EMD Serono Takes on Exclusive Promotion of Rebif® (interferon beta-1a) in the US

- Broadens access to Rebif® through expanded formulary coverage, including the CVS Caremark™ National Formulary

- Advances outcome assessments and scientific programs for relapsing MS patients

(1)

ROCKLAND, Mass., Jan. 19, 2016 /PRNewswire/ -- EMD Serono, the biopharma business of Merck KGaA, Darmstadt, Germany today announced its continued commitment to serving the multiple sclerosis (MS) patient, medical and advocacy communities after taking on the sole rights to Rebif® (interferon beta-1a) in the United States as of January 1.

Rebif, the number one prescribed interferon for relapsing MS in patients new to therapy in the US*, is now the exclusive interferon beta-1a on CVS Caremark™ National Formulary and will also continue to be covered on most major national formulary plans.

said Drew Young, Senior Vice President, Neurology and Immunology, EMD Serono. "Since reimbursement can often be complicated for patients to navigate, we are working to ensure that all eligible patients are aware of our comprehensive suite of patient support programs, including our reimbursement support."

MS LifeLines®, a support service offered by EMD Serono averaging more than 300,000 annual connections with MS patients and their caregivers, provides valuable education and resources, including a broad range of comprehensive financial assistance programs for eligible people living with relapsing MS, including $0 co-pay or co-insurance for those with commercial insurance coverage. The MS LifeLines support center is also designed to connect patients to a nurse network, patient ambassadors and local patient programs.

"More than 130,000 people have taken Rebif for relapsing MS since launch, and we remain confident in the future of its role in the scientific, medical and patient communities," said Dr. Rick Munschauer, Vice President, Medical Affairs, Neurology and Immunology, EMD Serono. "In 2016, we are making significant investments in data analysis initiatives and real-world evidence to better understand the burden-of-disease, treatment pathways and comparative effectiveness as they relate to improved patient outcomes."

Data highlighting the clinical and MRI efficacy of Rebif, the company's high-dose, high-frequency interferon beta-1a for relapsing forms of multiple sclerosis, will be presented at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum taking place from February 18-20 in New Orleans, LA. Further information about this data can be found on the ACTRIMS 2016 Forum website: http://www.actrims.org/forum2016/.

In 2016, EMD Serono is pleased to be supporting the below initiatives with the aim of enhancing patient outcomes and advancing scientific knowledge in the area of MS.

- *Study of clinical outcome assessments on quality of communication between HCPs and MS patients:* The study, planned for initiation in Q2, will evaluate a newly developed web- and mobile phone-based technology platform to complete a panel of clinical outcome assessments, which include MS-specific patient-reported assessments as well as functional assessments. Study results could potentially define a minimal set of key platform features to improve communication between patients or HCPs.

with the aim of improving the understanding of MS for the ultimate benefit of those living with the disease. The submission deadline for 2016 proposals is February 8, 2016.

- *National MS Society, Thorsten Eickenhorst Postdoctoral Fellowship:* The National MS Society Postdoctoral Research Fellowship program selects top candidates who are mentored by seasoned investigators through a course of training that readies them for future careers. This three-year fellowship embodies EMD Serono's late Chief Medical Officer, Dr. Thorsten Eickenhorst's dedication as a leader in the scientific community by supporting ongoing training and continued research in the field of MS. The awardee for the 2016 Thorsten Eickenhorst Postdoctoral Fellowship is Stefanie Giera, Ph.D., Boston Children's Hospital, for her work with "Characterization of a novel G protein-coupled receptor in oligodendrocyte development".

- *MS Resource Centre, Elsevier:* In 2016, EMD Serono will continue to serve as the sole sponsor of Elsevier's MS Resource Centre, which provides free access to the latest peer-reviewed clinical information relating to the treatment of MS.

*IMS NPA data, June 2015 – October 2015; Patients who are new to therapy are defined as patients who have not received a prescription in at least the prior 12 months

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.

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 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.

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 two million patients 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.

www.emdserono.com

About Merck KGaA, Darmstadt, Germany

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SITEMAP

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Gary Zieziula Appointed President and Managing Director of EMD Serono

(2)

ROCKLAND, Mass., Jan. 27, 2016 /PRNewswire/ -- EMD Serono, the North America biopharma business of Merck KGaA, Darmstadt, Germany, announced today that Gary Zieziula has been appointed President and Managing Director, North America, of the company. In this role, he will be responsible for all areas of the company's business, including driving overall strategic direction and maximizing growth across the region.

EMD Serono is a leader in specialty care, integrating cutting-edge science, innovative medicines and devices, as well as industry-leading patient support and access programs.

Mr. Zieziula joined EMD Serono in 2014 as Chief Commercial Officer, responsible for the performance of the company's franchises in multiple sclerosis, fertility, endocrinology and oncology. He has more than 30 years of experience in the

"As we look to grow our biopharma business in North America, including our progress in oncology and immuno-oncology, Gary's vision, experience and customer-centric approach are critical to lead the company forward," said Simon Sturge, Chief Operating Officer, Healthcare, Merck KGaA, Darmstadt, Germany.

"I'm honored to move into this role and continue to collaborate with our outstanding local and global teams, as we work with a sense of urgency and focus on finding and delivering solutions to patients with difficult-to-treat, specialty care diseases and conditions," said Mr. Zieziula.

Mr. Zieziula holds a Bachelor of Science degree from the State University of New York at Buffalo and an MBA from Canisius College.

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corporate group. Merck KGaA, Darmstadt, Germany holds the rights to the Merck KGaA, Darmstadt, Germany 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 EMD Serono

Merck KGaA, Darmstadt, Germany Initiates Phase III Study of MSB11022, a Proposed Biosimilar of Adalimumab, in Chronic Plaque Psoriasis

- First patient treated in global phase III clinical study AURIEL-Psoriasis
- Study will evaluate efficacy, safety and immunogenicity of adalimumab biosimilar candidate MSB11022 compared with Humira®

DARMSTADT, Germany, March 2, 2016 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the initiation of a global phase III clinical study of MSB11022, a proposed biosimilar of adalimumab, in chronic plaque psoriasis. This milestone is a strong reflection of Merck KGaA, Darmstadt, Germany's progress in biosimilars, with the goal of delivering high-quality biologics to patients all over the world.

"With the first patient now being treated in our adalimumab biosimilar candidate study, we are moving closer to expanding access to affordable, high quality biologics for people living with serious diseases," said Michael Soldan, Head of the Biosimilar Business of Merck KGaA, Darmstadt, Germany. "At the same time, this milestone supports our broader healthcare strategy to complement our innovative R&D pipeline with biosimilars that serve as important therapeutic options for patients in need."

adalimumab biosimilar candidate MSB11022 compared with the brand Humira® (adalimumab) in patients with moderate to severe chronic plaque psoriasis. Humira® is marketed globally by AbbVie, Inc.

The study is expected to recruit approximately 400 patients across Europe, Asia and North and Central America.

Adalimumab is a recombinant human monoclonal antibody that binds specifically to tumour necrosis factor-alpha (TNF-α), blocking interaction with its cell surface receptors and thereby reducing the impact of inflammation. Humira® (adalimumab) is approved for use in a range of chronic inflammatory conditions such as plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, ulcerative colitis, Crohn's disease and juvenile idiopathic arthritis.

For more information on the AURIEL-PsO study, or to find a participating center and eligibility criteria, please visit www.clinicaltrials.gov
Humira® is a registered trademark of AbbVie, Inc.

About MSB11022, a proposed biosimilar of Humira® (adalimumab)
MSB11022 is being developed as a high quality biosimilar of adalimumab in the Swiss facilities of Merck, KGaA, Darmstadt, Germany using advanced analytical methods. Adalimumab is a biologic therapy used in the treatment of several chronic conditions including plaque psoriasis, Crohn's disease, ulcerative colitis, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis and ankylosing spondylitis.

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SOURCE Merck KGaA, Darmstadt, Germany

EMD Serono to Present Data Assessing Comparative Effectiveness of Rebif® (interferon beta-1a) vs. TECFIDERA® (dimethyl fumurate) at AAN Annual Meeting

- Real-world data further supports more than 20 years of combined clinical trial and patient experience of Rebif

(1)

ROCKLAND, Mass., April 14, 2016 /PRNewswire/ -- EMD Serono, the North America biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced that clinical and real-world data about Rebif® (interferon beta-1a), will be presented at the American Academy of Neurology's (AAN) 68th Annual Meeting, taking place April 15-21, 2016, in Vancouver, BC, Canada. Rebif is the #1 prescribed interferon for patients with relapsing forms of multiple sclerosis (MS) new to therapy and switching therapy combined.+

A real-world assessment of relapse rates in patients with MS newly initiating self-injectable treatment with Rebif versus an oral disease-modifying therapy, as well as the clinical effect of

"Patients with MS have more choices than ever before, but, given the potential devastation of this disease, consistent validation and balance of comparative effectiveness is paramount to selecting the most appropriate treatment," said Dr. Rick Munschauer, Vice President, Medical Affairs, Neurology and Immunology, EMD Serono. "We are committed to enhancing care for people living with MS. That commitment includes continuing to deepen our understanding of the clinical and real-world impact of Rebif to inform the most optimal choice of therapy for patients. With a well-established safety profile supported by more than 20 years of combined clinical trial and patient experience and efficacy across three key disease measures – including reducing relapse rates and delaying disability progression – Rebif is an important treatment option for relapsing MS."

The following abstracts have been accepted for presentation at the 68th AAN Annual Meeting:

Title	**Lead Author**	**Abstract/ Poster #**	**Presentation date/time**	**Session**	**Room/ Details**
Predictive Value of 6-Month T2 and Enhancing Lesions Among Patients with RRMS Receiving Interferon β-1a Subcutaneously Thrice Weekly or Placebo: Post Hoc Analyses of PRISMS Data	D. Li	P1.401	April 16, 2016 5:30 p.m.	Poster Session P1: 8:30 a.m. to 7:00 p.m.	TBD
Age-, Sex-, and Geographic Region-Specific Comorbidity in	NC. Edwards	P2.190	April 17, 2016 4:00 p.m.	Poster Session P2: 8:30 a.m. to 5:30 p.m.	TBD

Magnetic Resonance Imaging (MRI) Outcomes in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS) Treated with Cladribine Tablets: Results from the 120-Week Phase IIIb Extension of the CLARITY Study	G. Comi	P2.114	April 17, 2016 4:00 p.m.	Poster Session P2: 8:30 a.m. to 5:30 p.m.	TBD
Role of Family Planning in Women of Child-Bearing Age with Multiple Sclerosis (MS) in Switzerland: Results of the Women with MS (WWMS) Patient Survey	S. Muehl	P2.105	April 17, 2016 4:00 p.m.	Poster Session P2: 8:30 a.m. to 5:30 p.m.	TBD
Adherence to Subcutaneous IFN-β1a - Final Analysis of the Non-Interventional Study READOUTsmart Using the Dosing Log	P. Rieckmann	P3.098	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD

Association of Timing of Disease-Modifying Drug Treatment Initiation on Multiple Sclerosis Relapse Rates in Newly Diagnosed Patients	AL. Phillips	P3.118	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD
Clinical Efficacy of Cladribine Tablets in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS): Final Results from the 120-Week Phase IIIb Extension Trial to the CLARITY Study	G. Giovannoni	P3.028	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD
Effect of Early Versus Delayed Subcutaneous Interferon (scIFN) β-1a to Achieve No Evidence of Disease Activity (NEDA) in Patients with Clinically Isolated Syndrome (CIS): a Post-Hoc Analysis of REFLEXION	P. Coyle	P3.111	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD

Efficacy of Cladribine Tablets* as Add-On to IFN-Beta Therapy in Patients with Active Relapsing MS: Final Results from the Phase II ONWARD Study	X. Montalban	P3.029	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD
Efficacy of Cladribine Tablets* in ORACLE Study Patients who Retrospectively Met 2010 McDonald Multiple Sclerosis (MS) Criteria at Baseline	MS. Freedman	P3.035	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD
Interferon β-1a SC tiw Reduces Mild to Moderate and Moderate to Severe Relapses and Disease Activity over 1 Year in Patients with Relapsing MS: Post Hoc Analyses of PRISMS Data	A. Boster	P3.036	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD
Natural and Inducible Regulatory T Cell Subsets in a Large	F. Serana	P3.077	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD

Sclerosis Patients Treated with Interferon-Beta and Followed for 24 Months					
Safety and Tolerability of Cladribine Tablets* in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS): Final Results from the 120-Week Phase IIIb Extension Trial to the CLARITY Study	S. Cook	P3.095	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD
Slowing of Disability Progression Based on 6-Month Confirmed EDSS in Patients with Relapsing-Remitting Multiple Sclerosis (RRMS) Treated with Cladribine Tablets* in the CLARITY Study: a Post-Hoc Subgroup Analysis	S. Cook	P3.058	April 18, 2016 5:30 p.m.	Poster Session P3: 8:30 a.m. to 7:00 p.m.	TBD
MRI Frequency and No Evidence of Disease	AT. Reder	P6.190	April 21, 2016 4:00 p.m.	Poster Session P6: 8:30 a.m.	TBD

Receiving IFN β-1a SC tiw or IFN β-1a IM qw: Post Hoc Analyses of EVIDENCE					
Predictive Value of Early MRI Measures for Long-Term Disease Activity in Patients with Relapsing–Remitting Multiple Sclerosis Receiving IFN β-1a SC tiw or IFN β-1a IM qw: Post Hoc Analyses of the EVIDENCE Study	PK. Coyle	P6.189	April 21, 2016 4:00 p.m.	Poster Session P6: 8:30 a.m. to 5:30 p.m.	TBD
Real-World Assessment of Relapse Rates in Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon β-1a vs Oral Disease-Modifying Drugs	CM. Kozma	P6.178	April 21, 2016 4:00 p.m.	Poster Session P6: 8:30 a.m. to 5:30 p.m.	TBD

**Cladribine tablets is an investigational product and not approved for use in any indication in the United States. RebiSmart®, an electronic device for self-injection of Rebif®, is also not approved in the United States.*

Learn more about EMD Serono's programs, pipeline and activities in neurology by visiting our booth at this year's AAN Annual Meeting.

therapy (including patients who stopped a DMT for greater than 30 days, then restarted on a different DMT) as well as patients who have not received a prescription in at least the prior 12 months.

TECFIDERA® (dimethyl fumarate) is a registered trademark of Biogen.

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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.

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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=

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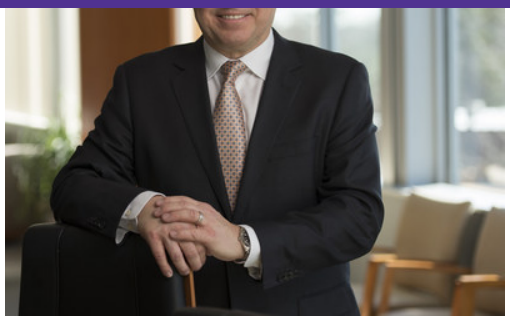
Merck KGaA, Darmstadt, Germany Supports Next Generation of Scientists at USA Science & Engineering Festival

- Scientists seek to spark curiosity among festival attendees
- 350,000 K-12 students and families expected to attend

(1)

DARMSTADT, Germany, and WASHINGTON, April 14, 2016 /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 it is participating in the 4th USA Science & Engineering Festival (USASEF), April 16-17, 2016 in Washington D.C. The festival is the largest Science, Technology, Engineering and Mathematic (STEM) gathering in the United States, bringing together more than 350,000 K-12 students and parents, as well as more than 5,000 teachers and 3,000 professionals.

"The USA Science & Engineering Festival aligns with our company's commitment to furthering STEM education and igniting a passion for science in the next generation of innovators," said Gary Zieziula, President and Managing Director of EMD Serono, which is Merck KGaA, Darmstadt, Germany's North America biopharma business. "Our participation in the festival is



Researchers representing the company's three businesses sectors - Healthcare, Life Science, and Performance Materials - will guide festival participants through experiments that are at the heart of their work in the laboratory and illustrate important societal challenges:

- Scientists from EMD Serono will lead an experiment to extract DNA from plants and discuss how molecular genetics and biotechnology are underpinning innovation in healthcare, such as biomarker testing for cancer therapies.
- Scientists from MilliporeSigma will lead an experiment on pH testing and discuss the difference between acids and bases.
- Scientists from EMD Performance Materials will lead an experiment demonstrating the protective qualities of organic and inorganic sun filter materials against UV rays, and discuss the importance of sun protection.

The company has a long tradition of supporting cultural and educational programs around the world and fostering an interest in science. It's Smarter Together in the Classroom program provides public schools in Massachusetts as well as St. Louis, Missouri, with critical funding for projects that explore pressing scientific questions. In addition, MilliporeSigma's SPARK global skills-based volunteer program provides volunteer opportunities for its network of employees, with a focus on science education.

For a hands-on look at experiments used in real-world applications and to learn more about Merck KGaA, Darmstadt, Germany, please visit Booth 715 in Exhibit Hall A.

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 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.

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

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. Merck KGaA, Darmstadt, Germany operates as EMD Serono, MilliporeSigma and EMD Performance Materials in the United States and Canada.

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Photo - http://photos.prnewswire.com/prnh/20160414/355533

SOURCE Merck KGaA, Darmstadt, Germany

EMD SERONO

THERAPEUTIC AREAS

YOUR REQUESTS

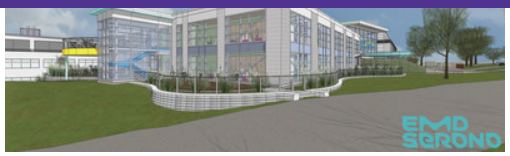
EMD Serono Expands Biopharmaceutical R&D Facility in Billerica, MA to Accelerate Innovation

- EMD Serono investing $12 million in campus expansion
- Expansion will create additional 30,000 square feet of space
- Company planning to hire 150 new employees across the business in 2016

(1)

BILLERICA, Mass., May 2, 2016 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in North America, today announced a $12 million investment for the expansion of its R&D facility in Billerica, Massachusetts. The new building will span more than 30,000 square feet and accommodate approximately 120 new and current employees whose focus will be on accelerating innovation in R&D, with a focus on oncology, immuno-oncology and immunology.

"The purpose of this expansion is to advance innovation and knowledge-sharing across our R&D teams, with the goal of accelerating the discovery and development of new therapies for patients in need," said Luciano Rossetti, MD, Head of Global R&D for Merck KGaA, Darmstadt, Germany, at a groundbreaking ceremony today in Billerica. "This investment is a reflection of



With approximately 2,000 R&D professionals working across four global R&D hubs—Darmstadt, Germany; Boston, US; Tokyo, Japan; and Beijing, China—Merck KGaA, Darmstadt, Germany endeavours to make a meaningful difference in the lives of people with serious medical needs.

"The growth of EMD Serono's Billerica campus over the past several years and its decision to continue to grow in Massachusetts is a testament to our state's leadership in biopharmaceutical innovation," said Robert K. Coughlin, President & CEO of MassBio, the life sciences trade association. "The company's long-standing investment here ensures that we continue to retain and attract the top scientific minds and that the medical advances that make a real difference in people's lives occur here in Massachusetts."

The new two-story, 30,000 square foot building will be an extension of the existing Sagamore Building and will feature amenities including open plan work areas, a central auditorium, and numerous meeting spaces including bleacher seating for spontaneous collaboration and interaction. In addition to seeking LEED certification to complement the Sagamore Building's Platinum LEED status, EMD Serono will also apply for the WELL Institute certification. The WELL Institute standards measures the human health and wellness of occupants in the building environment. If achieved, EMD Serono would have one of the first projects in the United States with that certification distinction.

Construction on the expansion is scheduled to begin in May 2016 with a planned completion date of June 2017. In addition to its R&D facility in Billerica, EMD Serono's corporate headquarters are located in Rockland, Massachusetts and in total the company has approximately 800 employees across the state.

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

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SOURCE EMD Serono

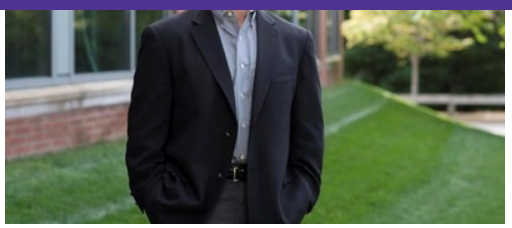
12th Edition of the EMD Serono Specialty Digest™ Now Available

- Value of specialty medicines, appropriate clinical use identified as critical managed care challenges

(1)

ROCKLAND, Mass., May 9, 2016 /PRNewswire/ -- EMD Serono, the North America biopharmaceutical business of Merck KGaA, Darmstadt, Germany, announced the release of the 12th edition of the EMD Serono Specialty Digest™. The Digest, which was featured last week at the Asembia Specialty Pharmacy Summit in Las Vegas, NV, is an industry resource that provides market data on health plans' management of specialty pharmaceuticals in 2015 and identifies common trends occurring across plans. The Digest is available to those who request a copy at http://www.specialtydigest.emdserono.com.

"EMD Serono has a longstanding commitment to customers and patients to further the understanding of trends in the management of specialty pharmaceuticals and ultimately, improve patient outcomes," said Scott Filosi, Senior Vice President, Market Access & Customer Solutions, EMD Serono. "It is our hope that this year's Digest findings will help spur conversations around ways to ensure continued patient access to optimal care."



representing more than 140 million covered lives. New to the Digest this year is an oncology-specific supplement that includes a deeper analysis into the therapeutic category, which continues to be a major focus for health plans. The new oncology-specific supplement is scheduled to be available in June.

"The findings in the area of oncology shed light on new trends such as the adoption of clinical pathways as well as concerns around restricting product use and the cost of infusion site visits for payers," said Kevin Host, President, Artemetrx, who oversaw the development of this year's Digest. "Understanding these managed care challenges as they relate to oncology is an important step in better meeting the needs of patients."

Further findings from this year's Digest show that while alignment of pharmacy and medical benefits has improved, it still remains a major issue for some plans. Additionally, plans are more likely to select preferred products and to exclude non-preferred agents as a therapy class matures post-launch.

The EMD Serono Specialty Digest was first developed in 2004 to provide a comprehensive reference for managed care decision makers regarding the management of specialty products. Over the past twelve years, health plans, Pharmacy Benefit Managers (PBMs), employers, specialty pharmacies, and pharmaceutical companies have relied on the Digest to identify current and future trends in the management of specialty pharmaceuticals.

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EMD Serono Supports Military Community By Providing Access to Fertility Care Through Focused Patient Assistance Programs

-- Company leads efforts to increase opportunities for injured veterans to start families through its Compassionate Corps program

-- More than 1,400 active U.S. military and veterans have been assisted by the Compassionate Care program

ROCKLAND, Mass., May 19, 2016 /PRNewswire/ -- In recognition of Military Appreciation Month, EMD Serono, the North America biopharmaceutical business of Merck KGaA, Darmstadt, Germany, is working to bridge significant gaps in coverage of fertility treatment for eligible active U.S. military and veterans who have been injured in service and are uninsured through its Compassionate Corps and Compassionate Care programs.

Experience the interactive Multimedia News Release here: http://www.multivu.com/players/English/7829451-emd-serono-fertility-care-military-veterans/

"More than 2,200 service people have suffered catastrophic injury which has rendered them infertile, and many of these patients have been medically retired, which compromises their coverage for infertility treatment," said Alan Copperman, MD, Director of the Division of Reproductive Endocrinology and Infertility at The Mount Sinai Hospital and Medical Director of Reproductive Medicine Associates of New York. "It's crucial that the infertility community work together to help increase access to fertility treatment for these men and women, who have made such great sacrifices for our country."

Since launching less than two years ago, EMD Serono's Compassionate Corps program has helped more than 70 veterans obtain medication for IVF/advanced reproductive technology (ART), and over 50 fertility clinics in the U.S. have signed up to partner with EMD Serono to provide access to the program. EMD Serono's Compassionate Care program, which helps uninsured, income-eligible patients receive discounted fertility medications, has helped more than 30,000 underserved patients gain access to fertility medications. Of these, more than 1,400 are active U.S. military or veterans.

"EMD Serono has a legacy of leading efforts to increase access to medications for underserved patients," said Craig Millian, Senior Vice President, Head of U.S. Endocrinology and Fertility. "With more than a million Gulf War veterans living in the U.S., many of whom are still of child-bearing age, the veteran community is significant in number and highly in need of increased access to family-building resources. Through the Compassionate Corps and Compassionate Care programs we have advanced our mission of advocating for people who want to have a child."

To be eligible for the Compassionate Corps program, patients must:

- Be a retired member of the military or the spouse of one;

- Not privately insured for infertility medications;
- Medically retired;

- Have been diagnosed by a physician as infertile and requiring IVF/ART.

Uninsured active U.S. military as well as uninsured military veteran patients who do not qualify for the Compassionate Corps Program are encouraged to apply for EMD Serono's Compassionate Care Program in which they will now receive a minimum discount of 25% off the self-pay price of EMD Serono medicines if eligible, and can also qualify for 50 to 75% off of EMD Serono medications if they meet financial eligibility criteria.

EMD Serono collaborates with Veteran Support Organizations to raise awareness of issues facing U.S. veterans attempting to build families, and to enhance the impact of their programs.

For more information about the Compassionate Care and Compassionate Corps programs, and about infertility, treatment options, and to find a specialist near you, please visit www.FertilityLifelines.com.

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SITEMAP

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New Data at CMSC Assess Real-World Impact of Rebif® (interferon beta-1a) in People with Relapsing MS

EXPLORE MORE

- Data compare Rebif vs. Tecfidera® and Aubagio® in the first year of treatment
- Assessments include likelihood of relapse, medical costs and outpatient management resources needs

ROCKLAND, Mass., June 2, 2016 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced that it will present real-world data that evaluate relapse rates, outcomes of disease activity and healthcare costs in patients initiating Rebif® (interferon beta-1a) at the 2016 Consortium of Multiple Sclerosis Centers (CMSC) Annual Meeting, taking place June 1-4, 2016, in National Harbor, MD.

Rebif is the #1 prescribed interferon for patients with relapsing forms of multiple sclerosis (MS) new to therapy and switching therapy combined.+ Real-world data to be presented at CMSC include relapse rates, cost of care and outpatient resource use in MS patients newly initiating Rebif versus those beginning treatment with oral disease-modifying drugs (DMDs), including Tecfidera® (teriflunomide) or Aubagio® (dimethyl fumarate).

and enable completion of clinical outcome assessments.

"Since its approval in 2002, the clinical value of Rebif in people with relapsing MS has been well-established," said Dr. Rick Munschauer, Vice President, Medical Affairs, Neurology and Immunology, EMD Serono. "The data being presented at CMSC highlight the real-world impact of Rebif on outcomes including disease activity and healthcare costs."

The following abstracts have been accepted for presentation at the 2016 CMSC Annual Meeting:

Title	**Lead Author**	**Abstract/ Poster #**	**Presentation date/time**
Cost of Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon ß-1a Vs Oral Disease-Modifying Drugs – a Real-World Assessment	C. Kozma	DX14	June 2, 2016 6:15 – 8:15 p.m.
Real-World Outpatient Resource Use of Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon ß-1a vs Oral Disease-Modifying Drugs	C. Kozma	DX13	June 2, 2016 6:15 – 8:15 p.m.
Relapse Rates of Patients with Multiple Sclerosis Newly Initiating Subcutaneous Interferon ß-1a vs Oral Disease-Modifying Drugs in the Real World	C. Kozma	DX35	June 2, 2016 6:15 – 8:15 p.m.
A Phase IV Open-Label Study of Clinical Outcome Assessments to Facilitate Patient–HCP Interaction in MS: Study Design and Rationale	D. Barone	PO06	June 2, 2016 6:15 – 8:15 p.m.

Relapsing Multiple Sclerosis: Post Hoc Analyses of PRISMS Data			p.m.
≥4 Active T2 Lesions at 6 Months Predicts Future Relapse/Disability in Patients with RMS on Placebo but Not IFN ß1a SC tiw: Post Hoc PRISMS Analyses	A. Traboulsee	DX16	June 2, 2016 6:15 – 8:15 p.m.
Autoinjector Ease of Use in Patients with Multiple Sclerosis Treated with Interferon ß1a Subcutaneously: Preliminary Data from REDEFINE	S. Wray	PO04	June 2, 2016 6:15 – 8:15 p.m.

Learn more about EMD Serono's programs, pipeline and activities in neurology by visiting our booth at this year's CMSC Annual Meeting.

Tecfidera® (dimethyl fumarate) is a registered trademark of Biogen.
Aubagio® (teriflunomide) is a registered trademark of Genzyme Corporation, a Sanofi Company.

[+]IMS NPA Market Dynamics Data, February 2016-April 2016 (rolling 3 months/New To Brand Rx). New To Brand Rx is defined as the sum of patients who are switching from another therapy (including patients who stopped a DMT for greater than 30 days, then restarted on a different DMT) as well as patients who have not received a prescription in at least the prior 12 months.

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

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.

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.

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 two million patients 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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EMD Serono Provides Grant To The Skin Cancer Foundation To Raise Awareness Of Rare Cancer

Patient Education Grant to provide resources on Merkel cell carcinoma

(1)

ROCKLAND, Mass., June 22, 2016 /PRNewswire/ -- EMD Serono, the U.S. and Canada biopharma business of Merck KGaA, Darmstadt, Germany, today announced its award of a patient education grant to The Skin Cancer Foundation, the only international organization solely devoted to skin cancer prevention, early detection and treatment. While skin cancer is the most common cancer in the U.S., with nearly 3.3 million people diagnosed each year[i], there remained a need for educational resources about rare and lesser-known forms of the disease, including Merkel cell carcinoma (MCC).

The Skin Cancer Foundation used the grant funds to further develop its patient education materials on MCC on its website, SkinCancer.org. The site is the number one online resource for skin cancer education, with nearly 10 million people visiting the website annually. MCC is a very aggressive form of skin cancer[ii] with high rates of recurrence[iii], and is more frequently fatal than melanoma[iv], a more well-known skin cancer. While still rare, the number of reported cases

survival rate for patients with metastatic MCC is less than 20 percent[vii] [viii]. It primarily affects people who have sustained exposure to an excessive amount of natural or artificial sunlight, the elderly and people with compromised immune systems, such as people living with HIV or transplant recipients[ix].

"Merkel cell carcinoma is extremely rare, but very dangerous," said Deborah S. Sarnoff, MD, senior vice president of The Skin Cancer Foundation. "Not many people know about it, so they're not aware of their risk. As leaders in the fight against skin cancer, we have a responsibility to fill this education gap so that we can prevent some of the deaths that result from a lack of knowledge."

"As with many rare cancers, there is a lack of resources for people to understand and learn about Merkel cell carcinoma," said Zhen Su, Vice President and Head of Global Medical Affairs, Oncology, EMD Serono. "Our company is working to help people with cancers where there remains a significant need, and we are proud to support The Skin Cancer Foundation to help educate people about this relatively unknown and devastating cancer."

Merck KGaA, Darmstadt, Germany – which operates as EMD Serono in the U.S. and Canada – and Pfizer, Inc. formed a global strategic alliance in 2014 focusing on developing high-priority international clinical programs to investigate immunotherapy regimens, and is striving to find new ways to treat cancer, including Merkel cell carcinoma.

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About the Merck KGaA, Darmstadt, Germany and Pfizer Alliance

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, U.S., enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of immunotherapy. The alliance is focused on developing high-priority international clinical programs to investigate immunotherapy regimens, and is striving to find new ways to treat cancer.

About The Skin Cancer Foundation

The Skin Cancer Foundation is the only global organization solely devoted to the prevention, early detection and treatment of skin cancer. The mission of the Foundation is to decrease the incidence of skin cancer through public and professional education and research. Since its inception in 1979, the Foundation has recommended following a complete sun protection regimen that includes seeking shade and covering up with clothing, including a wide-brimmed hat and UV-blocking sunglasses, in addition to daily sunscreen use. For more information, visit SkinCancer.org.

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References:

[i] American Cancer Society. Skin Cancer Facts. Available at http://www.cancer.org/cancer/cancercauses/sunanduvexposure/skin-cancer-facts. Accessed May 12, 2016.

[ii] Poulsen M. Merkel-Cell Carcinoma of the Skin. The Lancet Oncology. 2004;5(10):593-599.

[iii] Wolff K, et al. Merkel Cell Carcinoma. Fitzpatrick's Dermatology in General Medicine. 2006: 7th Edition.

[iv] Wolff K, et al. Merkel Cell Carcinoma. Fitzpatrick's Dermatology in General Medicine. 2006: 7th Edition.

[v] Wolff K, et al. Merkel Cell Carcinoma. Fitzpatrick's Dermatology in General Medicine. 2006: 7th Edition.

[vi] American Cancer Society. What are they key statistics about Merkel cell carcinoma? Available at http://www.cancer.org/cancer/skincancer-merkelcell/detailedguide/skin-cancer-merkel-cell-carcinoma-key-statistics. Accessed May 12, 2016.

[vii] NCCN Merkel Cell Carcinoma Guidelines version I. 2016. Available from: www.nccn.org/professionals/physician_gls/PDF/mcc.pdf. Accessed April 2016.

[viii] Iyer JG, Blom A, Doumani R, et al. Response Rate and Durability of Chemotherapy for Metastatic Merkel Cell Carcinoma Among 62 Patients. Abstract. Presented at the American Society of Clinical Oncology Annual Meeting (ASCO) 2014.

carcinoma-risk-factors. Accessed May 12, 2016.

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Merck KGaA, Darmstadt, Germany Welcomes ZEISS and Hamilton Thorne as New Members of the Global Fertility Alliance

- New partners are joining founding members Merck KGaA, Darmstadt, Germany, Illumina and Genea to support standardization of processes in assisted reproductive treatment laboratories

- Update on the alliance's activities to be presented at ESHRE

ROCKLAND, Mass., June 30, 2016 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, which operates its biopharmaceutical business as EMD Serono in the U.S. and Canada, today announced together with Illumina Inc., San Diego, US, and Genea Limited, Sydney, Australia, that the Global Fertility Alliance welcomed two new members. The alliance is a collaboration to advance excellence in fertility technologies and processes within the assisted reproductive treatment (ART) laboratory. Effective immediately, ZEISS, Oberkochen, Germany, an internationally leading technology enterprise operating in the optics and optoelectronics industries, and Hamilton Thorne Ltd., Beverly, Massachusetts, US, a leading provider of precision laser devices and advanced image analysis systems for ART, regenerative medicine and developmental biology research markets, are joining the alliance and its quest to improve the consistency in ART laboratories worldwide. Following the announcement of the alliance's

ESHRE in Helsinki, Finland (3-6 July, 2016).

"Through our work with the fertility community, we know that ART outcomes strongly depend on routines and technologies applied in laboratories. As such, we are committed to overcoming current variation in ART practices and techniques," explained Rehan Verjee, Chief Marketing and Strategy Officer at Merck KGaA, Darmstadt, Germany's biopharma business. "We are working in the alliance to support the development of global standards in ART laboratories. We understand this as a critical factor for ensuring a consistently high level of performance across centers and countries, ultimately supporting the goal of women and couples of having a baby."

Seeing the importance of recognizing innovation in ART technologies, the Global Fertility Alliance was founded by Merck KGaA, Darmstadt, Germany, together with two strategic partners: Illumina, a leader in developing and commercializing systems for analysis of genetic variation and function, and Genea, a developer of innovative fertility technologies. The collaboration is part of Merck KGaA, Darmstadt, Germany's Fertility Technologies strategy to partner with experts in the field to address unmet needs together and support the market with innovations, with a clear focus on extending its product portfolio for the benefit of the fertility community.

"ZEISS has a strong heritage in the development of specialized microscopes and we are committed to using our expertise in this field to drive the standardization of ART processes and techniques further," commented Peter Kraemer, Director Market Segment Education & Routine at ZEISS Microscopy Business Group. "We are impressed by the alliance's progress so far and look forward to contributing to improvements in ART practices through technology innovation."

"As a pioneer in the field of developing instruments for the in vitro fertilization clinic, advancing the science of fertility treatment is in the DNA of our company," said David Wolf, CEO of Hamilton Thorne. "With excellence in ART as its tenet, the goal of the Global Fertility Alliance is to drive automation and standardization in fertility laboratories worldwide to promote better outcomes for patients."

The collaboration partners are aiming to welcome further members which share the common objectives and complement the expertise of the existing partner companies.

About the Global Fertility Alliance

Recognizing the importance of innovation in ART technologies, the alliance aims to enhance

collaborate with leading health care professionals and medical societies to develop global standards. And finally, as technologies in the fertility space are rapidly advancing, the alliance will also develop educational resources for health care professionals worldwide. These efforts will include training curricula and workshops as well as access to model labs, symposia and events at medical meetings. The Global Fertility Alliance was launched at the 31st Annual Meeting of the European Society of Human Reproduction and Embryology (ESHRE) in June 2015. First members besides Merck KGaA, Darmstadt, Germany were Illumina, a leader in developing and commercializing systems for analysis of genetic variation and function, and Genea, a developer of innovative fertility technologies.

About ZEISS

ZEISS is an internationally leading technology enterprise operating in the optics and optoelectronics industries. The ZEISS Group develops and distributes semiconductor manufacturing equipment, measuring technology, microscopes, medical technology, eyeglass lenses, camera and cine lenses, binoculars and planetarium technology. With its solutions, the company constantly advances the world of optics and helps shape technological progress. ZEISS is divided up into the four segments Semiconductor Manufacturing Technology, Research & Quality Technology, Medical Technology, and Vision Care/Consumer Optics. ZEISS is represented in over 40 countries and operates more than 30 production sites, over 50 sales and service locations and about 25 research and development facilities. In fiscal year 2014/15 the company generated revenue approximating €4.5 billion with around 25,000 employees. Founded in 1846 in Jena, the company is headquartered in Oberkochen, Germany. Carl Zeiss AG is the strategic management holding company that manages the ZEISS Group. The company is wholly owned by the Carl Zeiss Stiftung (Carl Zeiss Foundation).

About Hamilton Thorne Ltd.

Hamilton Thorne designs, manufactures and distributes precision laser devices and advanced imaging systems that reduce cost, increase productivity, improve results and enable breakthroughs in the assisted reproduction, regenerative medicine and developmental biology research markets. Hamilton Thorne's laser products attach to standard inverted microscopes and operate as robotic micro-surgeons, enabling a wide array of scientific applications and IVF procedures. Its imaging systems improve outcomes in human IVF clinics and animal breeding facilities and provide high-end toxicology analyses. Hamilton Thorne's growing worldwide customer base consists of pharmaceutical companies, biotechnology companies, fertility clinics, university research centers, animal breeding companies, and other commercial and academic

Novartis, Pfizer, and Dow Chemical.

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EMD Serono Commits €1.5 million to the Grant for Fertility Innovation (GFI) for 2016/17

- Investment reflects company's commitment to innovation in fertility research
- Globally, six projects receive funding from this grant cycle

ROCKLAND, Mass., July 6, 2016 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced it would continue to support the advancement of medical science in the field of fertility through the Grant for Fertility Innovation (GFI) program by awarding grants totalling €1.5 million in 2016/17. The announcement was made at the 32nd annual meeting of European Society of Human Reproduction and Embryology (ESHRE), currently taking place in Helsinki, Finland.

Launched in 2009 at ESHRE, the GFI is dedicated to transforming innovative translational fertility research projects into concrete health solutions to improve the outcomes of assisted reproductive technologies (ART). This year, 6 winning projects were selected from 112 global proposals with the common goal of improving the chances for couples to conceive a baby. The grant will be divided up into three milestone payments per project.

Chief Medical Officer and Head of Global Medical and Safety at the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. "The GFI program has already enabled advanced researchers to accelerate scientific discovery and translational work to fertility care by leveraging an impactful global network of expertise across the academic and industry continuum."

The GFI awardees were announced during a ceremony at ESHRE on July 5th.

- **Stephen Andrew Krawetz**, Ph.D. - Wayne State University School of Medicine, Detroit, USA – Project "A Retrospective Controlled Cohort Study of Sperm RNAs Guiding the 2 Treatment of the Idiopathic Infertile couple"
- **Lynne O'Shea**, B.Sc. (Hons.), Ph.D. - UCD School of Medicine and Medical Science, University College Dublin, Ireland – Project "Using a biomarker of oocyte quality to improve embryo selection during assisted reproduction"
- **Paola Piomboni**, PhD- University of Siena, Italy – Project "Exosomal Profile of the Receptive Endometrium: A source of non-invasive biomarkers for Guiding of a Successful Embryo Implantation"
- **Qingling Yang** received his Ph.D. – Reproductive Medical Center of the first Affiliated Hospital of Zhengzhou University, China - Project "Telomere length test of cell free genomic DNA in spent embryo medium as a non-invasive biomarker for assessing embryo developmental potential"
- **Professor Ernest Hung Yu Ng Professor William Shu -biu Yeung** – University of Hong Kong, China – Project "Human embryonic stem cell-derived trophoblastic spheroids (BAP-EB) as a predictive tool for endometrial receptivity and pregnancy rate of in vitro fertilization treatment"
- **Professor Fulvio Zullo** - University Magna Graecia of Catanzaro, Italy – Project "Periostin a new non-invasive parameter for evaluating oocyte/blastocyst quality and its impact on endometrial receptivity"

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EMD Serono Receives CEO Cancer Gold Standard™ Re-Accreditation

- Company maintains its status as a Gold Standard employer since first earning accreditation in 2011

(1)

ROCKLAND, Mass., Aug. 18, 2016 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced that it has earned *CEO Cancer Gold Standard*™ re-accreditation for maintaining a strong commitment to the health of its employees and satisfying the latest, comprehensive requirements of this national workplace wellness accreditation program established by the *CEO Roundtable on Cancer*.

The *CEO Roundtable on Cancer* is a forum that brings together key cancer leaders from government, business, academic and non-profit sectors to develop and implement initiatives that reduce the risk of cancer, enable early diagnosis, facilitate access to the best available treatments and hasten the discovery of novel anti-cancer therapies.

cancer in the workplace. EMD Serono is one of nearly 200 private, nonprofit and government employers in a wide range of occupational categories that have earned *Gold Standard* accreditation, including the National Cancer Institute (NCI) and a number of NCI-designated cancer centers.

"Nearly all of us are impacted by cancer in some way. At EMD Serono we are committed to making a difference in the lives of patients, their loved ones and healthcare professionals, by accelerating innovation in oncology in order to develop therapies with the potential to transform the way cancer is treated," said Gary Zieziula, President and Managing Director, North America. "This commitment extends to our corporate family through employee wellness programs that are designed to help reduce the risk of cancer, promote early detection and provide quality care."

In order to earn and maintain *CEO Cancer Gold Standard* accreditation, EMD Serono met specific requirements in corporate culture and health benefits, including: establishing policies and programs to reduce cancer risk by prohibiting tobacco use in the workplace and supporting tobacco cessation efforts; promoting physical activity, healthy nutrition and weight management; providing health insurance options that include detecting cancer at its earliest stages, access to quality care, and participation in clinical trials; promoting employee awareness of these initiatives; and supporting the needs of cancer survivors in the workplace.

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About The CEO Roundtable on Cancer

The CEO Roundtable on Cancer was founded in 2001, when former President George H.W. Bush challenged a group of executives to "do something bold and venturesome about cancer within your own corporate families." Since then, the Roundtable has created the CEO Cancer Gold Standard, the CEO Life Sciences Consortium, and Project Data Sphere. More information about the Roundtable can be found at www.CEORoundTableonCancer.org.

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SOURCE EMD Serono

EMD Serono Appoints Craig Millian Senior Vice President, Neurology and Immunology

ROCKLAND, Mass., Sept. 16, 2016 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the US and Canada, today announced the appointment of Craig Millian as Senior Vice President, Neurology and Immunology. Mr. Millian most recently served as Senior Vice President, Head of US Fertility and Endocrinology at EMD Serono. In his new role, he will lead the strategic direction of the Company's US Neurology and Immunology franchise.

"Craig is a dynamic leader with a proven track record of success," said Gary Zieziula, President and Managing Director of EMD Serono. "He has been instrumental in expanding our leadership in Fertility and Endocrinology, and he will bring that passion and expertise to the Neurology and Immunology business, furthering our commitment to improving care for people living with multiple sclerosis and other conditions as we advance our pipeline."

Mr. Millian joined EMD Serono in 2010 to lead the Fertility and Endocrinology marketing team. He previously served as Vice President, Commercial at Vertex, where he helped design and build the commercial infrastructure, organizational capabilities and go-to-market plans in

degree in Finance from the University of Pennsylvania.

Drew Young, who previously served as Senior Vice President, Neurology and Immunology for EMD Serono, has recently been appointed to a new position within Merck KGaA, Darmstadt, Germany. He will serve as General Manager and Managing Director, Merck KGaA, Darmstadt, Germany, Biopharma, Australia & New Zealand, effective September 1, 2016. Mr. Young joined EMD Serono in June 2014 and had a positive impact on the company's neurology and immunology performance.

EMD Serono's neurology franchise includes Rebif (interferon beta-1a), the #1 prescribed interferon for patients with relapsing forms of MS new to therapy and switching therapy combined in the US.[i] Rebif has a well-established safety profile with more than 20 years of accrued clinical trial and patient experience. Since its approval in 2002, more than 130,000 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 14 years, this award-winning patient support service has provided round-the-clock education and support for people living with relapsing MS.

The company also has a pipeline of products it is investigating in the immunology and neurology space.

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.

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 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.

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[i] IMS NPA Market Dynamics Data, May 2016-July 2016 (rolling 3 months/New To Brand Rx). New To Brand Rx is defined as the sum of patients who are switching from another therapy (including patients who stopped a DMT for greater than 30 days, then restarted on a different DMT) as well as patients who have not received a prescription in at least the prior 12 months.

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EMD Serono Announces Launch of New Fertility Technologies Division at ASRM Annual Meeting

Additional presentations at ASRM highlight company's long-standing commitment to providing solutions for the infertility community

ROCKLAND, Mass., Oct. 17, 2016 /PRNewswire/ -- EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced the creation of a dedicated Fertility Technologies division that will advance the company's leadership in fertility innovation. The announcement took place at the 72nd American Society for Reproductive Medicine (ASRM) Scientific Congress and Expo in Salt Lake City, Utah.

"The knowledge we have gained from working in collaboration with the infertility community over many decades has provided us with a deep understanding of the needs of healthcare professionals as well as the medical and emotional struggles of couples undergoing assisted reproductive treatment," said Subhrangshu Datta, Senior Business Director, Fertility Technologies. "The goal for our fertility technologies portfolio is to bring new, innovative solutions to in vitro fertilization (IVF) laboratories, ultimately aiming for better outcomes for patients facing infertility through automated devices designed to improve standardization and consistency."

in May 2015. The partnership provided Merck KGaA, Darmstadt, Germany, with the global marketing and commercialization rights to Genea's product portfolio.

The Fertility Technologies division launched with Gidget™, a hand-held witnessing system for the in 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. The launch of additional products are planned for 2017.

At ASRM, EMD Serono is also sponsoring four presentations that are based on analyses of a real-world database containing data from 15 fertility clinics across the US. The two oral presentations will demonstrate changes in embryo transfer protocols over time and the effect of these changes on birth outcomes, while the two poster presentations will evaluate the use over time of gonadotropin-releasing hormone analogs and ovulation triggers in controlled ovarian stimulation cycles during IVF treatment.

"To ensure that we were researching the most relevant Assisted Reproductive Technologies (ART) treatment and gathering the information that would be most beneficial to the medical community, we partnered with some of the largest fertility centers in the United States and sought the expertise of scientific advisors," said Mary Mahony, PhD, Vice President, Fertility and Endocrinology, EMD Serono. "This real-world data analysis has provided key insights into clinical and laboratory trends and associated outcomes and we are pleased that medical organizations like ASRM and the broader healthcare industry find this information helpful as we seek to improve patient care and outcomes in fertility treatment."

Also being featured at ASRM is EMD Serono's Compassionate Corps program, the first patient assistance program to provide fertility medications for eligible US veterans who are infertile due to a service-related injury. Through the program, select IVF stimulation medications are provided by EMD Serono at no charge for up to two IVF cycles per year.

For more information onsite, please visit booth #607.

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SOURCE EMD Serono

Merck KGaA, Darmstadt, Germany Partners with American Cancer Society to Address Cancer in Women

Cancer deaths in women are expected to increase to 5.5 million by 2030

Darmstadt, Germany, November 1, 2016 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, and the American Cancer Society (ACS) today released a report that shows all four of the top causes of cancer deaths in women worldwide are mostly preventable or can often be detected early, when treatment is more successful. The report, titled "The Global Burden of Cancer in Women," is the first tangible output from an innovative partnership between Merck KGaA, Darmstadt, Germany, and the American Cancer Society focused on raising awareness and strengthening advocacy around women's cancers.

"We are proud to partner with the American Cancer Society to address the impact cancer has on women worldwide," said Belén Garijo, member of the Executive Board and CEO Healthcare at Merck KGaA, Darmstadt, Germany. "This collaboration is a first-of-its-kind public-private partnership that recognizes that no one sector can tackle this challenge alone. Improving women's health and well-being has an uplifting ripple effect on our world, and we know when women do better, our communities do better."

impact of the disease for women, their families and healthcare systems. Cancer is the second leading cause of death in women, with breast, colorectal, lung and cervical cancers claiming the most lives each year. With cancer rates on the rise as the global population grows and ages, the number of women who will lose their lives to cancer is expected to increase, particularly in low- and middle-income countries. In 2012, there were 3.5 million deaths among women due to cancer; by 2030, that number is expected to increase to 5.5 million deaths – a more than 57 percent increase in less than two decades. Increased education and prevention efforts will be essential to addressing this growing global health crisis.

"It's incumbent upon both the public and private sectors, as members of the global health community, to find ways to reduce the impacts of cancer on women by increasing prevention and treatment, saving the lives of women across the globe," said Ambassador Sally Cowal, senior vice president, global cancer control at the American Cancer Society.

In addition to the physical challenges women with cancer and their families experience, the burden of cancer also extends to the economy. The study found that in 2009, the global economic burden of cancer was estimated at about $286 billion, and much of that cost was due to premature death of members of the workforce. In the United States alone in 2008, years of productive life lost due to cancer in women corresponded to $82 billion, not to mention the many professional achievements that might have been realized.

The report was released at the World Cancer Congress during a panel moderated by Ambassador Cowal. Other participants included HRH Princess Dina Mired of Jordan; Dr. Alise Reicin, Head of Global Clinical Development in the biopharma business of Merck KGaA, Darmstadt, Germany; and Dr. Edward L. "Ted" Trimble, director, Center for Global Health at the National Cancer Institute.

This partnership will also catalyse the evolution of the American Cancer Society's' All of Me Young Scholars program, which aims to educate and cultivate health and civil society professionals in Brazil, Mexico, Colombia and India to affect meaningful change in prevention and early detection of cancers among women in low- and middle-income countries.

This report is part of the involvement of Merck KGaA, Darmstadt, Germany, with the Healthy Women, Healthy Economies initiative, which explicitly links the issue of women's health and

About the Healthy Women, Healthy Economies Initiative

Merck KGaA, Darrmstadt, Germany, is a founding partner of the Healthy Women, Healthy Economies initiative, which brings together the evidence about women's health and well-being and its impact on economic growth with the best practices that governments, employers and non-governmental organizations can follow. It aims to identify and implement policies that advance women's health and well-being to increase their economic participation in the societies in which they live.

About the American Cancer Society

The American Cancer Society is a global grassroots force of more than three million volunteers saving lives and fighting for every birthday threatened by every cancer in every community. As the largest voluntary health organization, the Society's efforts have contributed to a 20 percent decline in cancer death rates in the U.S. since 1991, and a 50 percent drop in smoking rates. Thanks in part to our progress, nearly 14 million Americans who have had cancer and countless more who have avoided it will celebrate more birthdays this year. We're determined to finish the fight against cancer. We're finding cures as the nation's largest private, not-for-profit investor in cancer research, ensuring people facing cancer have the help they need and continuing the fight for access to quality health care, lifesaving screenings, clean air and more. For more information, to get help, or to join the fight, call us anytime, day or night, at 1-800-227-2345 or visit cancer.org

About the American Cancer Society's All of Me Young Scholars Program

The American Cancer Society's All of Me Young Scholars program aims to educate and cultivate young health and civil society professionals around the world to bring their energy, voice and new ideas to the new and growing field of integration of women's cancer prevention and early detection.

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 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. Merck KGaA, Darmstadt, Germany, holds the global rights to the Merck KGaA, Darmstadt, Germany, 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

EMD Serono Appoints Brian Barry as Chief Compliance Officer

Rockland, Massachusetts, December 15, 2016 – EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, today announced the appointment of Brian Barry, Esq., as Chief Compliance Officer. In this role, Mr. Barry will be responsible for the ongoing development and implementation of the company's comprehensive compliance program and will also be a member of the organization’s leadership team.

Mr. Barry joined EMD Serono in January 2011, as Compliance Counsel. In this role, he was integral to the implementation and oversight of a comprehensive compliance program at EMD Serono, which has served as a key component in the company’s ability to deliver on its commitment to integrity.

“Brian’s deep understanding of our business and compliance program is critical to achieving the highest level of legal and ethical standards that all of us at EMD Serono hold ourselves accountable for across our business activities,” said Gary Zieziula, President and Managing Director of EMD Serono. “Brian has demonstrated tremendous leadership and expertise by

Prior to joining EMD Serono, Mr. Barry spent several years as an attorney in private practice at Choate, Hall & Stewart LLP, as well as other prominent international law firms, focused in the Government Enforcement and Major Commercial Litigation groups, and represented companies and individuals in government investigations.

Mr. Barry succeeds Daniel Moynihan who was recently appointed to Global Compliance Officer for Life Science at MilliporeSigma, the life science business of Merck KGaA, Darmstadt, Germany.

Mr. Barry received his J.D. from the University of Virginia School of Law and B.A. from the College of the Holy Cross.

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 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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Melissa Manganello 1-781-681-2393

EMD Serono named 'Top Place to Work' by The Boston Globe

EMD Serono receives recognition based on positive employee survey responses

Rockland, Massachusetts – 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.

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 named to the list of "Top Places to Work."

"The fact that we achieved this recognition based on the positive input of our employees is extremely meaningful, as we are always exploring ways to ensure our company is one where everyone can do their best work each and every day," said Gary Zieziula, President and Managing Director, EMD Serono. "Our employees are going above and beyond to achieve our collective mission of accelerating innovation for difficult to treat diseases."

The Boston Globe's research partner, Workplace Dynamics, ranked 125 Massachusetts employers by analysing employee responses to a confidential 24-question survey. The survey

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SOURCE EMD Serono

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SITEMAP

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

EXPLORE MORE

IF APPROVED BY THE FDA, AVELUMAB, AN INVESTIGATIONAL IMMUNOTHERAPY, COULD BE THE FIRST TREATMENT INDICATED FOR PATIENTS WITH METASTATIC MERKEL CELL CARCINOMA (MCC)

AVELUMAB HAS PREVIOUSLY RECEIVED FDA BREAKTHROUGH THERAPY AND FAST TRACK DESIGNATIONS FOR METASTATIC

DESIGNATION FOR MCC

Rockland, Massachusetts, and New York, US, November 29, 2016 – EMD Serono Inc., 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 accepted for Priority Review EMD Serono's Biologics License Application (BLA) for avelumab. This review relates to avelumab's proposed use in patients with metastatic Merkel cell carcinoma (MCC), based on tumor response results from the JAVELIN Merkel 200 trial. Avelumab is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody and could be the first treatment indicated for metastatic MCC in the US, if approved.* MCC is a rare and aggressive skin cancer, which impacts approximately 2,500 Americans a year.[1,2]

"We are pleased the FDA has granted a Priority Review designation for avelumab," said Luciano 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. "There are currently no approved treatment options for metastatic MCC, and we are committed to working with the FDA to potentially bring the first approved cancer immunotherapy to patients with this aggressive disease."

The avelumab metastatic MCC BLA submission is supported by data from JAVELIN Merkel 200, a multicenter, single-arm, open-label, Phase II study of 88 patients with metastatic MCC, whose disease had progressed after at least one chemotherapy treatment.[1] The JAVELIN Merkel 200 study represents the largest data set of any anti-PD-L1/PD-1 antibody reported in this patient population. These data were presented in June 2016 at the Annual Meeting of the American Society of Clinical Oncology (ASCO) and published in the Lancet Oncology in October 2016.[1]

"Metastatic Merkel cell carcinoma is an aggressive disease, and patients face a very poor prognosis, with less than 20 percent surviving beyond five years," 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 are encouraged by the results of our Phase II trial and believe avelumab may have potential to be an important treatment option for patients living with this hard-totreat skin cancer."

The FDA's Priority Review status reduces the review time from 10 months to a goal of six months from the day of filing and is given to drugs that may offer major advances in treatment or may provide a treatment where no adequate therapy exists. The FDA previously granted

after at least one previous chemotherapy regimen. Breakthrough Therapy Designation is intended to expedite the development and review of treatments for serious or life-threatening disease where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies for one or more endpoints.[3] Additionally, the European Medicines Agency has validated for review Merck KGaA, Darmstadt, Germany's Marketing Authorization Application (MAA) for avelumab, for the proposed indication of metastatic MCC.

The clinical development program for avelumab, known as JAVELIN, involves at least 30 clinical programs and more than 3,000 patients evaluated across more than 15 different tumor types. In addition to metastatic MCC, these cancers include breast, gastric/gastroesophageal junction, head and neck, Hodgkin's lymphoma, melanoma, mesothelioma, non-small cell lung, ovarian, renal cell carcinoma and urothelial (primarily bladder).

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

References

1. 1. Kaufman HL, et al. Avelumab in patients with chemotherapy-refractory metastatic Merkel cell carcinoma: a multicentre, single-group, open-label, phase 2 trial. Lancet Oncology. 2016;17(10);1374–85.
2. 2. Fitzgerald T et al. Dramatic increase in the incidence and mortality from Merkel cell carcinoma in the United States. The American Journal of Surgery. 2015;81(8):802-6.
3. 3. FDA. Priority Review. http://www.fda.gov/ForPatients/Approvals/Fast/ucm405405.htm. Last accessed October 2016.
4. 4. National Cancer Institute. Merkel cell carcinoma treatment–patient version (PDQ®). http://www.cancer.gov/types/skin/patient/merkel-cell-treatment-pdq. Last accessed October 2016.
5. 5. American Cancer Society. What is Merkel cell carcinoma? http://www.cancer.org/cancer/skincancer-merkelcell/detailedguide/skin-cancer-merkel-cellcarcinoma-what-is-merkel-cell-carcinoma. Last accessed October 2016.
6. 6. Desch L and Kuntsfeld R. Merkel cell carcinoma: chemotherapy and emerging new therapeutic options. Journal of Skin Cancer. 2013(2013):327150.
7. 7. Heath M, Jaimes N and Lemos B. Clinical characteristics of Merkel cell carcinoma at diagnosis in 195 patients: the AEIOU features. Journal of the American Academy of Dermatology. 2008;58:375–81.

9. Swann MH and Yoon J. Merkel cell carcinoma. Seminars in Oncology. 2008;34(1):51–56.
10. NCCN Merkel Cell Carcinoma Guidelines version I. 2017. www.nccn.org/professionals/physician_gls/PDF/mcc.pdf. Last accessed October 2016.

About Metastatic Merkel Cell Carcinoma (MCC)

Metastatic MCC is a rare and aggressive disease in which cancer cells form in the top layer of the skin, close to nerve endings.[1,4] 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.[5] Risk factors for MCC include sun exposure and having a weak immune system (i.e., solid organ transplant recipients, people with HIV/AIDS and people with other cancers, such as chronic lymphocytic leukemia, are at higher risk). Caucasian males older than 50 are at increased risk.5 MCC is often misdiagnosed for other skin cancers and grows at an exponential rate on chronically sun-damaged skin. [6-9] Current treatment options for MCC include surgery, radiation and chemotherapy.[10] Treatment for metastatic or Stage IV MCC is generally palliative.

About Avelumab

Avelumab (also known as MSB0010718C) is an investigational, fully human anti-PD-L1 IgG1 monoclonal antibody. 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 cocommercialize avelumab. In the JAVELIN Merkel 200 trial, treatment-related adverse events (AEs) occurred in 62 (70%) of 88 patients including fatigue and infusion-related reactions. Five grade 3 treatment-related AEs were reported in four of 88 patients and include two patients with lymphopenia and three patients with isolated laboratory abnormalities (elevated blood creatine phosphokinase, blood cholesterol, and hepatic aminotransferase).[1] There were no grade 4 treatment-related AEs or deaths related to treatment.[1]

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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 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.

About Merck KGaA, Darmstadt, Germany
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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 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 November 29, 2016. 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 Merkel Cell carcinoma (the "Potential Indication"), Pfizer's and Merck KGaA, Darmstadt, Germany's immuno-oncology alliance involving anti-PD-L1 and antiPD-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 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 or MAA for the Potential Indication or any such 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

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, 2015, 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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