadotropins.

Serious systemic hypersensitivity reactions, including anaphylaxis, have been reported.

The couple should be advised of the potential risk of multi-fetal gestation and birth before beginning therapy. During clinical trials, multiple births occurred in 20% of live births in women receiving therapy for ovulation induction and 35.1 % of live births in women undergoing ART.

The incidence of congenital malformations after some ART specifically in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI) may be slightly higher than after spontaneous conception.

The incidence of spontaneous abortion and ectopic pregnancy may be increased.

Both benign and malignant ovarian neoplasms have been infrequently reported; causality has not been established.

Both ultrasound and serum estradiol measurement should be used to monitor follicular growth and maturation, timing of the ovulatory trigger, detecting ovarian enlargement and minimizing the risk of the OHSS and multiple gestation.

The most common adverse reactions (≥5%) in OI include: headache, abdominal pain, and ovarian hyperstimulation. The most common adverse reactions (≥5%) in ART include:

In addition to advising patients about the proper use of treatment, the duration and necessity of monitoring, handling of missed doses, OHSS, and multi-fetal gestation and birth, patients should be advised to review the Patient Information Leaflet which contains risk information, follow the Instructions for Use for the GONAL-*f*® RFF Redi-ject®, not share the device or reuse needles, and to ask their HCP about questions.

*RFF Revised Formulation Female

Full prescribing information for GONAL-*f*® RFF Redi-ject® can be found at: http://www.emdserono.com/ms.country.us/en/images/Gonal-f_RFF_Redi-ject_PI_tcm115_140008.pdf?Version

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www.emdserono.com

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For further information: Melissa Beglin, 781-681-2609

EMD Serono Appoints Zhen Su, M.D., MBA to Chief Medical Officer, North America

ROCKLAND, Mass., Dec. 1, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US and Canada, today announced the appointment of Zhen Su, M.D., MBA as Chief Medical Officer for North America. In this role, Dr. Su will collaborate with the local and global medical, development and regulatory teams to drive the progress of EMD Serono's portfolio and pipeline, as well as enhance scientific leadership in the US.

"Zhen has made significant contributions to our organization through his previous positions, including building our US oncology medical affairs team from the ground up and leading multiple global oncology launches this past year," said Gary Zieziula, President and Managing Director, EMD Serono. "Zhen has the strategic vision and medical leadership to help develop and move our growing portfolio and pipeline of compounds forward for patients in need."

Dr. Su's expertise complements the global organization's R&D strategy, which focuses on delivering a transformative pipeline in the core

A physician executive with more than 20 years of experience, Dr. Su held roles at a number of academic institutions – including Duke University and University of Florida, where he led early clinical development in Immuno-Oncology as a faculty member – before joining the biopharmaceutical industry. Within EMD Serono, he most recently held the position of Global Head of Medical Affairs, Oncology, prior to which, he held leadership roles in general management, clinical development and medical affairs at Sanofi and GlaxoSmithKline.

Dr. Zhen Su will be based in Rockland, Mass.

Dr. Su earned his MD degree from the Technical University of Dresden, Germany and completed his MBA training at the University of Toronto, Canada.

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EMD Serono Announces FDA 510(k) Clearance of Partner Genea Biomedx's Fertility Benchtop Incubator Geri™

- Expanded Fertility Technology portfolio highlights EMD Serono's commitment to improve fertility treatment outcomes for patients
- U.S. commercial availability expected in first half of 2018

ROCKLAND, Mass., Dec. 5, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced the FDA 510(k) clearance of the benchtop embryo incubator Geri™. This innovative technology, designed to improve processes in fertility laboratories, will be commercially available to IVF clinics in the U.S. in the first half of 2018.

With the FDA 510(k) clearance of Geri™, an incubator for continuous embryo monitoring, EMD Serono will help to advance assisted reproductive treatment (ART) technologies by offering new, relevant solutions to patients and their healthcare professionals.

Verjee, Chief Marketing and Strategy Officer of the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. "Offering Geri™ in the U.S. will allow us to further our aspiration of becoming an integrated fertility treatment partner, continuously aiming to improve treatment outcomes."

An incubator is critical for embryo development while it is being cultured outside of the uterus. Getting as close as possible to in-vivo incubation conditions is essential to ensure the most favorable environment for embryonic development, given that exposure to non-optimal conditions outside of an incubator may affect the viability and quality of embryos.[i,ii,iii,iv]

Geri™ was designed by embryologists who know the lab processes and what optimizes successful embryo growth. Geri™ has six individual chambers, each independently controlled, facilitating the care of the embryos of six patients at the same time. It is equipped with high-definition cameras to take a picture of the embryos every 5 minutes and provide continuous imaging so the supervising embryologist can observe embryos as they develop without removing them from their optimum environment. This minimizes lid openings and potential disruptions that can cause stress to embryos.

"Genea Biomedx is an IVF medical device company uniquely positioned within a clinical fertility business allowing it direct access to world leading IVF laboratories. This enabled us to develop Geri™ in collaboration with the embryologists that use it day in, day out," said Dr. Tammie Roy, General Manager at Genea Biomedx. "We are looking forward to working with EMD Serono to bring our innovative technology to clinics across the U.S."

Geri™ will be distributed by EMD Serono in the U.S. through its Fertility Technologies unit, in accordance with a global distribution agreement executed with Genea Biomedx in May 2015. Additional products in EMD Serono's Fertility Technologies portfolio include Gems™, culture media allowing for high-quality embryo cultivation that was granted an FDA 510(k) clearance this summer, and Gidget™, a hand-held witnessing system that provides electronic witnessing, visual lab workflow management and support for traceability and audit reporting.

About Geri™

Geri™ is a benchtop incubator with individually controlled incubation chambers per patient to minimize disruptive events to the early-stage embryo. It also incorporates a camera to real-time monitor the developing embryos. Geri™ was developed by Genea Biomedx, a company

About Gems™

Gems™ is the latest generation of Genea Biomedx's culture media suite for high-quality embryo cultivation.

About Gidget™

Gidget™ is a hand-held witnessing system for the IVF laboratory that allows the embryologist to focus on the science by helping to ensure that gametes and embryos are matched correctly. Gidget™ provides electronic witnessing, visual lab workflow management and support for traceability and audit reporting.

About EMD Serono, Inc.

EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada - a leading science and technology company - focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has approximately 1,300 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.
www.emdserono.com

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Your Contact
Melissa Beglin 781-681-2609

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John Walsh, M.D. Joins EMD Serono as Vice President of Neurology & Immunology, US Medical Affairs

(1)

ROCKLAND, Mass., Dec. 7, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US and Canada, today announced the appointment of John Walsh, M.D. as Vice President, Neurology & Immunology (N&I), US Medical Affairs. In this role, Dr. Walsh will direct and manage the N&I Medical Affairs team to develop and implement plans for Rebif® (interferon beta-1a) and our products in development, both in the US and in collaboration with Global Medical Affairs.

"We are proud to welcome Dr. John Walsh to EMD Serono. The breadth of John's experience – from his years as a family medicine physician to his expertise with multiple sclerosis therapies – will be a tremendous asset to our team," said Zhen Su, Chief Medical Officer, EMD Serono. "John's medical knowledge and deep understanding of the unique needs of patients with conditions such as MS will be invaluable as we continue to advance treatment outcomes for patients with high unmet medical needs."

he managed a team across several disease areas, including multiple sclerosis (MS), Alzheimer's and neurodegeneration, among others.

Dr. Walsh is a Board-Certified physician with more than 19 years of experience providing medical care to patients. He also serves as a National Disaster Medical Assistance Team Medical Officer for the US Department of Health & Human Services, a position he has held for more than seven years.

Dr. Walsh holds an undergraduate degree in Science from St. Joseph's College in Patchogue, NY and received his Medical Doctorate from St. George's University School of Medicine. He completed his residency and chief residency at North Shore-LIJ / Southside Hospital in Bay Shore, NY.

EMD Serono's N&I franchise features Rebif, an established treatment option for relapsing MS; Cladribine Tablets, an investigational treatment for MS; and several pipeline products.

Rebif has a well-established efficacy and safety profile with more than 20 years of accrued clinical trial and patient experience. Since its approval in 2002, more than 140,000 people have chosen Rebif to treat their relapsing MS. In addition to providing this important treatment option, EMD Serono offers comprehensive support to patients through MS LifeLines. For more than 15 years, this award-winning patient support service has provided education and support for people living with relapsing MS.

About Rebif® (interferon beta-1a)

Rebif (interferon beta-1a) is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS. The efficacy and safety of Rebif in controlled clinical trials beyond 2-years has not been established.

Important Safety Information:

Rebif is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation.

reported to occur with increased frequency in patients receiving interferon compounds, including Rebif.

Severe liver injury, including some cases of hepatic failure requiring liver transplantation, has been reported rarely in patients taking Rebif. The potential for liver injury should be considered when used in combination with other products associated with liver injury. Monitor liver function tests and patients for signs and symptoms of hepatic injury. Consider discontinuing Rebif if hepatic injury occurs.

Anaphylaxis and other allergic reactions (some severe) have been reported as a rare complication of Rebif. Discontinue Rebif if anaphylaxis occurs.

In controlled clinical trials, injection site reactions occurred more frequently in Rebif-treated patients than in placebo-treated and Avonex-treated patients. Injection site reactions including injection site pain, erythema, edema, cellulitis, abscess, and necrosis have been reported in the postmarketing setting. Do not administer Rebif into affected area until fully healed; if multiple lesions occur, discontinue Rebif until skin lesions are healed.

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif-treated patients than in placebo-treated patients. Patients should be monitored for symptoms or signs of decreased blood counts. Monitoring of complete blood and differential white blood cell counts is also recommended.

Cases of thrombotic microangiopathy (TMA), some fatal, have been reported with interferon beta products, including Rebif, up to several weeks or years after starting therapy. Discontinue Rebif if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.

Caution should be exercised when administering Rebif to patients with pre-existing seizure disorders. Seizures have been temporally associated with the use of beta interferons, including Rebif, in clinical trials and in postmarketing reports.

The most common side effects with Rebif are injection-site disorders, headaches, influenza-like symptoms, abdominal pain, depression, elevated liver enzymes, and hematologic

There are no adequate and well-controlled studies in pregnant women. Rebif should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Rebif full prescribing information is available at http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=

About Cladribine Tablets

Cladribine Tablets is an investigational short-course oral therapy that is thought to selectively and periodically targets lymphocytes thought to be integral to the pathological process of relapsing MS (RMS). Cladribine Tablets is currently under clinical investigation and not yet approved for the treatment for any use in the United States. In August 2017, the European Commission (EC) granted marketing authorization for Cladribine Tablets, marketed as MAVENCLAD® in the European Union (EU), for the treatment of relapsing forms of multiple sclerosis (RMS) in the 28 countries of the EU in addition to Norway, Liechtenstein and Iceland. In December 2017, Health Canada approved MAVENCLAD for the treatment of relapsing-remitting MS (RRMS).

The clinical development program for Cladribine Tablets includes:

- The CLARITY (Cladribine Tablets Treating MS Orally) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with RRMS.
- The CLARITY extension study: a two-year Phase III placebo-controlled study following on from the CLARITY study, designed to evaluate the safety and efficacy of Cladribine Tablets over an extended administration for four years.
- The ORACLE MS (Oral Cladribine in Early MS) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS).
- The ONWARD (Oral Cladribine Added ON To Interferon beta-1a in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled study designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy.
- PREMIERE (Prospective Observational Long-term Safety Registry of Multiple Sclerosis Patients Who Have Participated in Cladribine Clinical Studies) study: interim long-term

patients included in the clinical trial program, and more than 10 years of observation in some patients.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately 2.3 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

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About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of €15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the "Merck" name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

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conditions as set out in our Legal Statement and Privacy Policy.

This site contains information that is intended for US residents only. Canadian residents should consult the EMD Inc. website at www.emdserono.ca for information on products and services approved in Canada.

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EMD Serono Named 'Top Place to Work' by The Boston Globe for Second Consecutive Year

Company makes prestigious Massachusetts top employer list based on positive employee feedback

Rockland, Massachusetts, November 17, 2017 – EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced that it has been named to *The Boston Globe*'s annual "Top Places to Work" list for the second consecutive year.

EMD Serono submitted a joint nomination with MilliporeSigma, the life science business of Merck KGaA, Darmstadt, Germany as the Massachusetts-based businesses of Merck KGaA, Darmstadt, Germany. Based on employee survey results, both were together named to the list of "Top Places to Work."

"We're honored to be recognized by *The Boston Globe* for the second year in a row, and grateful to our team of bold difference-makers who made it happen," said Gary Zieziula, President and Managing Director, EMD Serono. "This distinction underscores the value of

According to *The Boston Globe*, employers named to the "Top Places to Work" list share several key traits, including progressive benefit offerings, a culture of autonomy and inclusion, as well as an element of "fun" in the workplace.

"Top Places to Work" recognizes the best places to work in the state based on internal employee surveys. Award selection is based on anonymous employee surveys conducted by *The Boston Globe*'s research partner, Energage (formerly WorkplaceDynamics), from nearly 75,060 individuals at 334 Massachusetts organizations.

Employers who enter to be surveyed are placed into one of four groups: small, with 50 to 99 employees; midsize, with 100 to 249 workers; large, with 250 to 999; and largest, with 1,000 or more. In total, the Massachusetts-based businesses of Merck KGaA, Darmstadt, Germany employ approximately 2,500 team members across the area. Included in that number are roughly 100 EMD Performance Materials employees based in Haverhill, Mass., who also participated in this year's survey.

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expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has approximately 1,300 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.
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For further information: Melissa Beglin 781-681-2609

FDA Grants Approval for BAVENCIO® (avelumab), the First Immunotherapy Approved for Metastatic Merkel Cell Carcinoma

- Only FDA-approved treatment for metastatic Merkel cell carcinoma, a rare and aggressive skin cancer

- First indication for BAVENCIO, a human anti-PD-L1 antibody

ROCKLAND, Mass. and NEW YORK, March 23, 2017 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US and Canada, and Pfizer Inc. (NYSE: PFE) today announced that the US Food and Drug Administration (FDA) has approved BAVENCIO® (avelumab) Injection 20 mg/mL, for intravenous use, for the treatment of adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC). This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[1] BAVENCIO was developed, reviewed and approved through the FDA's Breakthrough Therapy Designation and Priority Review programs.

BAVENCIO, a human anti-PD-L1 antibody, is the first FDA-approved therapy for patients with mMCC.[2] Metastatic MCC is a rare and aggressive skin cancer, with fewer than half of patients surviving more than one year and fewer than 20% surviving beyond five years.[3]

"At the heart of this FDA approval is our drive to make a meaningful difference for patients with hard-to-treat cancers like metastatic Merkel cell carcinoma," said Belén Garijo, CEO Healthcare and Member of the Executive Board of Merck KGaA, Darmstadt, Germany. "BAVENCIO's journey has included years of hard work – from the scientists who discovered this molecule in our labs, to our alliance with Pfizer and to the study participants and investigators worldwide. We are grateful to all who have made it possible for us to bring this important new treatment option to patients."

"Today is a significant milestone for people fighting metastatic Merkel cell carcinoma, who until now have not had any options beyond chemotherapy," said Albert Bourla, Group President, Pfizer Innovative Health. "This approval demonstrates the power of collaboration to accelerate meaningful new choices for cancer patients."

"Merkel cell carcinoma is rarer than some of the more well-known skin cancers, however, it's very aggressive and the proportion of people who die from MCC is much higher than that of people with melanoma," said Deborah S. Sarnoff, MD, President of the Skin Cancer Foundation. "With this approval, I believe there is new hope for people and their families touched by this rare form of skin cancer."

The efficacy and safety of BAVENCIO was demonstrated in the JAVELIN Merkel 200 trial, an open-label, single-arm, multi-center study conducted in 88 patients with histologically confirmed metastatic MCC whose disease had progressed on or after chemotherapy administered for distant metastatic disease. Sixty-five percent of patients were reported to have had one prior anti-cancer therapy for metastatic MCC and 35% had two or more prior therapies. The major efficacy outcome measures were confirmed overall response rate (ORR) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by a blinded independent central review committee (IRC) and IRC-assessed duration of response.

The overall response rate (ORR) was 33% (95% confidence interval [CI]: 23.3–43.8%).[1] Eleven percent of patients experienced a complete response (95% CI: 6.6-19.9%) and 22% of patients experienced a partial response (95% CI: 13.5-31.7%). Tumor responses were durable,

The warnings and precautions for BAVENCIO include immune-mediated adverse reactions (such as pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, and other adverse reactions), infusion-related reactions and embryo-fetal toxicity. The most common adverse reactions (reported in at least 20% of patients) included fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), infusion-related reactions (22%), rash (22%), decreased appetite (20%) and peripheral edema (20%).[1] For more information, please see Important Safety Information for BAVENCIO below.

BAVENCIO is designed to potentially engage both the adaptive and innate immune systems. By binding to PD-L1, BAVENCIO is thought to prevent tumor cells from using PD-L1 for protection against white blood cells, such as T-cells, exposing them to anti-tumor responses.[1] BAVENCIO has been shown to induce antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro.[1]

BAVENCIO is available for order now.

The alliance is committed to providing industry-leading patient access and reimbursement support through its CoverOne™ program. This program provides a spectrum of patient access and reimbursement support services intended to help patients receive appropriate access to BAVENCIO in the United States. CoverOne may be reached by phone at 844-8COVER1 (844-826-8371) or online at www.CoverOne.com.

About JAVELIN Merkel 200

The efficacy and safety of BAVENCIO was demonstrated in the JAVELIN Merkel 200 trial, an open-label, single-arm, multi-center study conducted in 88 patients with histologically confirmed metastatic MCC whose disease had progressed on or after chemotherapy administered for distant metastatic disease. Sixty-five percent of patients were reported to have had one prior anti-cancer therapy for metastatic MCC and 35% had two or more prior therapies. The major efficacy outcome measures were confirmed overall response rate (ORR) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by a blinded independent central review committee (IRC) and IRC-assessed duration of response.

The trial excluded patients with autoimmune disease; medical conditions requiring systemic immunosuppression; prior organ or allogenic stem cell transplantation; prior treatment with

BAVENCIO 10 mg/kg as an intravenous infusion over 60 minutes every two weeks until disease progression or unacceptable toxicity.

The international clinical development program for avelumab, known as JAVELIN, involves at least 30 clinical programs, including nine Phase III trials, and more than 4,000 patients across more than 15 tumor types. In October 2016, the alliance announced the European Medicines Agency accepted the Marketing Authorisation Application for avelumab for the proposed indication of metastatic MCC.

For full prescribing information and medication guide for BAVENCIO, please see www.BAVENCIO.com or the FDA website.

IMPORTANT SAFETY INFORMATION and INDICATION

BAVENCIO can cause **immune-mediated pneumonitis**, including fatal cases. Monitor patients for signs and symptoms of pneumonitis and evaluate suspected cases with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold BAVENCIO for moderate (Grade 2) and permanently discontinue for severe (Grade 3), life-threatening (Grade 4), or recurrent moderate (Grade 2) pneumonitis. Pneumonitis occurred in 1.2% (21/1738) of patients, including one (0.1%) patient with Grade 5, one (0.1%) with Grade 4, and five (0.3%) with Grade 3.

BAVENCIO can cause **immune-mediated hepatitis**, including fatal cases. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater hepatitis. Withhold BAVENCIO for moderate (Grade 2) immune-mediated hepatitis until resolution and permanently discontinue for severe (Grade 3) or life-threatening (Grade 4) immune-mediated hepatitis. Immune-mediated hepatitis was reported in 0.9% (16/1738) of patients, including two (0.1%) patients with Grade 5 and 11 (0.6 %) with Grade 3.

BAVENCIO can cause **immune-mediated colitis**. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold BAVENCIO until resolution for moderate or severe (Grade 2 or 3) colitis and permanently discontinue for life-threatening (Grade 4) or recurrent (Grade 3) colitis upon re-initiation of BAVENCIO. Immune-mediated colitis occurred in 1.5% (26/1738) of patients, including seven (0.4%) with Grade 3.

Monitor patients for signs and symptoms of **adrenal insufficiency** during and after treatment and administer corticosteroids as appropriate. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Adrenal insufficiency was reported in 0.5% (8/1738) of patients, including one (0.1%) with Grade 3.

Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation. Manage hypothyroidism with hormone replacement therapy and hyperthyroidism with medical management. Withhold BAVENCIO for severe (Grade 3) or life threatening (Grade 4) thyroid disorders. Thyroid disorders including hypothyroidism, hyperthyroidism, and thyroiditis were reported in 6% (98/1738) of patients, including three (0.2%) with Grade 3.

Type 1 diabetes mellitus, including diabetic ketoacidosis: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Withhold BAVENCIO and administer anti-hyperglycemics or insulin in patients with severe or life-threatening (Grade 3 or greater) hyperglycemia and resume treatment when metabolic control is achieved. Type 1 diabetes mellitus without an alternative etiology occurred in 0.1% (2/1738) of patients, including two cases of Grade 3 hyperglycemia.

BAVENCIO can cause **immune-mediated nephritis and renal dysfunction**. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater nephritis. Withhold BAVENCIO for moderate (Grade 2) or severe (Grade 3) nephritis until resolution to Grade 1 or lower. Permanently discontinue BAVENCIO for life-threatening (Grade 4) nephritis. Immune-mediated nephritis occurred in 0.1% (1/1738) of patients.

BAVENCIO can result in **other severe and fatal immune-mediated adverse reactions** involving any organ system during treatment or after treatment discontinuation. For suspected immune-mediated adverse reactions evaluate to confirm or rule out an immune-mediated adverse reaction and to exclude other causes. Depending on the severity of the adverse reaction, withhold or permanently discontinue BAVENCIO, administer high-dose corticosteroids, and initiate hormone replacement therapy if appropriate. Resume BAVENCIO when the immune-mediated adverse reaction remains at Grade 1 or lower following a corticosteroid taper. Permanently discontinue BAVENCIO for any severe (Grade 3) immune-mediated adverse reaction that recurs and for any life-threatening (Grade 4) immune-mediated adverse reaction.

arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, and systemic inflammatory response.

BAVENCIO can cause severe (Grade 3) or life-threatening (Grade 4) **infusion-related reactions**. Patients should be premedicated with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent doses based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for mild (Grade 1) or moderate (Grade 2) infusion-related reactions. Permanently discontinue BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Infusion-related reactions occurred in 25% (439/1738) of patients, including three (0.2%) patients with Grade 4 and nine (0.5%) with Grade 3.

BAVENCIO can cause **fetal harm** when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least one month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman **not to breastfeed** during treatment and for at least one month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

The most common adverse reactions (all grades, greater than or equal to 20%) in patients with metastatic MCC were fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), infusion-related reactions (22%), rash (22%), decreased appetite (20%), and peripheral edema (20%). The most common adverse reaction requiring dose interruption was anemia.

Selected treatment-emergent laboratory abnormalities (all grades, greater than or equal to 20%) in patients with metastatic MCC were lymphopenia (49%), anemia (35%), increased aspartate aminotransferase (34%), thrombocytopenia (27%). and increased alanine aminotransferase (20%). **Selected treatment-emergent Grade 3-4 laboratory abnormalities** (greater than or equal to 2%) were lymphopenia (19%), anemia (9%), hyperglycemia (7%), increased alanine aminotransferase (5%), and increased lipase (4%).

with metastatic Merkel cell carcinoma (MCC). This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Please see full Prescribing Information and Medication Guide.

About BAVENCIO® (avelumab)

BAVENCIO is a human programmed death ligand-1 (PD-L1) blocking antibody indicated in the US for the treatment of adults and pediatric patients 12 years of age and older with metastatic Merkel cell carcinoma.[1] This indication is approved under accelerated approval based on tumor response and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

BAVENCIO is not approved in any market outside the US.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

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About Merck KGaA, Darmstadt, Germany

All Merck KGaA, Darmstadt, Germany Press Releases are distributed by e-mail at the same time they become available on the Merck KGaA, Darmstadt, Germany Website. Please go to www.emdgroup.com/subscribe to register online, change your selection or discontinue this service.

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About Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about BAVENCIO (avelumab), including an indication in the US for BAVENCIO for the treatment of metastatic Merkel cell carcinoma (the Indication), Pfizer's and Merck KGaA, Darmstadt, Germany's immuno-oncology alliance involving anti-PD-L1 and anti-PD-1 therapies, and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of BAVENCIO; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any other jurisdictions for the Indication or in any jurisdictions for any other potential indications for BAVENCIO, combination therapies or other product candidates; whether and when any such applications (including the pending application for the Indication in the EU) may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of BAVENCIO, combination therapies or other product candidates; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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SOURCE EMD Serono; Pfizer

FDA Grants Breakthrough Therapy Designation for Avelumab in Combination with INLYTA® in Advanced Renal Cell Carcinoma

Not intended for UK-based media

- **Second Breakthrough Therapy Designation for avelumab in hard-to-treat cancer**
- **Renal cell carcinoma, the most common form of kidney cancer, has a poor prognosis in advanced stage[1,2]**
- **Javelin Renal clinical development program is ongoing, including Phase III first-line study**

Darmstadt, Germany, and New York, US, December 21, 2017 – Merck KGaA, Darmstadt, Germany, which operates its biopharmaceutical business as EMD Serono in the US and Canada, and Pfizer Inc. (NYSE: PFE) today announced that the US Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation for avelumab in combination with INLYTA® (axitinib)* for treatment-naïve patients with advanced renal cell carcinoma (RCC). Breakthrough Therapy Designation is designed to accelerate the development and review of potential medicines for serious conditions, and preliminary clinical evidence indicates that the therapy may demonstrate a substantial improvement over currently available therapies on one or more clinically significant endpoints. This is the second Breakthrough Therapy Designation granted to avelumab.

"A combination approach with an immunotherapy, whose activity may complement existing agents such as INLYTA, has the potential to improve outcomes for patients with advanced renal cancer – a disease where the five-year survival rate remains low," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-Oncology, Early Development and Translational Oncology, Pfizer Global Product Development. "Pfizer's expertise in developing treatments for advanced RCC is a distinct advantage in tackling this tumor type, and we look forward to the completion of our Phase III study combining avelumab with INLYTA, which we're expecting at the end of next year."

"This announcement reinforces the need for innovative first-line treatments for advanced RCC and our promise to advancing care for these patients," said Luciano Rossetti, M.D., Global Head of Research & Development at the Biopharma business of Merck KGaA, Darmstadt, Germany. "The second Breakthrough Therapy Designation by the FDA in another hard-to-treat cancer underlines our focus on challenging tumor types."

RCC is the most common form of kidney cancer, with an estimated 57,500 new cases diagnosed in the US in 2017.[1,3] This disease is serious and life-threatening, and approximately 20–30% of patients are first diagnosed at an advanced or metastatic stage.[4]

The Breakthrough Therapy Designation is based on the preliminary evaluation of clinical data from JAVELIN Renal 100, a global Phase Ib study assessing the safety and efficacy of avelumab in combination with INLYTA for the treatment of treatment-naïve patients with advanced RCC. Updated results from this Phase Ib study were presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. The FDA previously granted avelumab Breakthrough Therapy Designation for the treatment of patients with metastatic Merkel cell carcinoma (mMCC) whose disease has progressed after at least one previous chemotherapy regimen.

avelumab in combination with INLYTA versus sunitinib as a first-line treatment option for advanced RCC, which recently completed recruitment. In addition to RCC, cancer studies in the JAVELIN program include non-small cell lung cancer, breast cancer, head and neck cancer, Hodgkin's lymphoma, melanoma, mesothelioma, MCC, ovarian cancer, gastric/gastroesophageal junction cancer, and urothelial carcinoma (UC).

*Avelumab is under clinical investigation for advanced renal cell carcinoma and has not been demonstrated to be safe and effective for this indication. There is no guarantee that avelumab will be approved for advanced renal cell carcinoma by any health authority worldwide. INLYTA is under clinical investigation for this use in combination with avelumab. In the US, INLYTA is approved as monotherapy for the treatment of advanced RCC after failure of one prior systemic therapy.

About the FDA Designation

Breakthrough Therapy Designation is designed to expedite the development and review of drugs which are intended to treat a serious condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). The FDA's granting of the Breakthrough Therapy Designation for metastatic RCC does not alter the standard regulatory requirement to establish the safety and effectiveness of a drug through adequate and well-controlled studies to support approval.

About Renal Cell Carcinoma (RCC)

RCC is the most common form of kidney cancer, accounting for about 2–3% of all cancers in adults.[1,5] The most common type of RCC is clear cell carcinoma, accounting for approximately 70% of all cases.[3] In 2012, there were approximately 304,000 new cases of RCC diagnosed worldwide, with an estimated 57,500 cases in the US alone in 2017.[3,4,6] Incidence varies substantially worldwide with generally higher rates seen in Eastern Asia, North America and Central/Eastern Europe.[7] The five-year overall survival rate for patients with distant metastatic RCC is approximately 12%.[2]

About JAVELIN Renal 100

JAVELIN Renal 100 is a Phase Ib, open-label, multicenter, multiple-dose study investigating avelumab in combination with INLYTA® (axitinib), a tyrosine kinase inhibitor from Pfizer, for the treatment of treatment-naïve patients with advanced RCC. The study enrolled 55 patients from participating sites in the US, United Kingdom and Japan.

About Avelumab

Avelumab is a human anti-programmed death ligand-1 (PD-L1) antibody. Avelumab has been shown in preclinical models to engage both the adaptive and innate immune functions. By blocking the interaction of PD-L1 with PD-1 receptors, avelumab has been shown to release the suppression of the T cell-mediated antitumor immune response in preclinical models.[7-9] Avelumab has also been shown to induce NK cell-mediated direct tumor cell lysis via antibody-dependent cell-mediated cytotoxicity (ADCC) in vitro.[9-11] In November 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

Approved Indications in the US

The FDA granted accelerated approval for avelumab (BAVENCIO®) for the treatment of (i) adults and pediatric patients 12 years and older with metastatic Merkel cell carcinoma (mMCC) and (ii) patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. These indications are approved under accelerated approval based on tumor response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information from the US FDA Approved Label

BAVENCIO can cause immune-mediated pneumonitis, including fatal cases. Monitor patients for signs and symptoms of pneumonitis, and evaluate suspected cases with radiographic imaging. Administer corticosteroids for Grade 2 or greater pneumonitis. Withhold BAVENCIO for moderate (Grade 2) and permanently discontinue for severe (Grade 3), life-threatening (Grade 4), or recurrent moderate (Grade 2) pneumonitis. Pneumonitis occurred in 1.2% (21/1738) of patients, including one (0.1%) patient with Grade 5, one (0.1%) with Grade 4, and five (0.3%) with Grade 3.

BAVENCIO can cause immune-mediated hepatitis, including fatal cases. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater hepatitis. Withhold BAVENCIO for moderate (Grade 2) immune-mediated hepatitis

BAVENCIO can cause immune-mediated colitis. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 or greater colitis. Withhold BAVENCIO until resolution for moderate or severe (Grade 2 or 3) colitis, and permanently discontinue for life-threatening (Grade 4) or recurrent (Grade 3) colitis upon reinitiation of BAVENCIO. Immune-mediated colitis occurred in 1.5% (26/1738) of patients, including seven (0.4%) with Grade 3.

BAVENCIO can cause immune-mediated endocrinopathies, including adrenal insufficiency, thyroid disorders, and type 1 diabetes mellitus.

Monitor patients for signs and symptoms of adrenal insufficiency during and after treatment, and administer corticosteroids as appropriate. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) adrenal insufficiency. Adrenal insufficiency was reported in 0.5% (8/1738) of patients, including one (0.1%) with Grade 3.

Thyroid disorders can occur at any time during treatment. Monitor patients for changes in thyroid function at the start of treatment, periodically during treatment, and as indicated based on clinical evaluation. Manage hypothyroidism with hormone replacement therapy and hyperthyroidism with medical management. Withhold BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) thyroid disorders. Thyroid disorders, including hypothyroidism, hyperthyroidism, and thyroiditis, were reported in 6% (98/1738) of patients, including three (0.2%) with Grade 3.

Type 1 diabetes mellitus including diabetic ketoacidosis: Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Withhold BAVENCIO and administer antihyperglycemics or insulin in patients with severe or life-threatening (Grade ≥ 3) hyperglycemia, and resume treatment when metabolic control is achieved. Type 1 diabetes mellitus without an alternative etiology occurred in 0.1% (2/1738) of patients, including two cases of Grade 3 hyperglycemia.

BAVENCIO can cause immune-mediated nephritis and renal dysfunction. Monitor patients for elevated serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater nephritis. Withhold BAVENCIO for moderate (Grade 2) or severe (Grade 3) nephritis until resolution to Grade 1 or lower. Permanently discontinue BAVENCIO for life-threatening (Grade 4) nephritis. Immune-mediated nephritis occurred in 0.1% (1/1738) of patients.

BAVENCIO can result in other severe and fatal immune-mediated adverse reactions involving any organ system during treatment or after treatment discontinuation. For suspected immune-mediated adverse reactions, evaluate to confirm or rule out an immune-mediated adverse reaction and to exclude other causes. Depending on the severity of the adverse reaction, withhold or permanently discontinue BAVENCIO, administer high-dose corticosteroids, and initiate hormone replacement therapy, if appropriate. Resume BAVENCIO when the immune-mediated adverse reaction remains at Grade 1 or lower following a corticosteroid taper. Permanently discontinue BAVENCIO for any severe (Grade 3) immune-mediated adverse reaction that recurs and for any life-threatening (Grade 4) immune-mediated adverse reaction. The following clinically significant immune-mediated adverse reactions occurred in less than 1% of 1738 patients treated with BAVENCIO: myocarditis with fatal cases, myositis, psoriasis, arthritis, exfoliative dermatitis, erythema multiforme, pemphigoid, hypopituitarism, uveitis, Guillain-Barré syndrome, and systemic inflammatory response.

BAVENCIO can cause severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Patients should be premedicated with an antihistamine and acetaminophen prior to the first 4 infusions and for subsequent doses based upon clinical judgment and presence/severity of prior infusion reactions. Monitor patients for signs and symptoms of infusion-related reactions, including pyrexia, chills, flushing, hypotension, dyspnea, wheezing, back pain, abdominal pain, and urticaria. Interrupt or slow the rate of infusion for mild (Grade 1) or moderate (Grade 2) infusion-related reactions. Permanently discontinue BAVENCIO for severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Infusion-related reactions occurred in 25% (439/1738) of patients, including three (0.2%) patients with Grade 4 and nine (0.5%) with Grade 3.

BAVENCIO can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to a fetus including the risk of fetal death. Advise females of childbearing potential to use effective contraception during treatment with BAVENCIO and for at least 1 month after the last dose of BAVENCIO. It is not known whether BAVENCIO is excreted in human milk. Advise a lactating woman not to breastfeed during treatment and for at least 1 month after the last dose of BAVENCIO due to the potential for serious adverse reactions in breastfed infants.

The most common adverse reactions (all grades, ≥ 20%) in patients with metastatic Merkel cell carcinoma (MCC) were fatigue (50%), musculoskeletal pain (32%), diarrhea (23%), nausea (22%), infusion-related reaction (22%), rash (22%), decreased appetite (20%), and peripheral edema (20%).

The most common adverse reactions (all grades, ≥ 20%) in patients with locally advanced or metastatic urothelial carcinoma (UC) were fatigue (41%), infusion-related reaction (30%), musculoskeletal pain (25%), nausea (24%), decreased appetite/hypophagia (21%), and urinary tract infection (21%).

Selected laboratory abnormalities (Grades 3-4, ≥ 3%) in patients with locally advanced or metastatic UC were hyponatremia (16%), increased gamma-glutamyltransferase (12%), lymphopenia (11%), hyperglycemia (9%), increased alkaline phosphatase (7%), anemia (6%), increased lipase (6%), hyperkalemia (3%), and increased aspartate aminotransferase (3%).

Please see full US Prescribing Information and Medication Guide available at www.BAVENCIO.com.

About INLYTA® (axitinib)
INLYTA is an oral therapy that is designed to inhibit tyrosine kinases, including vascular endothelial growth factor (VEGF) receptors 1, 2 and 3; these receptors can influence tumor growth, vascular angiogenesis and progression of cancer (the spread of tumors). In the U.S., INLYTA is approved for the treatment of advanced RCC after failure of one prior systemic therapy. INLYTA is also approved by the European Medicines Agency (EMA) for use in the EU in adult patients with advanced RCC after failure of prior treatment with sunitinib or a cytokine.

INLYTA Important Safety Information
Hypertension including hypertensive crisis has been observed. Blood pressure should be well controlled prior to initiating INLYTA. Monitor for hypertension and treat as needed. For persistent hypertension, despite use of antihypertensive medications, reduce the dose. Discontinue INLYTA if hypertension is severe and persistent despite use of antihypertensive therapy and dose reduction of INLYTA, and discontinuation should be considered if there is evidence of hypertensive crisis.

Arterial and venous thrombotic events have been observed and can be fatal. Use with caution in patients who are at increased risk or who have a history of these events.

Hemorrhagic events, including fatal events, have been reported. INLYTA has not been studied in patients with evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. If any bleeding requires medical intervention, temporarily interrupt the INLYTA dose.

Cardiac failure has been observed and can be fatal. Monitor for signs or symptoms of cardiac failure throughout treatment with INLYTA. Management of cardiac failure may require permanent discontinuation of INLYTA.

Gastrointestinal perforation and fistula, including death, have occurred. Use with caution in patients at risk for gastrointestinal perforation or fistula. Monitor for symptoms of gastrointestinal perforation or fistula periodically throughout treatment.

Hypothyroidism requiring thyroid hormone replacement has been reported. Monitor thyroid function before initiation of, and periodically throughout, treatment.

No formal studies of the effect of INLYTA on wound healing have been conducted. Stop INLYTA at least 24 hours prior to scheduled surgery.

Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been observed. If signs or symptoms occur, permanently discontinue treatment.

Monitor for proteinuria before initiation of, and periodically throughout, treatment. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment.

Liver enzyme elevation has been observed during treatment with INLYTA. Monitor ALT, AST, and bilirubin before initiation of, and periodically throughout, treatment.

For patients with moderate hepatic impairment, the starting dose should be decreased. INLYTA has not been studied in patients with severe hepatic impairment.

Women of childbearing potential should be advised of potential hazard to the fetus and to avoid becoming pregnant while receiving INLYTA.

Avoid strong CYP3A4/5 inducers and, if possible, avoid moderate CYP3A4/5 inducers.

The most common (≥20%) adverse events (AEs) occurring in patients receiving INLYTA (all grades, vs sorafenib) were diarrhea (55% vs 53%), hypertension (40% vs 29%), fatigue (39% vs 32%), decreased appetite (34% vs 29%), nausea (32% vs 22%), dysphonia (31% vs 14%), hand-foot syndrome (27% vs 51%), weight decreased (25% vs 21%), vomiting (24% vs 17%), asthenia (21% vs 14%), and constipation (20% vs 20%).

The most common (≥10%) grade 3/4 AEs occurring in patients receiving INLYTA (vs sorafenib) were hypertension (16% vs 11%), diarrhea (11% vs 7%), and fatigue (11% vs 5%).

The most common (≥20%) lab abnormalities occurring in patients receiving INLYTA (all grades, vs sorafenib) included increased creatinine (55% vs 41%), decreased bicarbonate (44% vs 43%), hypocalcemia (39% vs 59%), decreased hemoglobin (35% vs 52%), decreased lymphocytes (absolute) (33% vs 36%), increased ALP (30% vs 34%), hyperglycemia (28% vs 23%), increased lipase (27% vs 46%), increased amylase (25% vs 33%), increased ALT (22% vs 22%), and increased AST (20% vs 25%).

For more information and full Prescribing Information for INLYTA, visit www.pfizer.com.

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Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US
Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance is jointly developing and commercializing avelumab and advancing Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab, as a monotherapy, as well as combination regimens, and is striving to find new ways to treat cancer.

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About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the "Merck" name and brand except in the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

About EMD Serono, Inc.
EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany – a leading science and technology company – in the US and Canada focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has 1,200 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

About Pfizer: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

PFIZER DISCLOSURE NOTICE

The information contained in this release is as of December 21, 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about BAVENCIO (avelumab), including a potential indication for avelumab in combination with INLYTA (axitinib) for the treatment of advanced renal cell carcinoma (the "Potential Indication"), the Merck, KGaA, Darmstadt, Germany-Pfizer Alliance involving anti-PD-L1 and anti-PD-1 therapies, and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of BAVENCIO; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any drug applications may be filed in any jurisdictions for the Potential Indication or for any other potential indications for BAVENCIO, combination therapies or other product candidates; whether and when regulatory authorities in any jurisdictions where applications may be submitted for the Potential Indication or where applications are pending or may be submitted for BAVENCIO, combination therapies or other product candidates may approve any such applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of BAVENCIO, combination therapies or other product candidates, including the Potential Indication; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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approved in Canada.

FDA Grants Second Approval for BAVENCIO® (avelumab)

EXPLORE MORE

Rockland, MA and New York, NY, May 9, 2017 – EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US and Canada, and Pfizer Inc. (NYSE: PFE) today announce that the US Food and Drug Administration (FDA) has granted accelerated approval for BAVENCIO® (avelumab) Injection for a second indication.

The full prescribing information for BAVENCIO will be available at www.BAVENCIO.com.

EMD Serono and Pfizer will provide additional details on the approval in a press release to follow.

Alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc., New York, US, enables the companies to benefit from each other's strengths and capabilities and further

develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The alliance is focused on developing high-priority international clinical programs to investigate avelumab as a monotherapy, as well as in combination regimens, and is striving to find new ways to treat cancer.

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www.emdserono.com

About Merck KGaA, Darmstadt, Germany

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Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the "Merck" name and brand except in the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of healthcare products. Our global portfolio includes medicines and vaccines, as well as many of the world's best-known consumer healthcare products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com. In addition, to learn more, follow us on Twitter at @Pfizer and @Pfizer_News, LinkedIn and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice

The information contained in this release is as of May 9, 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about BAVENCIO (avelumab), Pfizer's and Merck KGaA, Darmstadt, Germany's immuno-oncology alliance involving anti-PD-L1 and anti-PD-1 therapies, and clinical development plans, and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of BAVENCIO; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable study results, including unfavorable new clinical data and additional analyses of existing clinical data; risks associated with interim data; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any other jurisdictions for the Indication or in any jurisdictions for any other potential indications for BAVENCIO, combination therapies or other product candidates; whether and when any such applications (including the pending application for BAVENCIO for metastatic Merkel cell carcinoma in the EU) may be approved by regulatory authorities, which will depend on the assessment by such regulatory

that could affect the availability or commercial potential of BAVENCIO, combination therapies or other product candidates; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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Merck KGaA, Darmstadt, Germany Presents Late Breaking Clinical Data from Phase II Trial of Sprifermin for Osteoarthritis Disease Modification

EXPLORE MORE

Merck KGaA, Darmstadt, Germany, today announced results of the two-year primary analysis of FORWARD, a five-year, multicenter Phase II study of sprifermin in patients with knee OA.

- Late-breaking presentation at the 2017 American College of Rheumatology/Association of Rheumatology Health Professionals Annual Meeting (ACR/ARHP) provides data on cartilage thickness in patients with knee osteoarthritis

- Additional data at ACR/ARHP highlights the momentum of the company's clinical programs in systemic lupus erythematosus (SLE), osteoarthritis (OA), rheumatoid arthritis (RA) and fibrotic diseases

Darmstadt, Germany, November 4, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company which operates its healthcare business in the U.S. and Canada

“We are highly encouraged by the results of the FORWARD trial, in which sprifermin showed an increase in cartilage thickness in patients with osteoarthritis,” said Luciano Rossetti, Executive Vice President, Global Head of Research & Development at the biopharma business of Merck KGaA, Darmstadt, Germany. “We remain steadfast in our resolve to bring new therapies to areas of high unmet medical need such as this, and these phase II data are a testament to our commitment.”

The study of 549 patients met its primary endpoint, demonstrating statistically- significant, dose-dependent increases in MRI total femorotibial joint cartilage thickness from baseline in the two sprifermin groups receiving the highest doses as compared with the placebo group after the two-year treatment period (+0.03 mm with 100µg sprifermin every six months vs. -0.02 mm with placebo, $p<0.001$; +0.02 mm with 100µg sprifermin every twelve months vs. -0.02 mm with placebo, $p<0.001$). Demonstration of an increase in cartilage thickness as opposed to a delay in decreasing cartilage thickness has not been previously reported. The correlation of these changes with clinical endpoints is being evaluated.

"Osteoarthritis of the knee can make it challenging for sufferers to perform everyday activities, such as walking or climbing stairs, and there is a high unmet need for disease-modifying treatment options,” said Dr. Marc C. Hochberg, primary investigator of the FORWARD study and Division Head, Rheumatology and Clinical Immunology, University of Maryland School of Medicine. “These data suggest sprifermin may not only prevent decline in cartilage thickness compared with placebo, but may also increase cartilage thickness in patients with knee osteoarthritis."

Secondary endpoints included changes in cartilage thickness as measured by MRI in the medial and lateral compartments, as well as changes in the Western Ontario and McMaster Universities Arthritis Index (WOMAC) score over two years. Statistically significant treatment effects of increased cartilage thickness were observed in the medial and lateral femorotibial compartments, including the central medial and central lateral regions, in the highest sprifermin dose group. Total WOMAC scores decreased (indicating less symptoms) by approximately 50 percent compared to baseline in all treatment groups, including placebo.

There was no detectable systemic exposure following the intra-articular injections of sprifermin. Treatment-emergent adverse events were balanced between treatment groups, with

The results will be presented in a late-breaking oral presentation, "Efficacy and Safety of Intra-Articular Sprifermin in Symptomatic Radiographic Knee Osteoarthritis: Results of the 2-Year Primary Analysis from a 5-Year Randomised, Placebo-Controlled, Phase II Study" at the 2017 ACR/ARHP Annual Meeting in San Diego, U.S., on Tuesday, November 7, at 4:30 p.m. PT.

The company is presenting a total of 11 abstracts at ACR/ARHP, highlighting the momentum of its various clinical programs in Immunology. Other data of note includes an oral presentation on a phase II post-hoc study analysis of atacicept for SLE patients with high disease activity. In the analysis of ADDRESS II, a 24-week, randomized, placebo-controlled Phase IIb study of 306 people, those who had high disease activity at baseline had three- to five- times the odds of attaining low disease activity at 24 weeks when treated with atacicept 150mg dose (n=51) as compared to when treated with placebo (n=52).

For more information about the data presented, please visit the ACR/ARHP website.

About Sprifermin

Sprifermin is in clinical development to investigate its potential as a treatment for osteoarthritis (OA) in the knee. It is a truncated recombinant human FGF-18 protein thought to induce chondrocyte proliferation and increased extra-cellular matrix (ECM) production, with the potential of promoting cartilage growth and repair. Sprifermin is currently in Phase II studies.

About Osteoarthritis

There are approximately 237 million people worldwide living with symptomatic and activity-limiting OA, the third most rapidly rising condition associated with disability globally. By the end stage of the disease, total knee replacement is often necessary. OA is likely to be the number one cause of total hip and knee replacement in the US. Currently there are no approved drugs for preventing or slowing disease progression.

About Atacicept

Atacicept is in clinical development to investigate its potential as a treatment for systemic lupus erythematosus (SLE). It is a recombinant fusion protein which targets the cytokines APRIL and BlyS, two members of the tumor necrosis factor family that regulates B-cell maturation, function and survival and autoantibody production associated with certain autoimmune diseases such as SLE. Atacicept has been shown in animal models to affect several stages of B-cell

About Systemic Lupus Erythematosus (SLE)

SLE (often referred to as "lupus") is a chronic autoimmune disease, where the immune system attacks the body's own tissues and organs. SLE can result in swollen, painful joints, skin rash, extreme fatigue and kidney damage. Estimates vary widely, but SLE may affect as many as 300,000 patients in the U.S. alone. Women and individuals with African American, Asian, and Hispanic heritage are affected disproportionately by SLE.

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the „Merck" name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

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About EMD Serono, Inc.

EMD Serono is the biopharma business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada - a leading science and technology company - focused exclusively on specialty care. For more than 40 years, the business has integrated cutting-edge science, innovative products and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has

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New Data to be Presented on MS Portfolio, Rebif (interferon beta-1a), Cladribine Tablets, and Evobrutinib at ECTRIMS 2017

Important safety and immune cell analyses further characterize the selective immune reconstitution approach of Cladribine Tablets

Continued innovation with Rebif includes analysis of NEDA and use of MAGNIMS criteria in predicting clinical outcomes out to 15 years

Pre-clinical data for investigational evobrutinib highlight potential role in patients with relapsing MS

A total of 40 abstracts will be presented by lead investigators

Darmstadt, Germany, October 18, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that data for approved multiple sclerosis (MS)

October 2017 in Paris, France. Efficacy data will be presented from the CLARITY, CLARITY Extension and ORACLE-MS trials which highlight that Cladribine Tablets may have certain clinical benefits up to 4 years with a maximum of 20 days of oral treatment in the first 2 years. Additional safety analysis demonstrate that that there was no statistically significant difference in malignancy risk between Cladribine Tablets and placebo. Additional data for Cladribine Tablets detail how the treatment is thought to selectively target the adaptive immune system.

Data presentations for Rebif® will focus on long-term disease activity assessed by the MAGNIMS (Magnetic Resonance Imaging in MS) score. Real-world evidence presentations will evaluate relapse rates in patients newly initiating on Rebif®, and an assessment of treatment adherence rates for patients treated with Rebif® compared with dimethyl fumarate.

Furthermore, key preclinical data will be presented for Merck KGaA, Darmstadt, Germany's investigational evobrutinib (M2951), a Bruton's tyrosine kinase (BTK) inhibitor, which is thought to be important in the development and functioning of various immune cells including B lymphocytes, specifically in patients with MS.

"The breadth of data being presented at this year's congress underpin our commitment to deepening the understanding of how our portfolio of products, whether approved or investigational, target MS, and reinforce our dedication to provide differentiated treatment options to physicians and people living with MS," said Luciano Rossetti, Head of Global R&D for the biopharma business of Merck KGaA, Darmstadt, Germany.

In addition to data presentations, two Merck KGaA, Darmstadt, Germany-sponsored symposia will take place during the meeting:

- - Balancing benefits and risks of DMDs in MS, Thursday, October 26, 18:00-19:00, Hall A
- - Potential solutions to treatment burden in MS, Friday, October 27, 08:00-09:00, Hall A

On Wednesday, October 25, from 9:30-11:30am CEST, Merck KGaA, Darmstadt, Germany will be hosting a press event briefing with members of the leadership team and lead investigators. A link to view this event will be available for media offsite, please contact erinmarie.beals@emdserono.com for further information. This event is not intended for US media. Additionally, at 19:30pm CEST, Merck KGaA, Darmstadt, Germany will be hosting a session highlighting data from a report which will be published during MSParis 17 entitled, Addressing the Socio-economic impact of Multiple Sclerosis on Women in Europe.

Theatre. The award, first launched at ECTRIMS in 2012, supports the advancement of science and medical research in the field of MS, and provides a grant of up to €1,000,000 per year to one or more selected research projects.

On Friday, October 27, MS in the 21st Century (a Merck KGaA, Darmstadt, Germany sponsored initiative involving a joint Steering Group of international healthcare professionals and MS patient advocates) will host their first educational workshop titled 'Two monologues do not make a dialogue – Overcoming communications barriers between healthcare professionals and patient', to encourage better communication between healthcare professionals and people with MS.

For up-to-date information and activities during ECTRIMS 2017, follow Merck KGaA, Darmstadt, Germany on Twitter (@EMDGroup) or #AddressMS or visit booth 08.

The following Cladribine Tablets and Rebif® global abstracts have been accepted for presentation at MSParis 2017, 7th Joint ECTRIMS-ACTRIMS Meeting:

Title	**Lead Author**	**Abstract/Poster #**	**Presentation Date/Time/Session**
Cladribine Tablets Presentations			
Effects of Cladribine Tablets on CD4+ T Cell Subsets in the ORACLE-MS Study: Results from an Analysis of Lymphocyte Surface Markers	Stuve O	P667	Poster Session 1 Thursday 26 October 2017 Time: 15:30-17:00
Cladribine Tablets Produce Selective and Discontinuous Reduction	Stuve O	P690	

Patients with Early and Relapsing Multiple Sclerosis (ORACLE-MS,CLARITY and CLARITY Extension)			
Rates of Lymphopenia Year-by-year in Patients with Relapsing Multiple Sclerosis Treated and Retreated with Cladribine Tablets 3.5mg/kg	Cook S	P666	
Long-Term Lymphocyte Counts in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS) Treated with Cladribine Tablets 3.5 mg/kg: Total Lymphocytes, B and T Cell Subsets	Soelberg-Sorensen P	P655	
Effects of Cladribine Tablets on Radiological Outcomes in High Disease Activity (HDA) Subgroups of Patients with Relapsing Multiple Sclerosis (RMS) in the CLARITY Study	Giovannoni G	P1164	Poster Session 2 Friday 27 October 2017 Time: 15:30-17:00
Proportions of Patients with Highly Active RMS Achieving No Evidence of Disease Activity (NEDA) in	Giovannoni G	P1143	

Investigation of Cladribine Treatment Rules in Subjects with Relapsing-Remitting Multiple Sclerosis (RRMS) by means of Modelling & Simulation	Terranova N	P912	
Infections During Periods of Grade 3 or 4 Lymphopenia in Patients Taking Cladribine Tablets 3.5 mg/kg: Data from an Integrated Safety Analysis	Cook S	P1142	
Innate Immune Cell Counts in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS) Treated with Cladribine Tablets 3.5 mg/kg in CLARITY and CLARITY Extension	Soelberg-Sorensen P	P1141	
An analysis of malignancy risk in the clinical development programme of cladribine tablets in patients with relapsing multiple sclerosis (RMS)	Galazka A	P1878	Late-breaker Poster Session 2 Friday 27 October 2017 Time: 15:30-17:00
Pregnancy outcomes during the clinical development programme	Galazka A	P1874	

integrated analysis of safety for all exposed patients			

Rebif (interferon beta-1a) Presentations

Title	Lead Author	Abstract/Poster #	Presentation Date/Time/Session
Disease Activity as Assessed by the MAGNIMS Score Predicts Long-Term Clinical Disease Activity Free Status and Disability Progression in Patients Treated with Subcutaneous Interferon Beta-1a	Sormani MP	P770	Poster Session 1 Thursday 26 October 2017 Time: 15:30-17:00
The Association between Disease Activity and Disability Progression in Patients with Relapsing-Remitting Multiple Sclerosis	Spelman T	P348	
Clinical Characteristics and Treatment Patterns of Relapsing-Remitting Multiple Sclerosis Patients with High Disease Activity	Spelman T	P340	

perceptions on multiple sclerosis management and care where do their priorities differ? Results from a qualitative survey			
Infertility Diagnosis and Treatment in Women With and Without Multiple Sclerosis	Houtchens MK	P356	
Validation of MUSIQOL among Arabic-speaking MS Patients treated with High dose INF-β 1a sc injection New Formulation	Al Jumah M	P821	
RebiQoL: A telemedicine patient support program on health related quality of life and adherence in MS patients treated with Rebif	Landtblom AM	P826	
Serum Neurofilament light chain correlates with disease activity and predicts clinical and MRI outcomes in MS	Barro C	P636	
Impact of the Presence of Gadolinium-Enhancing Lesions at Baseline on No Evidence of Disease Activity Status in Patients	Freedman M	P1144	Poster Session 2 Friday 27 October 2017 Time: 15:30-17:00

Beta-1a: A Post-Hoc Analysis of REFLEXION		
Evolution of New Lesions and its Temporal Patterns in Patients with Clinically Isolated Syndrome Treated with Subcutaneous Interferon Beta-1a	Vrenken H	P1025
Using algorithms to identify High Disease Activity Relapsing-Remitting Multiple Sclerosis patients using electronic health record data with natural language processing	Kamauu AW	P877
Using United States Integrated Delivery Network (IDN) Electronic Health Records (EHR)/Natural Language Processing (NLP)-Based Algorithms to Identify Relapses in Relapsing-Remitting Multiple Sclerosis (RRMS) Patients	Kamauu AW	P885
Developing United States Integrated Delivery Network (IDN) Claims-Based Algorithms to	Kamauu AW	P878

Multiple Sclerosis (RRMS) Patients		
Rates of Pregnancy in Women With and Without Multiple Sclerosis Over Time	Houtchens MK	P890
Prevalence of Comorbidities in Patients With and Without Multiple Sclerosis by Age and Sex: A US Retrospective Claims Database Analysis	Kresa-Reahl K	P941
Infertility Treatment and Live Birth Rates in Women With and Without Multiple Sclerosis	Houtchens MK	P891
An Evaluation of Adherence Using Panel Survey Data From Patients With Multiple Sclerosis Treated With Subcutaneous Interferon β-1a or Dimethyl Fumarate	Perrin Ross A	P1251
Real-World Assessment of Relapse in Patients With Multiple Sclerosis Newly Initiating scIFNβ1a Compared With Oral Disease-Modifying Drugs	Bowen J	P1245

evaluation of treatment-induced modulation of Treg, Breg and CD56bright NK cell levels in multiple sclerosis patients			
Risk of stroke in patients with multiple sclerosis treated with subcutaneous interferon beta-1a	Venkatesh S	P1918	Late-breaker Poster Session 2 Friday 27 October 2017 Time: 15:30-17:00
Creating a healthcare claims-based adaptation of Kurtzke Functional Systems Scores for assessing multiple sclerosis severity and progression	Le Truong CTL	EP1767	ePoster
A mapping study to compare the educational offerings for patients in the fields of multiple sclerosis and HIV in Europe and Canada	Rieckman P	EP1838	
Long-term real-life retrospective analysis on interferon β1-a use in RRMS patients in Finland	Al Jumah M	EP1687	

relapsing-remitting MS (RRMS) patients using the electronic autoinjector RetainSmartTM: 1 and 2 year follow-up from the German multicenter RETAINsmart study			
Cerebrospinal fluid levels of neurofilament light chain, C-X-C ligand motif 13, and chitinase-3-like protein 1 reflect distinct pathological processes in multiple sclerosis	Zanoni M	EP1598	
Brain atrophy and disease free status over 3 years in multiple sclerosis patients under interferon beta 1a subcutaneous treatment	Rojas JI	EP1657	

Evobrutinib Presentations

Title	Lead Author	Abstract/Poster #	Presentation Date/Time/Session
B cell-mediated experimental CNS autoimmunity is modulated by inhibition of Bruton’s tyrosine kinase	Torke S	143	Oral Presentation Parallel Session 8: Immune Cells in Injury and Repair Thursday 26 October

Design of a Phase II Dose Range Finding, Efficacy and Safety Study of the Bruton's Tyrosine Kinase Inhibitor Evobrutinib (M2951) in Relapsing Multiple Sclerosis Patients	Montalban X	P675	Poster Session 1 Thursday 26 October 2017 Time: 15:30-17:00
T cell mediated experimental CNS autoimmunity induced by PLP in SJL mice is modulated by Evobrutinib (M2951) a novel Bruton's tyrosine kinase inhibitor	Boschert U	P678	

About Cladribine Tablets
Cladribine Tablets is an investigational short-course oral therapy that is thought to selectively and periodically target lymphocytes thought to be integral to the pathological process of relapsing MS (RMS). Cladribine Tablets is currently under clinical investigation and not yet approved for the treatment for any use in the United States and Canada. In August 2017, the European Commission (EC) granted marketing authorization for Cladribine Tablets, marketed as MAVENCLAD® in the European Union (EU), for the treatment of relapsing forms of multiple sclerosis (RMS) in the 28 countries of the EU in addition to Norway, Liechtenstein and Iceland.

The clinical development program for Cladribine Tablets includes:

- - The CLARITY (Cladribine Tablets Treating MS Orally) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with RRMS.
- - The CLARITY extension study: a two-year Phase III placebo-controlled study following on from the CLARITY study, designed to evaluate the safety and efficacy of Cladribine Tablets over an extended administration for four years.
- - The ORACLE MS (Oral Cladribine in Early MS) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS).

evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy.

- PREMIERE (Prospective Observational Long-term Safety Registry of Multiple Sclerosis Patients Who Have Participated in Cladribine Clinical Studies) study: interim long-term follow-up data from the prospective registry, PREMIERE, to evaluate the safety and efficacy of Cladribine Tablets. This includes more than 10,000 patient years of data with over 2,700 patients included in the clinical trial program, and more than 10 years of observation in some patients.

About Rebif® (interferon beta-1a)
Rebif (interferon beta-1a) is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS. The efficacy and safety of Rebif in controlled clinical trials beyond 2-years has not been established.

Important Safety Information:
Rebif is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation.

Rebif should be used with caution in patients with depression, a condition that is common in people with multiple sclerosis. Depression, suicidal ideation, and suicide attempts have been reported to occur with increased frequency in patients receiving interferon compounds, including Rebif.

Severe liver injury, including some cases of hepatic failure requiring liver transplantation, has been reported rarely in patients taking Rebif. The potential for liver injury should be considered when used in combination with other products associated with liver injury. Monitor liver function tests and patients for signs and symptoms of hepatic injury. Consider discontinuing Rebif if hepatic injury occurs.

Anaphylaxis and other allergic reactions (some severe) have been reported as a rare complication of Rebif. Discontinue Rebif if anaphylaxis occurs.

In controlled clinical trials, injection site reactions occurred more frequently in Rebif-treated patients than in placebo-treated and Avonex-treated patients. Injection site reactions including injection site pain, erythema, edema, cellulitis, abscess, and necrosis have been reported in the postmarketing setting. Do not administer Rebif into affected area until fully healed; if multiple lesions occur, discontinue Rebif until skin lesions are healed.

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif-treated patients than in placebo-treated patients. Patients should be monitored for symptoms or signs of decreased blood counts. Monitoring of complete blood and differential white blood cell counts is also recommended.

clinically indicated.

Caution should be exercised when administering Rebif to patients with pre-existing seizure disorders. Seizures have been temporally associated with the use of beta interferons, including Rebif, in clinical trials and in postmarketing reports.

The most common side effects with Rebif are injection-site disorders, headaches, influenza-like symptoms, abdominal pain, depression, elevated liver enzymes, and hematologic abnormalities.

There are no adequate and well-controlled studies in pregnant women. Rebif should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Rebif full prescribing information is available at
http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=

About Evobrutinib
Evobrutinib (M2951) is in clinical development to investigate its potential as a treatment for multiple sclerosis (MS), rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE). It is an oral, highly selective inhibitor of Bruton's Tyrosine Kinase (BTK) which is important in the development and functioning of various immune cells including B lymphocytes and macrophages. Evobrutinib is designed to inhibit primary B cell responses such as proliferation and antibody and cytokine release, without directly affecting T cells. BTK inhibition is thought to suppress autoantibody-producing cells, which preclinical research suggests may be therapeutically useful in certain autoimmune diseases. Evobrutinib is currently in Phase II studies.

About Multiple Sclerosis
Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately 2.3 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

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About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.
Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed

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New Data Analyses at ECTRIMS Highlight Benefit-Risk Profile of Investigational Cladribine Tablets in Relapsing Multiple Sclerosis

Data suggest Cladribine Tablets may significantly increase proportion of patients exhibiting no evidence of disease activity versus placebo in a post-hoc analysis

Analysis of 10,000 patient years of safety data provides additional characterization of safety profile

Further data evaluate the relative selectivity of Cladribine Tablets for the adaptive immune system

Darmstadt, Germany, October 26, 2017 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced new benefit-risk data for investigational Cladribine

subgroups from the 2-year CLARITY study demonstrated that Cladribine Tablets significantly increased the proportion of patients with no evidence of disease activity (NEDA) compared with placebo (43.7% vs 8.7%)[1]. This analysis is consistent with results seen in the broader CLARITY patient population.

Late-breaking safety analysis including patients with up to 8-years follow-up from the monotherapy oral (3.5 mg/kg) cohorts of CLARITY, CLARITY Extension, ORACLE-MS studies and the PREMIERE registry reinforced safety conclusions of the earlier meta-analysis.[2]

These data presented at MSParis2017 showed:

- - A detailed safety analysis from CLARITY, CLARITY Extension, ORACLE-MS studies, and the PREMIERE registry was consistent with findings of previous integrated safety analyses regarding Cladribine Tablets' association with lymphopenia Grade 3 or 4 (severe).[3]

- - An analysis of T lymphocyte (T cells) subpopulations from the ORACLE-MS study provide a detailed assessment of the changes that occur in the adaptive immune system following Cladribine Tablets treatment.[4]

- - An analysis of neutrophils and monocytes from patients in CLARITY or CLARITY Extension, including time spent in the PREMIERE registry, demonstrated that the effect of Cladribine Tablets treatment on these innate immune cell subsets, compared to patients treated with placebo.[5]

"These important data provide further detail on how Cladribine Tablets targets the immune system in patients with MS, as well as further insights into its efficacy and safety," said Dr. Andrew Galazka, Senior Vice President for Scientific Affairs at Merck KGaA, Darmstadt, Germany.

In addition to Cladribine Tablets presentations, Merck KGaA, Darmstadt, Germany, also presented data on its well-established relapsing MS product, Rebif® (interferon beta-1a). A post-hoc analysis of patient data from the PRISMS study investigated the association between the MAGNIMS (Magnetic Resonance Imaging in MS) score at Year 1 and long-term clinical disease activity free (CDAF) status and disability progression. The score, when calculated in Year 1 of treatment with Rebif®, was shown to accurately predict the risk of a CDA (clinical disease activity) event or disability progression in patients with MS.[6] Further data on NEDA and real-world evidence will be presented.

About Cladribine Tablets

Cladribine Tablets is an investigational short-course oral therapy that is thought to selectively and periodically target lymphocytes thought to be integral to the pathological process of relapsing MS (RMS). Cladribine Tablets is currently under clinical investigation and not yet approved for any use in the United States and Canada. In August 2017, the European Commission (EC) granted marketing authorization for Cladribine Tablets, marketed as MAVENCLAD® in the European Union (EU), for the treatment of adult patients with highly active relapsing forms of multiple sclerosis (RMS) as defined by clinical or imaging features in the 28 countries of the EU in addition to Norway, Liechtenstein and Iceland.

The clinical development program for Cladribine Tablets includes:

The CLARITY (Cladribine Tablets Treating MS Orally) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with RRMS.

The CLARITY extension study: a two-year Phase III placebo-controlled study following the CLARITY study, designed to evaluate the safety and efficacy of Cladribine Tablets over an extended administration for four years.

The ORACLE MS (Oral Cladribine in Early MS) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS).

The ONWARD (Oral Cladribine Added ON To Interferon beta-1a in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled study designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy.

PREMIERE (Prospective Observational Long-term Safety Registry of Multiple Sclerosis Patients Who Have Participated in Cladribine Clinical Studies) study: interim long-term

over 2,700 patients included in the clinical trial program, and more than 10 years of observation in some patients.

About Rebif® (interferon beta-1a)

Rebif (interferon beta-1a) is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS. The efficacy and safety of Rebif in controlled clinical trials beyond 2-years has not been established.

Important Safety Information

Rebif is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation.

Rebif should be used with caution in patients with depression, a condition that is common in people with multiple sclerosis. Depression, suicidal ideation, and suicide attempts have been reported to occur with increased frequency in patients receiving interferon compounds, including Rebif.

Severe liver injury, including some cases of hepatic failure requiring liver transplantation, has been reported rarely in patients taking Rebif. The potential for liver injury should be considered when used in combination with other products associated with liver injury. Monitor liver function tests and patients for signs and symptoms of hepatic injury. Consider discontinuing Rebif if hepatic injury occurs.

Anaphylaxis and other allergic reactions (some severe) have been reported as a rare complication of Rebif. Discontinue Rebif if anaphylaxis occurs.

In controlled clinical trials, injection site reactions occurred more frequently in Rebif-treated patients than in placebo-treated and Avonex-treated patients. Injection site reactions including injection site pain, erythema, edema, cellulitis, abscess, and necrosis have been reported in the postmarketing setting. Do not administer Rebif into affected area until fully healed; if multiple lesions occur, discontinue Rebif until skin lesions are healed.

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif-treated patients than in placebo-treated

Cases of thrombotic microangiopathy (TMA), some fatal, have been reported with interferon beta products, including Rebif, up to several weeks or years after starting therapy. Discontinue Rebif if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.
Caution should be exercised when administering Rebif to patients with pre-existing seizure disorders. Seizures have been temporally associated with the use of beta interferons, including Rebif, in clinical trials and in postmarketing reports.

The most common side effects with Rebif are injection-site disorders, headaches, influenza-like symptoms, abdominal pain, depression, elevated liver enzymes, and hematologic abnormalities.
There are no adequate and well-controlled studies in pregnant women. Rebif should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Rebif full prescribing information is available at
http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=

About Multiple Sclerosis
Multiple sclerosis (MS) is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately 2.3 million people have MS worldwide. While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2016, Merck KGaA, Darmstadt, Germany, generated sales of € 15.0 billion in 66 countries.
Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the ”Merck”

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Recipients of €1 Million Grant for Multiple Sclerosis Innovation Announced at ECTRIMS 2017

EXPLORE MORE

Merck KGaA, Darmstadt, Germany today announced recipients of the fifth annual Grant for Multiple Sclerosis Innovation (GMSI) during the 7th Joint ECTRIMSACTRIMS Meeting in Paris, France.

Grant awarded across three research projects focused on prediction and defining characteristics of multiple sclerosis

Investment of €5 million in multiple sclerosis research funding as awards mark fifth year

Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced recipients of the fifth annual Grant for Multiple Sclerosis Innovation (GMSI) during the 7th Joint ECTRIMSACTRIMS Meeting in Paris, France.

United States, were selected to share the €1 million grant to support their research:

Immunosenescence as a predictor of MS progression: Professor Catherine Larochelle and Professor Nathalie Arbour, Department of Neurosciences, Université de Montréal, Canada;

Targeting multiple sclerosis immune- and psycho-pathophysiology by modulation of neuroinflammation; development of the S100B knockout model studies: Professor Adelaide Fernandes, Faculty of Pharmacy, University of Lisbon, Portugal;

Defining Spatial Pattern and Surface Characteristics of Multiple Sclerosis and Non-Specific White Matter Lesions via 3-Dimensional Analysis and Machine Learning: Professor Darin Okuda, Department of Neurology & Neurotherapeutics, UT Southwestern Medical Center, Dallas, Texas.

"Merck KGaA, Darmstadt, Germany, is deeply committed to innovative science that improves the lives of patients living with severe diseases. Since its initiation, the funding of early stage research projects such as the Grant for Multiple Sclerosis Innovation, has enabled talented and inspiring researchers to advance our understanding of how we predict, diagnose, treat and monitor progression of this disabling disease," said Steven Hildemann, Global Chief Medical Officer and Head of Global Patient Safety, at the biopharma business of Merck KGaA, Darmstadt, Germany. "This year's Grant for Multiple Sclerosis Innovation winners exemplify recent innovation with promising concepts in artificial intelligence, augmented diagnosis of multiple sclerosis, as well as sophisticated monitoring of disease progression, supporting caregivers and patients with multiple sclerosis in their hopes to continue to lead a normal life."

The GMSI was launched in October 2012 with the aim of improving the understanding of multiple sclerosis (MS) for the ultimate benefit of those living with the disease. Previous recipients have studied molecular markers of MS, novel magnetic resonance imaging (MRI) and positron emission tomography (PET) imaging and analysis techniques to detect and monitor the disease, and methods to reduce and repair nerve damage caused by inflammation in patients with MS.

The awards symposium was chaired by Professor David Bates, Emeritus Professor of Clinical Neurology, Royal Victoria Infirmary, UK, and a member of the GMSI Scientific Committee. During the symposium, Merck KGaA, Darmstadt, Germany also announced the call for proposals for the 2018 GMSI. Up to €1 million will be awarded to fund innovative research in

support programs, mobile health devices or patient-reported outcomes.

More information about the GMSI can be found online at: www.grantformultiplesclerosisinnovation.org.

In addition to the GMSI, Merck KGaA, Darmstadt, Germany, awards annually the Grant for Fertility Innovation, the Grant for Oncology Innovation and the Grant for Growth Innovation. To-date over 90 innovation winners have received, or been committed, grant funding for their projects.

Merck KGaA, Darmstadt, Germany is committed to rewarding innovation and new thinking that could further advance the field of medicine. To learn more about the variety of innovation grants follow this link.

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GMSI Winner C Larochelle, Canada
(14 KB)

GMSI Winner A Fernandes, Portugal
(98 KB)

GMSI Winner N Arbour, Canada
(77 KB)

GMSI Winner Okuda, US
(1.6 MB)

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