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EMD Serono Strengthens Leadership With New Appointments

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- **Gary Zieziula, Chief Commercial Officer**
- **Allene Diaz, Senior Vice President, Managed Markets**
- **Lisa Buffington, Vice President of US Communications**
- **Alexander Kuta, Vice President and US Head of Regulatory Affairs**
- **Michael Ruggiero, Vice President of US Government Affairs and Policy**

Rockland, Massachusetts, February 13, 2014 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today the recent appointments of Gary Zieziula as the company's Chief Commercial Officer, Allene Diaz as Senior Vice President of Managed Markets, Lisa Buffington as Vice President of US Communications, Alexander Kuta as Vice President and Head of US Regulatory Affairs, and Michael Ruggiero as Vice President of US Government Affairs and Policy.

"We are committed to being an organization dedicated to patients and customers, and our leadership team is critical to our mission," said Paris Panayiotopoulos, President and Managing Director of EMD Serono. "Each of these talented individuals brings a wealth of knowledge and

Gary Zieziula, Chief Commercial Officer, is responsible for maximizing the growth of the US organization by driving the performance of our franchises. He has more than 30 years of experience in the pharmaceutical industry and in specialty care, most recently serving as an independent consultant focused on opportunity assessments for development-stage products, and mergers and acquisitions.

Previously, Mr. Zieziula held several senior leadership positions at Roche, Bristol Myers Squibb, AMAG Pharmaceuticals, and Merck & Co. He brings significant expertise across commercial strategy, including managed markets, market analytics, sales, marketing and health economics.

Allene Diaz, Senior Vice President, Managed Markets, is responsible for developing and executing Managed Markets marketing, sales, and contracting strategies and tactics to ensure optimal market access and pull through for EMD Serono products. She is also responsible for developing and executing Specialty Pharmacy patient adherence and retention strategies and tactics. She oversees four departments, including Account Management, Managed Markets Marketing and Contracting Strategy, Contracting Operations and Business Operations.

Ms. Diaz brings more than 25 years of both US-based and international industry experience to her new role with the organization, most recently serving as EMD Serono's Senior Vice President, Head of US Oncology. Prior to joining EMD Serono, Ms. Diaz served in senior leadership roles in marketing, new product planning and portfolio management at Amylin Pharmaceuticals, CancerVax Corporation, Biogen Idec and Pfizer.

Lisa Buffington, Vice President of US Communications, is responsible for driving and executing all aspects of the company's communications strategy, including external and employee communications, media relations, corporate reputation, product communications, community relations, as well as meetings and events.

Ms. Buffington brings nearly 20 years of industry and communications experience to EMD Serono, most recently serving as Vice President of Corporate Communications at Ironwood Pharmaceuticals. Prior to Ironwood, she was Vice President of Communications at Sanofi, where she led communications for the North American business.

Alexander Kuta, PhD, Vice President and US Head of Regulatory Affairs, is responsible for driving the strategic direction of EMD Serono's regulatory efforts with the FDA, overseeing

Mr. Kuta joins EMD Serono with nearly 25 years of regulatory experience, most recently from Lantheus Medical Imaging, where he was Vice President of Global Regulatory Affairs and a member of the Executive Leadership Team. His previous experience includes leadership positions at the FDA Center for Biologics Evaluation and Research, Genzyme Corporation, and AMAG Pharmaceuticals.

Michael Ruggiero, Vice President of US Government Affairs and Policy, is responsible for federal and state legislative, policy, political, and advocacy strategy and execution for EMD Serono's business. He will also serve as a member of the Global Government Affairs and Policy (GA&P) Leadership Team.

Mr. Ruggiero joins EMD Serono as a seasoned executive in the biopharmaceutical industry with more than twenty years of experience in government strategy, advocacy, and government relations. He most recently served as Vice President of Government Strategy for Astellas Pharma US, Inc., and prior to that counseled pharmaceutical and medical device companies as an attorney in Washington, D.C. with the law firms of Arnold & Porter LLP and Kind & Spalding LLP.

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a specialized biopharmaceutical company dedicated to developing therapies with groundbreaking potential. The company has strong market positions in neurology, endocrinology and in reproductive health. In addition, EMD Serono has an enduring commitment to solve the unsolvable, with state-of-the-art science dedicated to developing new therapies in our core focus areas of neurology, oncology, immuno-oncology and immunology. With a long-standing history of industry expertise and a dedication to shape the future of healthcare, the company's US footprint continues to grow, with approximately 1,000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com

2012, a history that began in 1668, and a future shaped by approx. 38,000 employees in 66 countries. Its success is characterized by innovations from entrepreneurial employees. Merck KGaA's operating activities come under the umbrella of Merck KGaA, Darmstadt, Germany, in which the Merck family holds an approximately 70% interest and shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

Worldwide there are two separate companies that bear the name "Merck", the original Merck KGaA from Darmstadt, Germany, the oldest pharmaceutical and chemical company in the world, and the pharmaceutical company Merck & Co. in the United States. The rights to the name and trademark MERCK in North America (USA and Canada) lie with Merck & Co., the former U.S. subsidiary of Merck, whereas Merck KGaA operates in North America under the umbrella brand EMD. In the rest of the world, Merck KGaA owns the rights to the Merck name and trademark. This press release was distributed by Merck KGaA, Darmstadt, Germany.

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EMD Serono Enters into Research Agreement with Pfizer and Broad Institute

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-Agreement aims to identify biomarkers relevant to future therapies in the area of Systemic Lupus Erythematosus and Lupus Nephritis

Rockland, Massachusetts April 1, 2014 – EMD Serono, a subsidiary of Merck KGaA, Darmstadt, Germany, today announced they have signed a research agreement with Pfizer Inc. and the Broad Institute in Cambridge, Massachusetts, U.S. The collaboration is focused on the genomic profiling of Systemic Lupus Erythematosus (SLE) and Lupus Nephritis (LN) patients. The research project will be jointly funded by EMD Serono and Pfizer.

SLE is a systemic autoimmune disease, and can cause LN, an inflammation of the kidney. In SLE patients, in addition to the kidney, other tissues and organs can be affected, including the skin, the nervous system, or joints.

As part of the collaboration, the Broad Institute will investigate clinical samples obtained from SLE and LN patients, applying biochemical and next-generation sequencing technologies. They will also analyze immune cell subpopulations. The goal is to identify biomarkers to better define target patient populations for future therapies. In addition, through computational modeling

Under the terms of the agreement, EMD Serono and Pfizer, as sponsoring members, will receive real-time access to all data and analysis. In addition, both companies will have the ability to send a research scientist to the Broad Institute to foster exchange of technology expertise in the area of computational and experimental genomic profiling.

"We are thrilled to align with EMD Serono and Pfizer on an innovative project to stratify SLE patients and identify candidate immune pathways underlying lupus nephritis," said Prof. Nir Hacohen, Associate Professor at Massachusetts General Hospital and Harvard Medical School, and Senior Associate Member at the Broad Institute. "Technical advances now make it possible for us to sequence RNA in very small numbers of cells, enabling us to be more comprehensive in our analysis of cell types and states in Lupus patients. We will collect millions of unbiased measurements from lupus patients over many time points along with key clinical variables. We will use this dataset to infer active biological pathways in these patients and develop novel dynamic models of Lupus pathogenesis."

"The research group of Prof. Nir Hacohen from the Broad Institute is a pioneer in the field of systems immunology and has developed a unique strategy to dissect Lupus and Lupus Nephritis," said Harsukh Parmar, Head of the Translational Innovation Platform Immunology & Neurodegenerative Diseases at EMD Serono. "Combined with the Broad Institute's technical know-how, we see this collaboration aiming for a significant contribution to potential future innovative treatments of Lupus and Lupus Nephritis. This is in line with our concept to integrate genomic profiling and system biology approaches throughout our preclinical and clinical programs."

"We are pleased to collaborate with EMD Serono and the Broad Institute on research designed to enhance our understanding of the molecular and cellular underpinnings of Lupus, a debilitating disease that has long been a mystery to the scientific community," said Johan Lund, Senior Vice President and Chief Scientific Officer of Immunoscience at Pfizer. "This collaboration builds on Pfizer's patient-centric and precision medicine-based approach to autoimmune disease research, applying cutting edge technologies and a wealth of patient level data with a goal of advancing our understanding of disease in order to develop innovative therapies."

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About Merck KGaA, Darmstadt, Germany

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors. Its subsidiaries in Canada and the United States operate under the umbrella brand EMD. Around 38,000 employees work in 66 countries to improve the quality of life for patients, to further the success of customers and to help meet global challenges. The company generated total revenues of €11.1 billion in 2013 with its four divisions: Biopharmaceuticals, Consumer Health, Performance Materials and Life Science Tools. Merck KGaA of Darmstadt, Germany is the world's oldest pharmaceutical and chemical company – since 1668, the name has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day.

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EMD Serono, Inc. Launches 10th Edition of The EMD Serono Specialty Digest™ at Annual Meeting of The Academy of Managed Care Pharmacy

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Rockland, Mass., April 1, 2014 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, today announced the launch of the 10th edition of the EMD Serono Specialty Digest™ at the 26th Annual Meeting of The Academy of Managed Care Pharmacy (AMCP) in Tampa, FL. The Digest is an educational resource that provides market data on health plans' management of specialty pharmaceuticals in 2013 and identifies common trends occurring across plans. The Digest is available to those who request a copy at <http://www.specialtydigest.emdserono.com>.

The 10th edition of the EMD Serono Specialty Digest™ includes data from 91 health plans across the country, representing more than 124 million covered lives. This year's digest has been enhanced to reflect current opportunities, challenges and solutions to specialty drug management, including new utilization management practices, integration of pharmacy and medical benefits, strategies to address reimbursement issues across different sites of service and oncology management.

utilizing a multi-tier cost share structure. Many plans have implemented a preferred and nonpreferred formulary for specialty therapies. Additionally, health plan management of oncology drugs is an important area of increasing payer focus - 51% of the 91 surveyed plans have either implemented oncology pathways or expect to implement oncology pathways in the next 12 months.

“We are committed to partnering with our customers to build an understanding of trends in the management of specialty pharmaceuticals,” said Allene Diaz, Senior Vice President, Managed Markets, EMD Serono. “The insights in this year’s EMD Serono Specialty Digest will help create a dialogue around access to therapy and improving patient outcomes.”

Since its inception in 2004, health plans, employers, specialty pharmacies and pharmaceutical companies have relied upon the EMD Serono Specialty Digest™ to identify current and future trends in the management of specialty pharmaceuticals. Findings are available in the full text of the EMD Serono Specialty Digest™, at <http://www.specialtydigest.emdserono.com>.

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EMD Serono Presents New Data on Rebif® (interferon beta-1a) and Advancing MS Pipeline at AAN Annual Meeting

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ROCKLAND, Mass., April 25, 2014 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today that new data from the company's multiple sclerosis (MS) portfolio will be presented at the American Academy of Neurology's 66th Annual Meeting, taking place from April 26 – May 3, in Philadelphia, PA.

Data from 14 study assessments presented by EMD Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, will focus on Rebif® (interferon beta-1a), as well as three pipeline candidates:

- Ceralifimod (ONO-4641) (S1P receptor agonist), an investigational oral compound being evaluated in a Phase II trial for relapsing-remitting MS

- ATX MS-1467, an investigational compound being evaluated in a Phase I trial for MS.

complex (MHC) class II allelic variants associated with MS, with the aim of promoting regulatory effects in the immune system.

“The data to be presented during the AAN meeting continue to advance our understanding of the important clinical effects of Rebif and demonstrate progress with our three pipeline candidates,” said, Thorsten Eickenhorst, Chief Medical Officer, EMD Serono. “Our company’s scientific commitment to MS includes more than 20 years of clinical experience with Rebif and we continue to work to develop innovative treatment options and solutions for those living with MS.”

The following abstracts have been accepted for presentation at the 66th AAN Annual Meeting:

Rebif (interferon beta-1a)

- Relationship between Immunological Markers and Short-Term Brain Volume Changes in Patients with Relapsing-Remitting Multiple Sclerosis Receiving Interferon Beta-1a (Poster P3.146 Session III; Tuesday, April 29, 2014)
- Correlations between Immunological Biomarkers and Conventional and Advanced MRI Measures Following Interferon Beta-1a Treatment for Relapsing-Remitting Multiple Sclerosis (Poster P3.147 Session III; Tuesday, April 29, 2014)
- Early and Consistent Reduction in Relapses among Patients with Relapsing-Remitting Multiple Sclerosis Receiving Subcutaneous Interferon Beta-1a: A PostHoc Analysis of PRISMS Data (Poster P3.182 Session III; Tuesday, April 29, 2014)
- Assessing a Scoring System to Predict Disease Activity in Patients with Multiple Sclerosis: Post Hoc Analyses of Data from Clinical Trials of Subcutaneous Interferon Beta-1a (Poster P3.178 Session III; Tuesday, April 29, 2014)
- Changes in Immunological Biomarkers in Patients with Relapsing-Remitting Multiple Sclerosis Treated with Interferon β -1a (Poster P4.132 Session IV; Wednesday, April 30, 2014)
- Associations Between Changes in Ferritin Levels and Susceptibility-Weighted Imaging Filtered Phase in Patients with Relapsing-Remitting Multiple Sclerosis over Six Months Therapy with Interferon β -1a (Poster P6.115, Session VI; Thursday, May 1, 2014)

2014)

-Adherence to, and Effectiveness of, Treatment with Subcutaneous Interferon Beta- 1a in Relapsing Multiple Sclerosis Patients using RebiSmart™ for Self-Injection: Final Results of the One-Year International, Observational SMART Study (P7.219, Session VII; Thursday, May 1, 2014)

Ceralifimod (ONO-4641)

-Ceralifimod (ONO-4641) Reduces MRI Lesions and Prevents Disease Progression in an Animal Model of Multiple Sclerosis (P1.219, Session I; Monday, April 28, 2014)

-Ceralifimod (ONO-4641) Prevents Evoked Potential Deficits in an Animal Model of Multiple Sclerosis (P1.218, Session I; Monday, April 28, 2014)

-Effect of Ceralifimod (ONO-4641), a Sphingosine-1-Phosphate Receptor-1 and -5 Agonist, on Magnetic Resonance Imaging Outcomes in Patients with Multiple Sclerosis: Interim Results from the Extension of the DreaMS Study (P3.161, Session III; Tuesday, April 29, 2014)

ATX-MS-1467

-ATX-MS-1467, An Immunotolerizing Agent, Halts Disease Progression and Reduces CNS Inflammation in Rodent Models of Multiple Sclerosis (P1.216, Session I, Monday, April 28, 2014)

-Preclinical Efficacy and Phase I Clinical Testing of ATX-MS1467, an AntigenSpecific Immunotherapy for Multiple Sclerosis (P1.189, Session I; Monday, April 28, 2014)

Plovamer Acetate (PI-2301)

EMD Serono is engaged in strategic research collaborations funding promising neurology research with leading academic and healthcare institutions. Learn more about EMD Serono's programs, pipeline and activities in neurology by visiting booths #1133 and #1332 at this year's AAN Annual Meeting.

About Rebif® (interferon beta-1a)

Rebif 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. Rebif is not approved for treatment of chronic progressive MS. Rebif is available in 22 mcg and 44 mcg prefilled, preassembled syringes and a titration pack.

Rebif will not cure MS but it has been shown to decrease the number of flare-ups and slow the occurrence of some of the physical disability that is common in people with MS. Rebif can cause serious side effects, so before taking Rebif, patients should talk with their doctor about the possible benefits of Rebif and its possible side effects.

Potential serious side effects of Rebif include depression, liver problems, risk to pregnancy, allergic reactions and injection-site problems. Patients who have had an allergic reaction such as difficulty breathing, flushing or hives to another interferon beta or to human albumin should not take Rebif.

Before taking Rebif (interferon beta-1a), patients should tell their doctor if they have a history of depression, anxiety, trouble sleeping, liver disease, thyroid problems, blood cell count or bleeding problems, epilepsy, or are planning to become pregnant. Patients should tell their doctor about all medicines they take, including prescription and nonprescription medicines, vitamins and herbal supplements. Rebif and other medicines may affect each other causing serious side effects. Patients should talk to their doctor before taking any new medicines.

Possible side effects of Rebif include flu-like symptoms (fever, chills, sweating, muscle aches and tiredness), injection-site reactions, depression and anxiety, liver problems, abdominal pain, blood problems, thyroid problems and severe allergic reactions. Patients should let their doctor

This information is not intended to replace discussions with a doctor. For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional. Information is also available at www.mslifelines.com or call toll-free 1-877-44-REBIF (1-877-447-3243). Rebif is available by prescription only.

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EMD Serono Announces Initiation of Phase III START2 Study with Tecemotide in Stage III Non-Small Cell Lung Cancer

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- ▶ **-First patient dosed in tecemotide Phase III trial; study recruiting across 250 sites in over 20 countries**
- ▶ **-START2 builds upon the data from the START* trial and explores the potential of tecemotide in patients with Stage III NSCLC who have demonstrated stable disease or objective response after concurrent chemoradiotherapy**

Rockland, Massachusetts, April 7, 2014 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, today announced the initiation of the international Phase III START2 study, which is designed to assess the efficacy and safety of its investigational MUC1 antitumor specific cancer immunotherapy tecemotide (also known as L-BLP25) in patients with unresectable, locally advanced Stage III non-small cell lung cancer (NSCLC).

The START2 study is a Phase III, multicenter, 1:1 randomized, double-blind, placebo-controlled clinical trial designed to assess the efficacy, safety and tolerability of tecemotide in patients suffering from unresectable, locally advanced (Stage IIIA or IIIB) NSCLC who have had a response or stable disease after at least two cycles of platinum-based concurrent

is expected to recruit about 1,000 patients. The study's primary endpoint is overall survival (OS). Secondary endpoints include time to symptom progression, progression-free survival and time to progression. EMD Serono received Scientific Advice from the European Medicines Agency (EMA) on the program, and reached an agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the trial.

"Sadly, the cure rate for stage III NSCLC has not improved in recent years; novel treatment strategies are urgently needed," said Professor Suresh Ramalingam, Winship Cancer Institute, Emory University, Atlanta, U.S., coordinating clinical investigator of the START2 trial and member of the corresponding steering committee. "Modulating the immune system to treat cancer has entered an exciting new phase in the past 2 to 3 years. We hope that the START2 trial will establish tecemotide as a new treatment option for patients with NSCLC."

The basis for the new Phase III trial is the outcome of the initial START study.¹ START did not meet the primary endpoint of demonstrating an improved OS with tecemotide compared with placebo in the overall patient population (n=1,239). Median OS was 25.6 months for patients in the tecemotide group compared with 22.3 months for those in the placebo group (adjusted hazard ratio [HR]: 0.88; 95% confidence interval [CI]: 0.75–1.03; p=0.123).

However, data from an exploratory analysis of a pre-defined subgroup of patients in the START trial, who received tecemotide after concurrent CRT, showed that these patients achieved a median OS of 30.8 months versus 20.6 months in patients treated with placebo (n=806; HR: 0.78; 95% CI: 0.64–0.95; p=0.016).

Dr. John Orloff, Global Head of Clinical Development for Merck Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, commented: "There is clearly a very real need for additional treatment options for people fighting NSCLC. The results of the initial START study provided scientific and clinical evidence to inform the design of this new pivotal Phase III program. We are pleased that START2 is now underway, and feel confident that this study will address the appropriate gaps in understanding the potential role that tecemotide could play in the management of patients living with unresectable stage III NSCLC."

Tecemotide is an investigational MUC1 antigen-specific cancer immunotherapy designed to stimulate the body's immune system to identify and target cancer cells expressing the

Globally, lung cancer is the most common cause of cancer-related deaths in men and the third most common in women, responsible for almost twice as many deaths as both breast and prostate cancer combined.⁵ NSCLC is the most common type of lung cancer, accounting for 80–85% of all lung cancers, and locally advanced or Stage III disease accounts for approximately 30% of patients with NSCLC.^{6,7} Unfortunately, at diagnosis, most patients have advanced disease with a very poor prognosis.⁸

*START: Stimulating Targeted Antigenic Responses To NSCLC

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Tecemotide is an investigational MUC1 antigen-specific cancer immunotherapy that is designed to stimulate the body's immune system to identify and target cells expressing the cell-surface glycoprotein MUC1. MUC1 is expressed in many cancers, including non-small cell lung cancer (NSCLC), and has multiple roles in tumor growth and survival. Tecemotide is currently being investigated in the Phase III START2, START and INSPIRE trials for the treatment of unresectable, locally advanced Stage III NSCLC.

Merck KGaA, Darmstadt, Germany obtained the exclusive worldwide rights for development and commercialization of tecemotide from Oncothyreon Inc., Seattle, Washington, U.S., in 2007, in an agreement replacing prior collaboration and supply agreements originally entered in 2001. In Japan, Merck KGaA, Darmstadt, Germany entered into a co-development and co-marketing agreement for tecemotide with Ono Pharmaceutical Co., Ltd., Osaka, Japan.

The START2 trial is a Phase III, multicenter, 1:1 randomized, double-blind, placebo-controlled clinical trial designed to assess the efficacy, safety and tolerability of tecemotide in patients suffering from unresectable, locally advanced (Stage IIIA or IIIB) NSCLC who have had a response or stable disease after at least two cycles of platinum-based concurrent chemoradiotherapy (CRT). The primary endpoint of START2 trial is overall survival.

The initial Phase III trial START is a multicenter, randomized, double-blind, placebo-controlled clinical trial designed to assess the efficacy, safety and tolerability of tecemotide in patients suffering from unresectable, locally advanced (Stage IIIA or IIIB) NSCLC who have had a response or stable disease after at least two cycles of platinum-based chemoradiotherapy (concurrent or sequential). The trial involves 1,239 patients in 33 countries. The primary endpoint of overall survival was not met in the START trial.

INSPIRE (tecemotide liposome vaccine trial In Asian NSCLC Patients: Stimulating Immune REsponse) is a Phase III, multicenter, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy, safety and tolerability of tecemotide in patients suffering from unresectable, locally advanced Stage IIIA or IIIB NSCLC who have had a response or stable disease after at least two cycles of platinum-based concurrent chemoradiotherapy. INSPIRE is recruiting approximately 500 unresectable, locally advanced Stage III NSCLC patients across China, Hong Kong, Korea, Singapore and Taiwan.

Tecemotide is currently under clinical investigation and has not been approved for use in the U.S., Europe, Canada, or elsewhere. Tecemotide has not been proven to be either safe or

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a specialized biopharmaceutical company dedicated to developing therapies with groundbreaking potential. The company has strong market positions in neurology, endocrinology and in reproductive health. In addition, EMD Serono has an enduring commitment to solve the unsolvable, with state-of-the-art science dedicated to developing new therapies in our core focus areas of neurology, oncology, immuno-oncology and immunology. With a long-standing history of industry expertise and a dedication to shape the future of healthcare, the company's US footprint continues to grow, with approximately 1,000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com

About Merck KGaA, Darmstadt, Germany Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors. Its subsidiaries in Canada and the United States operate under the umbrella brand EMD. Around 38,000 employees work in 66 countries to improve the quality of life for patients, to further the success of customers and to help meet global challenges. The company generated total revenues of €11.1 billion in 2013 with its four divisions: Biopharmaceuticals, Consumer Health, Performance Materials and Life Science Tools. Merck KGaA of Darmstadt, Germany is the world's oldest pharmaceutical and chemical company – since 1668, the name has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day.

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Phone: 781-681-2850



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EMD Serono Data at CMSC & ACTRIMS Annual Meeting Reinforces Proven Efficacy of Rebif® (interferon beta-1a) and Demonstrates Continued Commitment to Patients with Relapsing MS

[EXPLORE MORE](#)

ROCKLAND, Mass., May 28, 2014 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today that Rebif® (interferon beta-1a) data will be presented at the 2014 Cooperative Meeting of CMSC (Consortium of Multiple Sclerosis Centers) and ACTRIMS (Americas Committee on Research & Treatment in Multiple Sclerosis), taking place from May 28 - 31, in Dallas, TX.

Data from 11 study assessments will be presented at the meeting by EMD Serono – the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, including eight posters, two oral presentations and an industry-sponsored poster focusing on Rebif® (interferon beta-1a).

adherence and treatment management for patients,” said Thorsten Eickenhorst, Chief Medical Officer, EMD Serono. “Our company is committed to ongoing research to advance MS care and develop innovative solutions for those living with MS.”

The following abstracts have been accepted for presentation at the CMSC Annual Meeting (all times listed in CDT):

US-Scientific Presentations

- Early and Consistent Benefits of Subcutaneous Interferon Beta-1a in Relapsing Multiple Sclerosis: Post Hoc Analysis of PRISMS MRI Data (Poster DX46, Disease Management, Mechanisms and Treatment; Thursday, May 29, 2014; 7-8:30pm)
- Autoinjector Ease-of-Use in Patients with Multiple Sclerosis Treated with Interferon Beta-1a Subcutaneously: REDEFINE Study Design (Poster DX60, Disease Management, Mechanisms and Treatment; Thursday, May 29, 2014; 7-8:30pm)
- Changes in Immunologic Biomarkers in Patients with Relapsing–Remitting Multiple Sclerosis Treated with Interferon Beta-1a (Poster DX61, Disease Management, Mechanisms and Treatment; Thursday, May 29, 2014; 7-8:30pm)
- Relapsing–Remitting Multiple Sclerosis Treated With Interferon Beta-1a: Immunologic and Short-Term Brain Volume Changes (Platform Presentation DX02, Disease Management, Mechanisms and Treatment; Friday, May 30, 2014; 1:20- 1:40pm)
- Immunological Markers and Conventional and Advanced MRI after Interferon Beta- 1a for Relapsing–Remitting Multiple Sclerosis (Platform Presentation DX05, Disease Management, Mechanisms and Treatment; Friday, May 30, 2014; 2:20-2:40pm)

U.S. Industry-Sponsored Presentation

- EMD Serono Phase IV Studies in Relapsing Multiple Sclerosis (Poster; Available in Exhibit Hall during all open hours)

Merck KGaA, Darmstadt, Germany-Sponsored Scientific Presentations

The presentations from Merck KGaA, Darmstadt, Germany, concern a formulation of Rebif and an administration device which are not approved in the U.S.

-A Prospective Multicenter Study for Assessing the Validity of the MusiQOL Instrument Among Arabic-Speaking Patients with Multiple Sclerosis (Poster CG28, Cognition, Depression and Psychosocial; Thursday, May 29, 2014; 7-8:30pm)

-Good Treatment Adherence Is Maintained in Multiple Sclerosis Patients Using RebiSmart™: Assessment of the MEASURE Primary Endpoint (Poster DX07, Disease Management, Mechanisms and Treatment; Thursday, May 29, 2014; 7- 8:30pm)

-RebiSmart™ Pressure Profile Accessories Can Reduce Injection-Site Pain (Poster DX08, Disease Management, Mechanisms and Treatment; Thursday, May 29, 2014; 7-8:30pm)

-Consensus on Optimal Multiple Sclerosis Injectable Treatment Management to Improve Patient Adherence: The Multiple Sclerosis Delphi Project (Poster DX49, Disease Management, Mechanisms and Treatment; Thursday, May 29, 2014; 7- 8:30pm)

-Nursing Challenges in the Care of People with Multiple Sclerosis: Results from an International Needs Assessment (Poster DX59, Disease Management, Mechanisms and Treatment; Thursday, May 29, 2014; 7-8:30pm)

EMD Serono is engaged in strategic research collaborations funding promising neurology research with leading academic and healthcare institutions. Learn more about EMD Serono's programs, pipeline and activities in neurology by visiting U.S. Medical Affairs booth #240 at this year's CMSC Annual Meeting.

About Rebif® (interferon beta-1a)

Rebif 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. Rebif is not approved for treatment of chronic progressive MS.

serious side effects, so before taking Rebif, patients should talk with their doctor about the possible benefits of Rebif and its possible side effects.

Potential serious side effects of Rebif include depression, liver problems, risk to pregnancy, allergic reactions and injection-site problems. Patients who have had an allergic reaction such as difficulty breathing, flushing or hives to another interferon beta or to human albumin should not take Rebif.

Before taking Rebif (interferon beta-1a), patients should tell their doctor if they have a history of depression, anxiety, trouble sleeping, liver disease, thyroid problems, blood cell count or bleeding problems, epilepsy, or are planning to become pregnant. Patients should tell their doctor about all medicines they take, including prescription and nonprescription medicines, vitamins and herbal supplements. Rebif and other medicines may affect each other causing serious side effects. Patients should talk to their doctor before taking any new medicines.

Possible side effects of Rebif include flu-like symptoms (fever, chills, sweating, muscle aches and tiredness), injection-site reactions, depression and anxiety, liver problems, abdominal pain, blood problems, thyroid problems and severe allergic reactions. Patients should let their doctor know if they have any of these symptoms or feel sad, tired, hot or cold, or experience hives, rashes, bruising, yellowing of the skin, or a change in body weight (gain or loss).

This information is not intended to replace discussions with a doctor. For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional. Information is also available at www.mslifelines.com or call toll-free 1-877-44-REBIF (1-877-447-3243). Rebif is available by prescription only.

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integrated commercial, clinical and research operations in the company's home state of Massachusetts.

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EMD Serono to Release New Pipeline Data at ASCO 2014 from Early-Stage Investigational Compounds in Difficult-to-Treat Cancers

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- ◆ **Robust pipeline reflects commitment to innovation in oncology and immuno-oncology**
- ◆ **Data from nine EMD Serono pipeline products across oncology and immuno-oncology to be presented, including anti-PD-L1, c-Met inhibitor and TH-302**
- ◆ **ASCO Abstract # Anti-PD-L1: 3064; c-Met: 2521, TPS4151, TPS8121; tecemotide: TPS3658, TPS7608; TH- 302: 8534, 2029; further pipeline: 3551, TPS9107, 5030, 2050, e13552**

ROCKLAND, Massachusetts, May 29, 2014 /[PRNewswire](#)/ --

ASCO abstract #: Anti-PD-L1: 3064; c-Met: 2521, TPS4151, TPS8121; tecemotide: TPS3658, TPS7608; TH-302: 8534, 2029; further pipeline: 3551, TPS9107, 5030, 2050, e13552

- ◆ **Robust pipeline reflects commitment to innovation in oncology and immuno-oncology**
- ◆ **Data from nine EMD Serono pipeline products across oncology and immuno-oncology to be presented, including anti-PD-L1, c-Met inhibitor and TH-302**

oncology pipeline will be included at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) held in Chicago, Illinois, U.S., from May 30 to June 3, 2014. These data represent EMD Serono's commitment to research and development in oncology and immuno-oncology, and to improving patient outcomes through internally developed compounds, as well as those acquired and in development with the company's strategic partners.

"We are excited to present the most recent data from our oncology development candidates, including Phase I data on our promising anti-PD-L1 monoclonal antibody - a key milestone which highlights the potential of our immuno-oncology pipeline," said Belén Garijo, President and CEO of the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. "Through the spectrum of our efforts, from discovery through development, we keep the patients at the center of our activities, with the goal of transforming innovative research into differentiated medicines that are tailored to their needs."

EMD Serono's oncology and immuno-oncology pipeline includes more than 22 programs in early- and late-stage development, targeting a variety of difficult-to-treat cancers. Notable data presented at this year's ASCO include preliminary data from the investigational anti-PD-L1 monoclonal antibody (MSB0010718C) and the investigational c-Met inhibitor (MSC2156119J), both in advanced solid malignancies, and TH-302, an investigational hypoxia-activated prodrug, in multiple myeloma and glioblastoma.

Abstracts are currently available on the ASCO [website](#).

Notes to Editors

Abstracts related to EMD Serono's oncology and immuno-oncology pipeline include:

Anti-PD-L1

Title: Phase I open-label, multiple ascending dose trial of MSB0010718C, an anti-PD-L1 monoclonal antibody, in advanced solid malignancies.

Lead author: CR Heery

Abstract #: 3064

Presentation date/time (CDT): Jun 1, 08:00-11:45

Session: General Poster Session: Developmental Therapeutics - Immunotherapy

Room/Details: S Hall A2 (Poster Board: 131)

Title: Results of the first-in-human phase I trial assessing MSC2156119J (EMD 1214063), an oral selective c-Met inhibitor, in patients (pts) with advanced solid tumors.

Lead author: GS Falchook

Abstract #: 2521

Presentation date/time (CDT): Time 1: May 30, 13:00-16:00. Time 2: May 30, 16:30-17:45

Session: Poster Highlights Session: Developmental Therapeutics: Clinical Pharmacology and Experimental Therapeutics

Room/Details: Time 1: E354b Time 2: E Arie Crown Theater (Poster Board: 35)

Title: A multicenter, randomized, phase Ib/II trial of the oral c-Met inhibitor MSC2156119J as monotherapy versus sorafenib in Asian patients with MET-positive (MET+) advanced hepatocellular carcinoma (HCC) and Child-Pugh class A liver function.

Lead author: S Qin

AbstractAb#: TPS4151

Presentation date/time (CDT): May 31, 08:00-11:45

Session: General Poster Session: Gastrointestinal (Noncolorectal) Cancer

Room/Details: S Hall A2 (Poster Board: 234B)

Title: Phase I/II multicenter, randomized, open-label trial of the c-Met inhibitor MSC2156119J and gefitinib versus chemotherapy as second-line treatment in patients with MET-positive (MET+), locally advanced, or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor mutation (EGFRm+) and progression on gefitinib.

Lead author: Y-L Wu

Abstract #: TPS8121

Presentation date/time (CDT): May 31, 13:15-17:00

Session: General Poster Session: Lung Cancer - Non-small Cell Metastatic

Room/Details: S Hall A2 (Poster Board: 300B)

Tecemotide

Title: A randomized, double-blind, placebo-controlled, multicenter, binational, phase II trial of immunotherapy with L-BLP25 (tecemotide) in patients with colorectal carcinoma following R0/R1 hepatic metastasectomy. (Investigator-sponsored trial).

Lead author: S Kasper

Abstract #: TPS3658

Room/Details: S Hall A2 (Poster Board: 116A)

Title: START2: Tecemotide in unresectable stage III NSCLC after first-line concurrent chemoradiotherapy.

Lead author: S Ramalingam

Abstract #: TPS7608

Presentation date/time (CDT): May 31, 13:15-17:00

Session: General Poster Session: Lung Cancer - Non-small Cell Local-regional/Small Cell/Other Thoracic Cancers

Room/Details: S Hall A2 (Poster Board: 216A)

TH-302

Title: Preliminary safety and efficacy of TH-302, an investigational hypoxia-targeted drug, and dexamethasone (dex) in patients (pts) with relapsed/refractory multiple myeloma (RR MM).

Lead author: J Laubach

Abstract #: 8534

Presentation date/time (CDT): Time 1: May 30, 13:00-16:00. Time 2: May 30, 16:30-17:45.

Session: Poster Highlights Session: Lymphoma and Plasma Cell Disorders

Room/ Details: Time 1: S405. Time 2: S406 (Poster Board: 14)

Title: Phase 1/2 study of investigational hypoxia-targeted drug, TH-302, and bevacizumab (bev) in recurrent glioblastoma (GBM) following bev failure. (Investigator-sponsored trial).

Lead author: AJ Brenner

Abstract #: 2029

Presentation date/time (CDT): Time 1: May 30, 13:00-16:00. Time 2: May 30, 16:30-17:45.

Session: Poster Highlights Session: Central Nervous System Tumors

Room/Details: Time: 1 E354b. Time 2: E450 (Poster Board: 20)

Additional Pipeline Projects: Oncology and Immuno-Oncology

Title: Phase 1 study of biweekly (Q2W) anti-EGFR monoclonal antibody (mAb) mixture Sym004 in patients (pts) with metastatic colorectal cancer (mCRC) resistant to previous anti-EGFR

Abstract #: 3551

Presentation date/time (CDT): May 31, 08:00-11:45

Session: General Poster Session: GI (Colorectal) Cancer

Room/ Details: S Hall A2 (Poster Board: 14)

Title: Targeted modified IL-2 (NHS-IL2, MSB0010445) combined with stereotactic body radiation in advanced melanoma patients after progression on ipilimumab: Assessment of safety, clinical, and biologic activity in a phase 2a study.

Lead author: H Kaufman

Abstract #: TPS9107

Presentation date/time (CDT): May 31, 08:00-11:45

Session: General Poster Session: Melanoma/Skin Cancers

Room/Details: S Hall A2 (Poster Board: 308B)

Title: Primary outcomes of the placebo-controlled phase 2 study PERSEUS (NCT01360840) investigating two dose regimens of abituzumab (DI17E6, EMD 525797) in the treatment of chemotherapy-naïve patients (pts) with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC).

Lead author: M Hussain

Abstract #: 5030

Presentation date/time (CDT): May 31, 13:15-16:15

Session: Poster Highlights Session: Genitourinary (Prostate) Cancer

Room/Details: E354b (Poster Board: 45)

Title: Radiotherapy (RT), temozolomide (TMZ), procarbazine (PCB), and the integrin inhibitor cilengitide in patients (pts) with glioblastoma (GBM) without methylation of the MGMT gene promoter (ExCentric): Results of an Australian phase II clinical trial.

Lead author: M Khasraw

Abstract #: 2050

Presentation date/time (CDT): May 31, 13:15-17:00

Session: General Poster Session: Central Nervous System Tumors.

Room/Details: S Hall A2 (Poster Board: 15)

Title: Absolute bioavailability, mass balance, elimination route, and metabolite profile of the selective oral MEK1/2 inhibitor pimasertib in cancer patients.

Presentation date/time (CDT): Abstract only

Tecemotide, TH-302 and all early-stage products are currently under clinical investigation and have not been approved for use in the U.S., Europe, Canada, or elsewhere. All investigational products have not yet been proven to be either safe or effective and any claims of safety and effectiveness can be made only after regulatory review of the data and approval of the labeled claims.

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EMD Serono Launches Compassionate Corps Program to Reduce Cost of Fertility Treatment for Eligible Military Veterans and their Spouses

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PR Newswire
ROCKLAND

ROCKLAND, Mass., June 11, 2014 /[PRNewswire](#)/ -- EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany announced today its commitment to U.S. military veterans and their spouses with the introduction of the Compassionate Corps Program. Through the program, veterans and their spouses may be eligible to receive free fertility medicine.

"As a leader in fertility health, EMD Serono works to provide the products, devices and patient support that enable families who want to have a child," said Craig Millian, Senior Vice President, Head of US Endocrinology and Fertility. "We are proud to add to our comprehensive access programs a new way to help serve the men and women of our military who may be experiencing financial barriers to fertility treatment."

not otherwise insured for infertility medications; have been properly screened and diagnosed as infertile and requiring in vitro fertilization/advanced reproductive technology.

For more information about Compassionate Corps, including eligibility requirements, program details and enrollment forms, please visit www.CompassionateCorps.com.

Those U.S. military veteran patients who do not qualify for the Compassionate Corps Program and do not have insurance for fertility medications are encouraged to apply for EMD Serono's Compassionate Care Program in which they will now receive an automatic discount of 25% off the self-pay price of EMD Serono medicines. These patients can also qualify for 50 to 75% off of EMD Serono medications if they meet the financial eligibility criteria of EMD Serono's Compassionate Care Program. For more information about this program, and about infertility, treatment options, and to find a specialist near you, please visit www.FertilityLifelines.com.

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, endocrinology and in reproductive health. In addition, EMD Serono is growing its expertise and presence in the area of oncology, with more than 15 projects currently in development. With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with approximately 1,000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

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family remains the majority owner of the company to this day.

Contact: Lisa Buffington

Phone 781-681-2340

To view the multimedia assets associated with this release, please click:

<http://www.multivu.com/mnr/7244251-emd-serono-compassionate-corps-program-veterans-spouses-fertility>

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EMD Serono and Mersana to Develop Next-Generation Antibody-Drug Conjugates

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- ▶ - **Collaboration and license agreement allows Merck Serono to expand its oncology drug portfolio**
- ▶ - **Mersana Therapeutics' Fleximer® technology to be leveraged to create multiple antibody-drug conjugates**

PR Newswire
ROCKLAND

ROCKLAND, Mass., June 24, 2014 /[PRNewswire](#)/ -- EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, and Mersana Therapeutics, Inc., Cambridge, Mass., U.S., announced today an agreement to collaboratively develop next-generation antibody-drug conjugates (ADCs). ADCs are composed of an antibody linked to cytotoxic drugs, whereby the antibody part specifically targets and delivers the cytotoxic drug to cancer cells which could lead to higher drug levels at the tumor site.

Mersana and EMD Serono will leverage Mersana's Fleximer® technology to generate ADCs for multiple undisclosed targets. Both parties have agreed to test a variety of ADCs by utilizing Mersana's platform technologies, and several cytotoxic agents as conjugates. This agreement further underlines EMD Serono's approach to employ a collaborative research and development

"This new collaboration provides an exciting opportunity to expand our oncology drug discovery and development portfolio into the evolving ADC space," said Dr. Andree Blaukat, head of the Translational Innovation Platform Oncology at EMD Serono. "At EMD Serono, we have a long-standing commitment to improving oncology care, and we aim to deliver the best benefit possible to patients. Partnering with Mersana allows us to incorporate cutting-edge research and technical excellence to enrich our pipeline."

"We look forward to working with EMD Serono to apply our proprietary platform technologies to rapidly develop and demonstrate preclinical proof-of-concept of several customized, novel Fleximer-ADC candidates," said Timothy B. Lowinger, Ph.D., Mersana's Chief Scientific Officer.

Under the agreement, EMD Serono will provide monoclonal antibodies to Mersana which will generate the Fleximer-ADCs and conduct drug discovery and preclinical development activities. EMD Serono will be responsible for clinical development and commercialization of any products under an exclusive license from Mersana. In addition to an upfront payment, Mersana is eligible to receive milestones plus royalties on worldwide net sales of products. Further financial details are not being disclosed.

About Fleximer[®] Antibody-Drug Conjugate Technology

Mersana's next-generation Fleximer[®] antibody-drug conjugate (ADC) technology is based on the Company's proprietary biodegradable polymer system, known as Fleximer, and a wide variety of linkers that allow for the attachment of an extensive range of anti-tumor payloads to Fleximer. As an example, once loaded with drug(s), Fleximer is then attached through a stable linker that is different from the drug linker(s), to an antibody or antibody alternative to create a Fleximer-ADC.

Mersana's novel linker systems are designed to be stable in the blood-stream and to release the potent payloads once inside the targeted cancer cell. Mersana's Fleximer-ADC technology provides several key advantages over currently available approaches, including: the ability to deliver diverse payloads; the opportunity to significantly increase drug loading per antibody; and the potential use with antibody fragments and alternative targeting moieties in addition to monoclonal antibodies. Mersana's proprietary payload platforms include Dolaflexin[™], an auristatin derivative; Vindeflexin[™], a vindesine derivative; and Cytoflexin[™], a tubulysin derivative.



of new and established therapeutic classes. Mersana is developing, with select pharmaceutical partners, a portfolio of next-generation Fleximer[®] ADC) with superior properties not found with current ADC technologies. The company is also advancing its own pipeline of Fleximer-ADCs with best-in-class potential to address unmet needs and improve patient outcomes in multiple oncology indications. www.mersana.com

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a leading US biopharmaceutical company focused exclusively on specialty care. For more than 40 years, EMD Serono has integrated cutting-edge science, innovative products and devices, 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 neurology, oncology, immunology and immuno-oncology. Today, EMD Serono has more than 1,100 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com

About Merck KGaA, Darmstadt, Germany

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EMD Serono Commits EUR 2 million to the Grant for Fertility Innovation (GFI) for 2014 /15

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

PR Newswire
ROCKLAND

ROCKLAND, Mass., July 1, 2014 /[PRNewswire](#)/ -- EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, today announced its strong support of the Grant for Fertility Innovation (GFI) fund with grants totaling up to € 2 million for the years 2014/2015. The announcement was made during the 30th annual meeting of the European Society of Human Reproduction and Embryology (ESHRE) currently taking place in Munich.

Launched in 2009, the GFI is dedicated to transforming innovative translational fertility research projects into concrete health solutions to improve the outcomes of assisted reproductive technologies (ART). In the last five years, approximately 640 applications to GFI were received from over 50 countries around the world; of these applications, nine projects from eight countries were awarded a grant for a total of € 2 million.

Dr. Steven Hildemann, Global Chief Medical Officer and Head of Global Medical and Safety at the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. "The GFI enables the novel ideas that exist among forward-thinking fertility researchers from around the world, accelerating our collective ability to positively impact the final outcome of patients undergoing assisted reproductive technology treatments."

Every year, the GFI awardees are announced during a ceremony at ESHRE's annual meeting. This year, nine winning projects were announced during the ceremony:

- ◆ **Marcos Meseguer - Instituto Valenciano de Infertilidad, Valencia** (Spain): *Embryo viability measurement combining Oxidative stress and time-lapse*
- ◆ **Kazuhiro Kawamura - Reproduction Center, St. Marianna University School of Medicine, Kanagawa** (Japan): *Infertility treatment of patients with diminished ovarian reserve using in vitro activation of follicles*
- ◆ **Andrea Borini - Tecnobios Procreazione, Bologna** (Italy): *IR Microspectroscopy on GCs: a new non-invasive oocyte assesment*
- ◆ **Semra Kahraman- Istanbul Memorial Hospital, ART and Genetics Center, Istanbul** (Turkey): *Identifying markers of oocyte competence through a maturation analysis*
- ◆ **Douglas Carrell - University of Utah, Salt Lake City, UT** (USA): *Micro-Electrophoresis: To select mature and genetically fit sperm*
- ◆ **Nathan Treff - Reproductive Medicine Associates of NJ, Basking Ridge, NJ** (USA): *Predicting Reproductive Potential from the Maternal Exome*
- ◆ **Marc-André Sirard- Laval Universit, Quebec City** (Canada): *COST2: Control Ovarian Stimulation Timing Test*
- ◆ **José Gonçalves Franco Junior- Centro de Reprodução Humana Prof. Franco Junior, Ribeirão Preto** (Brazil): *Genetic biomarkers to predict ovarian response and pregnancy outcomes*
- ◆ **Tracey Edgell- Prince Henry's Institute, Clayton** (Australia): *Clinical Trial of a Test to Predict Outcome in Women Undergoing ART*

About the Grant for Fertility Innovation (GFI)

EMD Serono announced the initiation of the GFI program in 2009 to support the advancement of science and innovative technologies in the fertility field. This grant is awarded every year to translational research projects that can potentially improve baby birth rate for the benefit of the patients. Each project is blinded and evaluated by a jury of experts according to five criteria:

For further information about the GFI and how to apply for next year's grants, please visit:

www.grantforfertilityinnovation.com

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a specialized biopharmaceutical company dedicated to developing therapies with groundbreaking potential. The company has strong market positions in neurology, endocrinology and in reproductive health. In addition, EMD Serono has an enduring commitment to solve the unsolvable, with state-of-the-art science dedicated to developing new therapies in our core focus areas of neurology, oncology, immuno-oncology and immunology. With a long-standing history of industry expertise and a dedication to shape the future of healthcare, the company's US footprint continues to grow, with approximately 1,000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com.

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EMD Serono Participates in Global Grants Program to Fund Scientific Innovation and Medical Education

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-Global program provides €20 million annually for research grants and medical education

Rockland, Massachusetts, July 8, 2014 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, today announced its participation in the Global Grants initiative – a program that underscores the company’s commitment to funding scientific innovation via research grants and supporting medical education of healthcare providers and patients around the world. The initiative encompasses all of the various grants that EMD Serono offers, including its Grants for Innovation in Research, its Independent Medical Grants, and Grants for Medical Education of Healthcare Providers and Patients.

The global program totals an annual commitment of €20 million across all grants programs, highlighting the company’s collective efforts to promote advances in the field of medicine, address recognized gaps in healthcare knowledge, and improve the quality of patient care.

high-quality, innovative healthcare to patients,” said Steven Hildemann, Global Chief Medical Officer and Head of Global Medical and Safety at the biopharmaceutical division of Merck KGaA, Darmstadt, Germany.

EMD Serono’s research grants program supports investigator-initiated clinical and preclinical research in various therapeutic areas. Its Innovation Grants focus on areas in which EMD Serono has a strong R&D presence, such as the Grant for Oncology Innovation, the Grant for Multiple Sclerosis Innovation, and the Grant for Fertility Innovation. For information about EMD Serono’s Innovation Grants, visit the following:

- <http://www2.grantforoncologyinnovation.org/EMDSerono/index.html>
- <http://www2.grantformultiplesclerosisinnovation.org/EMDSerono/index.html>
- <http://www2.grantforfertilityinnovation.com/EMDSerono/index.html>

EMD Serono’s medical education grants program supports accredited educational activities for healthcare providers that improve patient care and provide valuable information to the medical community. The program also supports fellowships and patient education initiatives. All grants are processed through an online web portal which allows highly transparent interactions with applicants. For more information on EMD Serono’s medical education grants, please visit www.grants.emdserono.com.

For more information on independent medical grants available in the United States, please visit www.img-emdserono.com.

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integrated commercial, clinical and research operations in the company's home state of Massachusetts.

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EMD Serono Initiates Phase II Study of Anti-PD-L1 Antibody MSB0010718C in Metastatic Merkel Cell Carcinoma

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- ▶ **-First patient begins treatment in an international Phase II study investigating the efficacy and safety of MSB0010718C in patients with metastatic Merkel cell carcinoma (mMCC)**
- ▶ **-mMCC is a rare and aggressive skin cancer lacking effective treatments**
- ▶ **-MSB0010718C is also currently being explored in a seven cohort Phase I clinical trial for the treatment of solid tumors that aims to recruit 590 patients**

Rockland, Massachusetts, July 29, 2014 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, today announced the initiation of an international Phase II study designed to assess the efficacy and safety of MSB0010718C, an investigational fully human IgG1 monoclonal antibody that binds to programmed death-ligand 1 (PDL1). This multicenter, single-arm, open-label study is being conducted in patients with metastatic Merkel cell carcinoma (mMCC), a rare and aggressive type of skin tumor, 1,2 who have previously received one line of chemotherapy. It is expected to recruit 84 patients across Asia Pacific, Australia, Europe and North America. The primary endpoint of the study is overall response.

The PD-L1/PD-1 pathway is implicated as a major mechanism by which tumors evade elimination by the immune system.³ The PD-L1 molecule is expressed in many cancer types,

tumor growth.

Immune mechanisms are implicated in the pathogenesis of MCC, with an increased risk observed in immunosuppressed individuals.⁵ MCC also is associated with the presence of the Merkel cell polyomavirus, which may have a role in tumor formation.⁶ Globally, the incidence of MCC is increasing, and outcomes for patients with this disease are poor.^{1,2} Therefore, new treatment approaches are required to improve the outcome of patients with this type of cancer.

“We believe that modulating the immune system by targeting PD-L1 represents a promising new approach in the treatment of this aggressive cancer, especially considering that many of the predisposing factors for mMCC seem to be related to functional disruptions of the immune system,” said Helen Sabzevari, Senior Vice President of Immuno-Oncology at the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. “Our anti-PD-L1 compound may present a potential new approach for the treatment of mMCC patients. The initiation of this Phase II study is an important milestone, as we endeavor to help those suffering from mMCC, a devastating disease with significant unmet need.”

In addition to this new study in mMCC, MSB0010718C is currently being explored in a Phase I clinical trial for the treatment of solid tumors. The study aims to recruit 590 patients and has enrolled 422 patients to date. On June 1, 2014, EMD Serono presented initial data from this dose escalation study in solid tumors at the annual American Society of Clinical Oncology (ASCO) meeting in Chicago. ⁷ This study is currently recruiting patients into expansion cohorts in seven cancer types: castrateresistant prostate cancer, colorectal cancer, gastric/gastroesophageal cancer, melanoma, metastatic breast cancer, non-small cell lung cancer and ovarian cancer.

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About MSB0010718C

MSB0010718C is an investigational fully human IgG1 monoclonal antibody that binds to the PD-L1 (programmed death-ligand 1) protein, which is present at high levels in many cancer types. By competitively blocking the interaction with PD-1 receptors, it is believed that MSB0010718C thereby restores anti-tumor T-cell responses.

About Merkel cell carcinoma (MCC)

MCC is a rare and aggressive disease in which cancer cells form in the top layer of the skin, close to nerve endings. 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, arms, legs, and trunk. Risk factors for MCC include sun exposure and having a weak immune system (i.e., solidorgan transplant recipients, people with HIV/AIDS and people with other cancers, such as chronic lymphocytic leukemia, are at higher risk). Caucasian males over age 50 are at increased risk.

MCC tends to metastasize at an early stage, spreading initially to nearby lymph nodes, and then potentially to more distant areas in the body, including other lymph nodes or areas of skin, lungs, brain, bones, or other organs.

Current treatment options for MCC include surgery, radiation and chemotherapy. Treatment for metastatic or Stage IV MCC is generally palliative.

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EMD Serono and Massachusetts General Hospital Collaborate to Better Understand Systemic Lupus Erythematosus and Lupus Nephritis

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Billerica, Massachusetts, September 2, 2014 – EMD Serono Research and Development Institute, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, entered into a collaborative research agreement with Massachusetts General Hospital (MGH) to further the understanding of Systemic Lupus Erythematosus and Lupus Nephritis pathogenesis.

Systemic Lupus Erythematosus (SLE) is an autoimmune disease, where the immune system produces proteins called autoantibodies that attack patients' own tissues and organs. According to the Lupus Foundation of America, approximately 1.5 million Americans have SLE. Up to 60% of patients with SLE develop inflammation in the kidneys known as Lupus Nephritis (LN), which if uncontrolled can lead to kidney failure. SLE and LN represent an area of high unmet medical need, where new therapies are vital.

targets, pathogenic immune cell types and biomarkers in SLE and LN patients.

“We have a very strong commitment to building our understanding of the pathology of disease in Immunology,” says Harsukh Parmar, Senior Vice President, Immunology & Neurology at the EMD Serono R&D Institute. “In collaboration with world-renowned academic centers such as MGH, we are well-positioned to advance the highest-quality science into the clinic for the benefit of patients in need.”

MGH investigators will prospectively collect biospecimens to be used in various translational research applications, including compound testing and gene expression analysis of target molecules.

“The Division of Nephrology at MGH is deeply committed to bringing novel therapies to patients who suffer from kidney disease, and this complementary collaboration with EMD Serono brings us closer to helping patients with lupus nephritis,” said Ravi Thadhani, MD, MPH, Chief of the Division of Nephrology at MGH.

A major aim of this collaboration is to generate supportive data for the role of certain proteins targeted by clinical stage assets in the EMD Serono portfolio in LN pathogenesis, as well as enable early discovery efforts in Immunology.

This strategic alliance with MGH highlights the commitment of EMD Serono to develop medicines for SLE and LN and the commitment to engaging in strategic partnerships that leverage Massachusetts’ biotech innovation hub.

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a leading US biopharmaceutical company focused exclusively on specialty care. An established leader in the Massachusetts life sciences industry, EMD Serono recently invested in expanding its research and development presence in the state to support the advancement of its pipeline and opportunities for partnerships in the academia and biotech sectors. Today, the EMD presence in Massachusetts includes approximately 2,200 employees, and the combined organizations of EMD Serono and EMD Millipore, the life sciences division of Merck KGaA, make EMD the fifth largest life science company in Massachusetts. EMD Serono engages in strategic partnerships that leverage Massachusetts’ rich biotech innovation hub to advance research in our core

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EMD Serono Appoints Drew Young to Senior Vice President, Neurology and Immunology

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PR Newswire
ROCKLAND

ROCKLAND, Mass., Sept. 2, 2014 /[PRNewswire](#)/ -- EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today that [Drew Young](#) has joined the company as Senior Vice President, Neurology and Immunology. In this capacity, he will be responsible for leading the strategic direction of the U.S. Neurology and Immunology franchise, including future products.

Bringing more than 20 years of experience leading global and U.S. marketing and sales efforts at pharmaceutical and biotech companies, Mr. Young comes to EMD Serono from Biogen Idec, Inc., where he was the Marketing Lead of the interferon franchise for the company's multiple sclerosis (MS) business.

"Drew is a proven commercial leader and a key addition to EMD Serono's strengthened leadership team," said Gary Zieziula, Chief Commercial Officer of EMD Serono. "His knowledge

EMD Serono's neurology franchise is led by Rebif® (*interferon beta-1a*) for the treatment of relapsing MS. Rebif is a high dose, high frequency interferon that has been proven superior to a low dose, low frequency interferon (Avonex) in a head-to-head clinical trial. Patients treated with REBIF 44 mcg three times per week were more likely to remain relapse-free at 24 and 48 weeks than were patients treated with AVONEX 30 mcg once per week. Rebif offers robust and compelling efficacy, and a well established safety profile supported by more than 20 years of clinical trial and patient experience. Since its launch in the U.S., more than 124,000 patients have chosen Rebif to treat their relapsing MS. EMD Serono has also offered support to the MS community for more than 10 years through MS LifeLines, a service that provides education, reimbursement and support to people living with MS.

Amongst other roles, Mr. Young has worked with Bristol-Myers Squibb Pharmaceutical Group (BMS) in both Canada and the U.S., where he held numerous sales and marketing roles of increasing responsibility, including Northeast Regional Sales Director for the company's cardiovascular/metabolic portfolio, U.S. Brand Lead for its hypertension portfolio and Global Brand Lead for a pre-launch diabetes product. Mr. Young has also held senior sales and marketing positions at Schering Plough Canada and Novartis Pharmaceuticals Canada.

Mr. Young received his bachelor's degree in Economics from McGill University in Montreal, Canada, where he also received the Scarlet Key Award for outstanding student leadership.

About Rebif® (interferon beta-1a)

Rebif 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. Rebif is not approved for treatment of chronic progressive MS.

Rebif will not cure MS but it has been shown to decrease the number of flare-ups and slow the occurrence of some of the physical disability that is common in people with MS. Rebif can cause serious side effects, so before taking Rebif, patients should talk with their doctor about the possible benefits of Rebif and its possible side effects.

Potential serious side effects of Rebif include depression, liver problems, risk to pregnancy, allergic reactions and injection-site problems. Patients who have had an allergic reaction such

Before taking Rebif (interferon beta-1a), patients should tell their doctor if they have a history of depression, anxiety, trouble sleeping, liver disease, thyroid problems, blood cell count or bleeding problems, epilepsy, or are planning to become pregnant. Patients should tell their doctor about all medicines they take, including prescription and non-prescription medicines, vitamins and herbal supplements. Rebif and other medicines may affect each other causing serious side effects. Patients should talk to their doctor before taking any new medicines.

Possible side effects of Rebif include flu-like symptoms (fever, chills, sweating, muscle aches and tiredness), injection-site reactions, depression and anxiety, liver problems, abdominal pain, blood problems, thyroid problems and severe allergic reactions. Injection site reactions, hepatic function disorders, and leukopenia were observed with greater frequency with Rebif® 44 mcg three times per week sc compared to the Avonex®.

This information is not intended to replace discussions with a doctor. For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional. Information is also available at www.msllifelines.com or call toll-free 1-877-44-REBIF (1-877-447-3243). Rebif is available by prescription only.

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help meet global challenges. The company generated total revenues of €11.1 billion in 2013 with its four divisions: Biopharmaceuticals, Consumer Health, Performance Materials and Life Science Tools. Merck KGaA of Darmstadt, Germany is the world's oldest pharmaceutical and chemical company – since 1668, the name has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day.

Erin-Marie Beals

Phone 781-681-2850

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EMD Serono Presents New Data on Rebif® (Interferon beta-1a) and Multiple Sclerosis Pipeline at Joint ACTRIMS-ECTRIMS Meeting in Boston

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- ▶ **- Data include post-hoc assessments of controlled studies in relapsing MS regarding evolution of gadolinium-enhancing lesions, assessments of predictive scores for disease activity and disability progression, and 'no evident disease activity' (NEDA) measure for interferon beta-1a SC vs. interferon beta-1a IM**
- ▶ **- Data presented on pipeline compounds underscore company's commitment to scientific advancements in MS**

PR Newswire
ROCKLAND

ROCKLAND, Mass., Sept. 9, 2014 /[PRNewswire](#)/ -- EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today that new data from the division's multiple sclerosis (MS) portfolio will be presented at ACTRIMS-ECTRIMS 2014, the joint meeting of the Americas Committee for Treatment and Research in MS (ACTRIMS) and European Committee for Treatment and Research in MS (ECTRIMS), taking place September 10-13 in Boston, U.S.A.

(interferon beta-1a), as well as two investigational compounds:

- ◆ ATX MS-1467, an investigational compound being evaluated in a Phase I clinical trial for MS.
- ◆ Plovamer Acetate (PI-2301), an investigational compound being evaluated in a Phase II clinical trial for MS.

Additionally, Merck KGaA, Darmstadt, Germany will announce the second annual recipients of the Grant for Multiple Sclerosis Innovation (GMSI) Awards at a satellite symposium on Friday, September 12 from 7:00 – 8:00 a.m. ET (Room 312, Level 3). The grant recipients will share up to €1 million to support their promising translational research projects, with the aim of improving understanding of MS for the ultimate benefit of people living with the disease.

"The research presented at the joint ACTRIMS-ECTRIMS meeting reinforces EMD Serono's commitment to addressing the unmet needs of people living with MS," said Steven Hildemann, Senior Vice President, Chief Medical Officer, and head of Global Medical Affairs and Global Drug Safety at Merck Serono. "We continue to advance our understanding of the clinical effects of Rebif and demonstrate progress with our pipeline candidates, with the ultimate goal of developing innovative solutions and therapies for the MS community."

The following abstracts have been accepted for presentation at ACTRIMS-ECTRIMS 2014:

Rebif® (interferon beta-1a) and Multiple Sclerosis

- ◆ No evident disease activity at 24 weeks in patients with relapsing MS treated with interferon beta-1a SC vs. interferon beta-1a IM in the EVIDENCE study (Poster P102, Clinical Trials; Thursday, September 11, 3:30 – 5:00 p.m. ET)
- ◆ No evident disease activity in relapsing MS patients treated with interferon beta-1a SC vs. interferon beta-1a IM: subgroup analyses of the EVIDENCE study (Poster P104, Clinical Trials; Thursday, September 11, 3:30 – 5:00 p.m. ET)
- ◆ Challenges experienced by neurologists in the individualization of multiple sclerosis treatment: findings from an international study (Poster P321, Disease Therapy; Thursday, September 11, 3:30 – 5:00 p.m. ET)
- ◆ Multiple sclerosis treatment practices in women of child-bearing age in Switzerland: results of the women with MS online survey (Poster P325, Disease Therapy; Thursday, September 11, 3:30 – 5:00 p.m. ET)

Thursday, September 11, 3:30 – 5:00 p.m. ET)

- ◆ Natural evolution of gadolinium-enhancing lesions into chronic black holes in multiple sclerosis: analysis of PRISMS and SPECTRIMS placebo arms (Poster P473, Imaging-1; Thursday, September 11, 3:30 – 5:00 p.m. ET)
- ◆ Assessing a predictive score for disease activity in secondary progressive multiple sclerosis: post-hoc analysis of data from the SPECTRIMS study (Poster P766, Prognostic Factors; Friday, September 12, 2:45 – 4:15 p.m. ET)
- ◆ Assessing a predictive score for long-term disability progression in relapsing-remitting multiple sclerosis: 7/8-year follow-up in the PRISMS study (Poster P765, Prognostic Factors; Friday, September 12, 2:45 – 4:15 p.m. ET)
- ◆ Cognition and fatigue in patients with relapsing multiple sclerosis treated by subcutaneous interferon beta-1a: an observational study SKORE (Poster P780, PROs and QoL; Friday, September 12, 2:45 – 4:15 p.m. ET)
- ◆ A prospective study comparing the impact of three levels of support services on interferon beta adherence in patients with relapsing MS: interim results (Poster P828, Rehabilitation and Comprehensive Care; Friday, September 12, 2:45 – 4:15 p.m. ET)

ATX-MS-1467

- ◆ ATX-MS-1467 reduces MRI lesions and prevents disease progression in a humanized mouse model of multiple sclerosis (Poster P378, Experimental Models; Thursday, September 11, 3:30 – 5:00 p.m. ET)

Plovamer Acetate (PI-2301)

- ◆ Plovamer acetate causes a more pronounced increase in eosinophils and CCL22 in naive and EAE mice compared with glatiramer acetate (Poster P398, Experimental Models; Thursday, September 11, 3:30 – 5:00 p.m. ET)

The clinical candidates above are currently under clinical investigation and have not been approved for use in the United States, Europe, Canada or elsewhere. The clinical candidates have not been proven to be safe or effective, and any claims of safety and effectiveness can be made only after regulatory review of the data and approval of the labeled claims.

About Rebif® (interferon beta-1a)

Rebif 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. Rebif is not

Rebif will not cure MS but it has been shown to decrease the number of flare-ups and slow the occurrence of some of the physical disability that is common in people with MS. Rebif can cause serious side effects, so before taking Rebif, patients should talk with their doctor about the possible benefits of Rebif and its possible side effects.

Potential serious side effects of Rebif include depression, liver problems, risk to pregnancy, allergic reactions and injection-site problems. Patients who have had an allergic reaction such as difficulty breathing, flushing or hives to another interferon beta or to human albumin should not take Rebif.

Before taking Rebif (interferon beta-1a), patients should tell their doctor if they have a history of depression, anxiety, trouble sleeping, liver disease, thyroid problems, blood cell count or bleeding problems, epilepsy, or are planning to become pregnant. Patients should tell their doctor about all medicines they take, including prescription and non-prescription medicines, vitamins and herbal supplements. Rebif and other medicines may affect each other causing serious side effects. Patients should talk to their doctor before taking any new medicines.

Possible side effects of Rebif include flu-like symptoms (fever, chills, sweating, muscle aches and tiredness), injection-site reactions, depression and anxiety, liver problems, abdominal pain, blood problems, thyroid problems and severe allergic reactions. Patients should let their doctor know if they have any of these symptoms or feel sad, tired, hot or cold, or experience hives, rashes, bruising, yellowing of the skin, or a change in body weight (gain or loss).

This information is not intended to replace discussions with a doctor. For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional. Information is also available at www.ms lifelines.com or call toll-free 1-877-44-REBIF (1-877-447-3243). Rebif is available by prescription only.

About multiple sclerosis

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For more information, please visit www.emdserono.com

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EMD Serono and Accelerated Cure Project Launch Collaborative Research Program to Optimize Treatment and Understand Progression of Multiple Sclerosis

[EXPLORE MORE](#)

- EMD Serono provides funding for ACP's multicenter longitudinal OPT-UP clinical study

PR Newswire
ROCKLAND and WALTHAM

ROCKLAND and WALTHAM, Mass., Sept. 10, 2014 /[PRNewswire](#)/ -- EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany and the Accelerated Cure Project for Multiple Sclerosis today announced a lead founding sponsor agreement to help launch the Optimizing Treatment—Understanding Progression (OPT-UP) study.

OPT-UP is a U.S.-based, multicenter longitudinal clinical research study that will enroll 2500 people with MS and follow them for up to five years. The goals of the study are to generate a robust evidence base of factors affecting treatment outcomes in MS to guide the choice of

"Our collaboration with the Accelerated Cure Project on the OPT-UP clinical research study offers us an extraordinary opportunity to combine complementary expertise and resources to improve patient outcomes," said Dr. Thorsten Eickenhorst, Senior Vice President and Chief Medical Officer, EMD Serono. "This study underscores our company's dedication to furthering breakthrough scientific research that can advance treatment options for those living with multiple sclerosis."

"We have been working diligently with leading MS clinicians, people living with MS, biopharma companies, and foundations to design a study that addresses the most critical medical needs in MS today," said Robert McBurney, President and CEO of the Accelerated Cure Project for MS. "We are thrilled that EMD Serono, a leader in the area of MS therapeutics, has chosen to take a lead founding sponsor role, providing the support needed to implement this important study."

Subjects will be enrolled at up to twenty MS clinics located throughout the U.S. and will be followed for a minimum of two years and up to five years. Using validated and standardized instruments, researchers will collect high-quality data on treatment outcomes, biological samples, and imaging data that will be analyzed by the ACP network investigators and partner organizations, as well as shared widely with research groups that can help accomplish the goals of OPT-UP.

"Although progress has been made in making more therapies available to people living with MS, we still make a lot of treatment decisions based on trial and error," said R. Philip Kinkel, MD, Director of the MS Program at the University of California San Diego and Chair of the OPT-UP Steering Committee. "The OPT-UP study objective is to provide data and insights to better match people living with MS with the treatments."

"In addition to data from clinical assessments, researchers will also have access to patient-reported outcomes that will be captured online at regular intervals," said Ben Greenberg, MD, Director of the Neurosciences Clinical Research Center at the University of Texas Southwestern. "I believe that the substantial amount of data and biosamples generated by this study will be enormously valuable in furthering our understanding of MS disease progression."

As of September 2014, nine sites are participating in OPT-UP including the University of California San Diego, University of Texas Southwestern Medical Center, University of Massachusetts Medical School, Tisch MS Research Center of New York, Johns Hopkins School of

about the OPT-UP study and how you can get involved, please contact [Accelerated Cure Project for MS](#).

About Accelerated Cure Project for MS

Accelerated Cure Project for MS (ACP) is a nonprofit organization whose mission is to accelerate research efforts to improve diagnosis, to optimize treatment and to cure MS. ACP believes that research is the only way to greatly improve the outlook for people with MS. The organization promotes scientific collaboration and accelerates research by rapidly and cost-effectively providing researchers with data and biospecimens they need to explore novel research ideas that can lead to better diagnoses, to new treatments and to cures for people with MS. Its resources have supported 77 research studies worldwide that have generated almost 700 million returned data points for collaborative data mining and disease modeling. To learn more about the activities, and impact of ACP, please visit <http://www.acceleratedcure.org>.

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a leading US biopharmaceutical company focused exclusively on specialty care. An established leader in the Massachusetts life sciences industry, EMD Serono recently invested in expanding its research and development presence in the state to support the advancement of its pipeline and opportunities for partnerships in the academia and biotech sectors. Today, the EMD presence in Massachusetts includes approximately 2,200 employees, and the combined organizations of EMD Serono and EMD Millipore, the life sciences division of Merck KGaA, make EMD the fifth largest life science company in Massachusetts. EMD Serono engages in strategic partnerships that leverage Massachusetts' rich biotech innovation hub to advance research in our core therapeutic areas and is also a supporter of science, technology, engineering and medical (STEM) education in Massachusetts. For more information, please visit www.emdserono.com.

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EMD Serono Honors Recipients of the Second Annual EUR 1 Million Grant for Multiple Sclerosis Innovation

[EXPLORE MORE](#)

◆ **- Research grants awarded for five out of more than 200 proposals, highlighting continued commitment to multiple sclerosis (MS)**

PR Newswire
ROCKLAND

ROCKLAND, Mass., Sept. 12, 2014 /[PRNewswire](#)/ -- EMD Serono Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, today announced the recipients of the second annual Grant for Multiple Sclerosis Innovation (GMSI) at the 2014 Joint ACTRIMS-ECTRIMS Meeting of the Americas Committee for Treatment and Research in MS (ACTRIMS) and European Committee for Treatment and Research in MS (ECTRIMS), taking place September 10-13, in Boston, U.S.A.

Five recipients hailing from France, Spain, the United States and the United Kingdom (UK), will share a total of €1 million to support their translational research projects:

- ◆ Dr. Bruno Stankoff, professor of Neurology, Pierre and Marie Curie University – Paris (France), received a grant to identify a new biomarker that can be imaged to determine the

- ◆ Drs. Maria Domercq and Carlos Matute, researchers, Añucarro Basque Center for Neuroscience and Department of Neurosciences at Universidad del Pais Vasco (Spain), received a grant to investigate whether immune cells of the central nervous system known as microglia may indirectly influence the repair of myelin—the insulating outer layer of neurons. The results of these investigations could support the identification of a new MS treatment option based on the modulation of microglia.
- ◆ Dr. Robert Axtell, assistant member at the Oklahoma Medical Research Foundation (United States), received a grant to examine the role of inflammation-inducing cell signaling molecules called BAFF and APRIL in two different animal models of neuro-inflammation, one that mimics MS and another that mimics neuromyelitis optica. The group will test whether inhibition of BAFF and APRIL improves or worsens disease in these two animal models.
- ◆ Dr. Margarita Dominguez-Villar, associate research scientist, Department of Neurology at Yale School of Medicine (United States), received a grant to examine whether individuals with MS have an altered immune system that interferes with the function of regulatory T cells, which normally help dampen the immune response. The results could potentially help in the design of new therapeutic interventions that could restore their ability to block inflammation in patients with MS.
- ◆ Dr. Su Metcalfe, senior research associate, John van Geest Centre for Brain Repair at the University of Cambridge (UK), received a grant to investigate targeted nanotechnology as a means of delivering therapeutic agents to the brain to reduce inflammatory auto-immunity and to promote repair of myelin in MS.

The awards symposium was chaired by David Bates, Emeritus Professor of Clinical Neurology at the University of Newcastle upon Tyne (UK), and a member of the GMSI Scientific Committee.

"At Merck Serono, we believe that medical research to advance improved care for patients suffering from multiple sclerosis is a very worthy undertaking and deserves our support. We are thrilled to invest in the Grant for Multiple Sclerosis Innovation to further this cause," said Steven Hildemann, Chief Medical Officer, and head of Global Medical Affairs and Global Drug Safety at Merck Serono. "The second-year recipients of the GMSI will help us to continue accelerating exceptional science that demonstrates the potential to generate an innovative medicine or a high-value solution for people living with multiple sclerosis."

The GMSI was launched in October 2012 at the 28th ECTRIMS Congress with the aim of improving the understanding of MS for the ultimate benefit of those living with the disease. In 2013, more than 100 proposals were received from around the globe describing promising translational research projects, and four grant awards were shared among researchers from the United States and Germany. To date, these researchers have utilized this support to continue

gene expression patterns specific to MS.

The third call for proposals for the 2015 GMSI was made by Merck Serono at today's Satellite Symposium. More information about the GMSI can be found at the following website:

<http://www2.grantformultiplesclerosisinnovation.org/EMDSerono/index.html>

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responsible entrepreneurship. Holding an approximately 70 percent interest, the founding family remains the majority owner of the company to this day.

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EMD Serono and Sutro Biopharma to Partner on Development of Antibody Drug Conjugates

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- **EMD Serono to enhance its access to antibody drug conjugate technologies and to expand its oncology pipeline**
- **Sutro's Xpress CF and Xpress CF+ platforms to be utilized to develop antibody drug conjugates for multiple undisclosed targets**

Rockland, Massachusetts, Sept. 17, 2014 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, and Sutro Biopharma, San Francisco, a biopharmaceutical company developing antibody drug conjugates and bispecific antibodies, today announced a collaboration and license agreement to develop antibody drug conjugates (ADCs). ADCs are composed of an antibody linked to a cytotoxic drug. The antibody is thought to specifically target and deliver the cytotoxic drug to the cancer cells.

The collaboration will allow EMD Serono to take advantage of Sutro's technology platforms in its oncology programs to develop ADCs for multiple undisclosed targets. Both companies believe that ADCs have the potential for directly targeting cancer cells while safeguarding healthy tissue, and will combine EMD Serono's knowledge about target biology with Sutro's

may ultimately address the unmet needs of patients.

"We continue to explore opportunities that will allow us to better understand the potential ADCs have in directly targeting cancer cells," said Andree Blaukat, Senior Vice President and Head of Translational Innovation Platform Oncology at the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. "This collaboration with Sutro is reflective of our ongoing commitment to advancing innovation that may provide new therapies for patients."

"This partnership will help us to advance our position as a leading drug discovery partner to renowned pharmaceutical companies like EMD Serono," said William J. Newell, chief executive officer of Sutro. "Together with EMD Serono, we will further advance our efforts to develop antibody therapeutics, engineered to deliver a cytotoxic agent to cancer cells. Our technology has been developed to allow loading of an antibody with multiple different agents, and to enable a potential higher uptake of the drug in the tumor cell through an improved stability of the ADC."

Under the terms of the agreement, Sutro and EMD Serono will collaborate to discover and develop multiple ADCs utilizing Sutro's cell-free protein synthesis platforms, Xpress CF™ and Xpress CF+™. Sutro will be responsible for delivering ADCs for Phase I clinical trials. EMD Serono will be responsible for clinical development and commercialization of any resulting products.

EMD Serono will make an upfront payment to Sutro and will fund certain R&D activities. Sutro is also eligible to receive payments on completion of certain research, development and regulatory milestones potentially totaling approximately \$298 million as well as royalties on product sales. Further financial details are not being disclosed.

About Sutro Biopharma

Sutro Biopharma, located in South San Francisco, is developing a new generation of antibody drug conjugate therapeutics and bifunctional antibody-based therapeutics for targeted cancer therapies. These therapeutics may significantly extend the clinical impact of current oncology therapeutic approaches and are beyond what can be envisioned with current, cell-based expression technologies. Sutro's biochemical synthesis technology, which underpins these therapeutics, allows the rapid and systematic exploration of many protein drug variants to identify drug candidates. Once the product candidates are identified, production can be rapidly

protein synthesis platform. Sutro has formed multiple partnerships with biopharma companies utilizing its technology. For more information, visit www.sutrobio.com.

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a specialized biopharmaceutical company dedicated to developing therapies with groundbreaking potential. The company has strong market positions in neurology, endocrinology and in reproductive health. In addition, EMD Serono has an enduring commitment to solve the unsolvable, with state-of-the-art science dedicated to developing new therapies in our core focus areas of neurology, oncology, immuno-oncology and immunology. With a longstanding history of industry expertise and a dedication to shape the future of healthcare, the company's US footprint continues to grow, with approximately 1,000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com.

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EMD Serono Awards Grant for Growth Innovation (GGI) for the first time

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- ▶ **-The first grants awarded to coincide with the 53rd European Society for Paediatric Endocrinology (ESPE) Meeting**
- ▶ **-Investment supports innovative projects for the advancement of science and medical research in the field of growth**

Rockland, Massachusetts, Sept. 19, 2014 – EMD Serono, a subsidiary of Merck KGaA, Darmstadt, Germany, today announced the first recipients of the Grant for Growth Innovation (GGI) for 2014. The awards were announced during a Satellite Symposium organized by EMD Serono at the 53rd European Society for Paediatric Endocrinology (ESPE) Meeting currently taking place in Dublin, Ireland.

Sixty applications were received from 19 countries and reviewed by an independent Scientific Steering Committee composed of internationally renowned endocrinologists and chaired by Professor Christian Strasburger, Head of Clinical Endocrinology at the Charité Universitätsmedizin Berlin. Following a rigorous selection process three awards have been granted to support innovative projects in Sweden, the United Kingdom and the United States.

Leo Dunkel, MD, PhD

Title: Defining the role of fibroblast growth factor 21 (FGF21) in the pathogenesis of growth hormone resistance and subsequent growth failure in chronic childhood conditions.

Julian Lui Ph.D.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD),
Bethesda, MD, USA

Title: Cartilage-Targeted Therapeutics for Growth Disorders

Lars Sävendahl, MD, PhD

Karolinska Institute and University Hospital, Solna, Sweden

Title: Early prediction of long-term growth response to GH treatment; Evaluation of a newly developed technique based on magnetic resonance imaging of the tibia growth plate

“The Grant for Growth Innovation reflects EMD Serono’s commitment to innovation which we believe is the foundation of our efforts to advance new possibilities in the treatment of disorders of human growth,” said Steven Hildemann, Global Chief Medical Officer and Head of Global Medical Affairs and Global Drug Safety at the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. He added: “Identifying and supporting forward thinking researchers in the field of growth, helps us achieve our collective goal to advance our understanding of this therapeutic area and deliver better outcomes for patients living with growth disorders.”

Notes to editors Photos of the awards ceremony are available

<http://www.grantforgrowthinnovation.org>

EMD Serono announced the initiation of the GGI program in 2013 to support the advancement of understanding of the field of growth. A total grant of up to €400,000 will be awarded to one or more selected projects. Each application was blinded and evaluated by a Scientific Steering Committee composed of internationally renowned endocrinologists, according to five criteria: innovation; scientific rationale; clarity; feasibility; and impact of research. For further information about the GGI and how to apply for next year's grants, please visit <http://www.grantforgrowthinnovation.org>

About EMD Serono, Inc.

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a specialized biopharmaceutical company dedicated to developing therapies with groundbreaking potential. The company has strong market positions in neurology, endocrinology and in reproductive health. In addition, EMD Serono has an enduring commitment to solve the unsolvable, with state-of-the-art science dedicated to developing new therapies in our core focus areas of neurology, oncology, immuno-oncology and immunology. With a longstanding history of industry expertise and a dedication to shape the future of healthcare, the company's US footprint continues to grow, with approximately 1,000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

For more information, please visit www.emdserono.com.

About Merck KGaA, Darmstadt, Germany

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EMD Serono Announces Award of \$1.3 Million to the Winners of the first Grant for Oncology Innovation

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- ▶ **- Global winners selected for their unique research projects that have the potential to advance research for the personalized treatment of solid tumors**
- ▶ **- Winners chosen by a Scientific Steering Committee comprising internationally renowned oncologists and researchers**

PR Newswire
ROCKLAND

ROCKLAND, Mass., Sept. 27, 2014 /[PRNewswire](#)/ -- EMD Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, today announced the winners of the first Grant for Oncology Innovation (GOI), who will receive grants totaling \$1.3 million. The 2014 winners were formally announced at an awards ceremony coinciding with the annual meeting of the European Society for Medical Oncology (ESMO) 2014 in Madrid, Spain.

Launched in September 2013 at the European Cancer Congress (ECCO-ESMO-ESTRO) in Amsterdam, the GOI aims to support researchers who are leading innovative projects that have the potential to advance research for the personalized treatment of solid tumors.

- ◆ Access to personalized treatment/care for patients
- ◆ Innovative research with clinical relevance and benefits for patients
- ◆ Solid tumor malignancies

The international Scientific Steering Committee of leading oncologists and researchers selected the following winners:

Dr Clara Montagut, Hospital del Mar, Barcelona, Spain; for proposed research on *Ultra-selection and molecular monitoring of CRC patients treated with anti-EGFR therapy using NGS platforms and serial liquid biopsies*

Dr Stefan Sleijfer, Erasmus MC Cancer Institute, Rotterdam, Netherlands; for proposed research on *Non-invasive monitoring of breast cancer therapy using cell-free tumor DNA in blood*

Dr Ulrich Guller, Cantonal Hospital, St. Gallen, Switzerland; for the proposed project entitled: *Prospective, double-blinded, placebo-controlled, phase III randomized trial of adjuvant aspirin treatment in PIK3CA mutated colon cancer patients*

"I would like to congratulate the winners and their teams for the quality of their proposed research projects. In the last decade alone, innovative research in oncology has made a number of ground-breaking discoveries leading to a better understanding of individual tumor biology that has allowed for a personalized approach to patient care," said Belen Garijo, President and CEO of the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. "We hope that this first Grant for Oncology Innovation will help enable further pioneering research into the personalized treatment of cancer that may ultimately lead to improved clinical outcomes for patients."

The Grant for Oncology Innovation builds on the success of the Grant for Fertility Innovation (GFI), the Grant for Multiple Sclerosis Innovation (GMSI) and the Grant for Growth Innovation (GGI), which between them have awarded grants totaling over \$12 million to research projects since 2010.

For more information on GOI and details of how to apply of the 2015 award, please visit:

www.grantforoncologyinnovation.org

biopharmaceutical company dedicated to developing therapies with groundbreaking potential. The company has strong market positions in neurology, endocrinology and in reproductive health. In addition, EMD Serono has an enduring commitment to solve the unsolvable, with state-of-the-art science dedicated to developing new therapies in our core focus areas of neurology, oncology, immuno-oncology and immunology. With a long-standing history of industry expertise and a dedication to shape the future of healthcare, the company's US footprint continues to grow, with approximately 1,000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

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EMD Serono to Collaborate with The Institute of Cancer Research, London, and Wellcome Trust to Co-Develop Anti-Cancer Drugs

[EXPLORE MORE](#)

- ◆ **- Joint program to develop drug candidates for the treatment of different forms of cancer**
- ◆ **- Collaboration will be funded by EMD Serono and the Wellcome Trust**

Rockland, Massachusetts, October 07, 2014 – EMD Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, The Institute of Cancer Research (ICR), and the Wellcome Trust, London, today announced a co-development and license agreement building on two independent research programs at both the ICR and EMD Serono to identify inhibitors of tankyrase, an enzyme of the poly (ADP-ribose) polymerase family.

The collaboration will be jointly funded by EMD Serono and the Wellcome Trust. The existing drug discovery program at the ICR is supported by a Wellcome Trust Seeding Drug Discovery Award.

In a joint effort, a team led by Dr. Chris Lord and Professor Alan Ashworth at the ICR and a research group at EMD Serono will aim to progress chemical compounds that have emerged

development candidate, with the goal of bringing a new cancer therapeutic drug to patients.

Dr. Chris Lord, Team Leader in the Division of Breast Cancer Research at The Institute of Cancer Research, London, said: "Tankyrase inhibitors provide a unique opportunity to target one of the most common characteristics of cancer cells - their dependency on the so-called 'Wnt signaling' pathway. Both EMD Serono and the group at the ICR have already made notable progress in developing tankyrase inhibitors. Working with EMD Serono will allow us to jointly accelerate our program with the aim to ultimately make tankyrase inhibitors available to cancer patients."

"We are delighted to work together with Dr. Chris Lord and Professor Alan Ashworth. With this partnership, we aim to harness the already well advanced tankyrase programs at both ICR and EMD Serono and hope to ultimately translate these into novel treatment options for cancer patients. We will build on a joint compound base of potent tankyrase inhibitors and will leverage both sites' scientific knowledge about the 'Wnt pathway' that plays a major role in signal transduction for tumor growth", said Dr. Andree Blaukat, Head of the Oncology Translational Innovation Platform at the biopharmaceutical division of Merck KGaA. "The interest of the Wellcome Trust shows its belief in our researchers' scientific data. It also shows the importance of academiaindustry collaboration models in pharmaceutical development to progress the most promising investigational compounds into clinics with the aim of bringing them to patients."

"This agreement highlights the importance of translational funding, such as the awards provided under the Seeding Drug Discovery scheme, to reduce the risk of drug discovery programs so that they become attractive to partners who have the ability to bring a product to market", said Dr. Ted Bianco, Director of Innovations at the Wellcome Trust. "We welcome the strategic collaboration with EMD Serono, which brings together a world-leading academic drug discovery group, and an industry partner with such a strong commitment to oncology, to give the program the best possible chances of success."

Some of the most promising advances in cancer research have been small-molecule inhibitors which block the activity of members of the poly (ADP-ribose) polymerase (PARP) enzyme family, which includes the enzyme tankyrase. 1

Under the terms of the agreement, EMD Serono will make milestone payments based on achieving regulatory and sales goals plus royalty payments on net sales of future products

References

1. J.L. Riffell et al, Tankyrase-targeted therapeutics: expanding opportunities in the PARP family. Nat Rev Drug Discov. 2012 Dec;11(12):923-36. doi: 10.1038/nrd3868

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EMD Serono Awards Grant for Growth - Countdown for Accepting Applications

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- ▶ **- EMD Serono's Grant for Growth Innovations (GGI) supports innovative projects to advance understanding in the field of growth**
- ▶ **- Closing date for entries is January 6, 2015**
- ▶ **- Awardees will be announced at the European Society for Paediatric Endocrinology meeting in Barcelona, October 2015**

Rockland, Massachusetts, December 4, 2014 - EMD Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, reminded today that there is just one month remaining for scientists leading innovative research projects to apply for grants as part of the EMD Serono Grant for Growth Innovation (GGI). Grants totalling up to \$500,000 will be awarded to one or more selected projects.

EMD Serono is supporting innovative projects that have the potential to advance the understanding of science and medical research in the field of growth. In 2014, the company announced the first recipients of the GGI at the 53rd European Society for Paediatric Endocrinology (ESPE) meeting. The winners were from Sweden, the United Kingdom and the United States.

commitment to advancing the treatment of growth hormone deficiency. The Grant for Growth Innovation demonstrates our support for novel scientific proposals by researchers seeking to accelerate understanding of growth disorders, improve adherence and deliver better outcomes for patients.”

Applications close on January 6, 2015. For the first application, submissions must contain a letter of intent and a brief description of the research project. The applications will be evaluated by an independent Scientific Steering Committee of internationally renowned endocrinologists according to five criteria:

- Innovation
- Scientific rationale
- Clarity
- Feasibility
- Impact of research

Successful applicants will then have the opportunity to develop the full protocol for a second round of consideration. The winners will be announced in 2015 at the 54 th European Society for Paediatric Endocrinology meeting in Barcelona, which will be held 1 to 3 October, 2015.

More information is available at www.grantforgrowthinnovation.com.

About the Grant for Growth Innovation (GGI)

EMD Serono announced the initiation of the GGI program in 2013 to support the advancement of understanding of the field of growth. A total grant of up to \$500,000 will be awarded to one or more selected projects. Each application is blinded and evaluated by a Scientific Steering Committee composed of internationally renowned endocrinologists, according to five criteria: innovation; scientific rationale; clarity; feasibility; and impact of research. For further

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EMD Serono Continues Leadership Role in Product Integrity by Launching Product Tracking Program and Check My Meds TM Smartphone App

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- ◆ **-Program launched in advance of U.S. Drug Supply Chain Security Act deadlines**
- ◆ **-Check My Meds TM product verification app now available for download for U.S. patients**

Rockland, Massachusetts, December 10, 2014 – EMD Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, announced that it has serialized all of its major brands in the U.S., which helps patients and physicians to authenticate the company's medicines at the unit level. This new serialization initiative builds on the company's track record of product integrity and will launch in advance of requirements set forth in new legislation for pharmaceutical companies to serialize their prescription drug products at the unit level by 2017.

"EMD Serono has been a long-standing leader in product integrity and patient safety, and we believe that every biopharmaceutical company has a responsibility to work toward a

Administration's (FDA) upcoming requirement that drug companies include a unique serial number on each package of drugs dispensed by 2017."

In conjunction with completing its serialization initiative, EMD Serono also launched Check My Meds TM, a smartphone app that will put the power to verify medicines in the hands of EMD Serono's patients. The app is now available for free download in English on iOS and Android mobile phones.

"Counterfeit and compromised drugs have breached the U.S. drug supply numerous times over the past decade," said Allan Coukell, senior director for health programs at The Pew Charitable Trusts. "By serializing medicines three years in advance of statutory requirements to do so, EMD Serono has taken steps to increase security of the drug supply chain and protect patients."

Through the serialization initiative, all major EMD Serono brands, which include therapies for multiple sclerosis (MS), infertility, growth disorders and HIV-associated wasting, will have unique and randomized serial numbers that are generated and printed on each package during the production process. The Check My Meds TM app allows patients to check this serial number to verify the authenticity of their medication, and also link to mobile sites for EMD Serono's industry-leading patient support and access programs, including MS LifeLines®, Fertility Lifelines®, The Axis Center® and Connections for Growth®.

As a subsidiary of Merck KGaA, Darmstadt, Germany, one of the largest and oldest global pharmaceutical and chemical companies, EMD Serono leveraged the resources and expertise of its global organization to complete this initiative in advance of requirements set forth by new legislation in the Drug Supply Chain Security Act (DSCSA), which was enacted on November 27, 2013. The requirements of the DSCSA are enforced by the FDA.

EMD Serono has been a pioneer in serialization advocacy and action since 2002 with the implementation of its first secure distribution program.

About EMD Serono

EMD Serono, a subsidiary of Merck KGaA, Darmstadt, Germany, is a leading U.S. biopharmaceutical company focused exclusively on specialty care. For more than 40 years, EMD Serono has integrated cutting-edge science, innovative products and devices, and industry-leading patient support and access programs. EMD Serono has deep expertise in neurology,

employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

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