# EMD Serono and Opexa Amend Agreement to Support Ongoing Development of Tcelna (imilecleucel-T) for Multiple Sclerosis



**- Personalized immunotherapy Tcelna (imilecleucel-T), an investigational compound currently in a Phase IIb clinical study in patients with secondary progressive multiple sclerosis (SPMS), an area of high unmet medical need**

**- EMD Serono pays Opexa additional $3 million to support clinical study in patients with SPMS**

PR Newswire
ROCKLAND, Mass.

ROCKLAND, Mass., March 9, 2015 /PRNewswire/ -- EMD Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, announced today the execution of an amendment to its agreement with Opexa Therapeutics, Inc. for the development and commercialization of its investigational compound Tcelna® (imilecleucel-T).

"Tremendous progress has been achieved in the treatment of multiple sclerosis over the past two decades but there remains a high unmet medical need for certain areas of the disease," said Belen Garijo, Member of the Executive Board of Merck KGaA, Darmstadt, Germany and CEO Healthcare. "Building on our strong heritage in multiple sclerosis, we will continue to focus

support to Opexa to further develop Tcelna (imilecleucel-T) is another sign of our long-standing and continuing commitment to improving the lives of people living with multiple sclerosis."

A $3 million payment to Opexa will support the ongoing Phase IIb clinical study (Abili-T Trial) in patients with secondary progressive MS (SPMS). Tcelna (imilecleucel-T) has received Fast Track Designation from the United States Food and Drug Administration.

EMD Serono and Opexa entered into an agreement in February 2013, at which time Opexa received a $5 million upfront payment for granting an option to EMD Serono for the exclusive license of the Tcelna (imilecleucel-T) program for the treatment of MS. The option may be exercised prior to or upon completion of Opexa's ongoing Abili-T Trial. Top-line data is expected in the second half of 2016.

"We are very pleased with this show of support by EMD Serono towards Opexa's potential personalized immunotherapy," said Neil K. Warma, Opexa's President and Chief Executive Officer. "Our relationship with EMD Serono over the last two years has been productive and we are pleased to strengthen this relationship and expand our development efforts with them in the critical work we are doing in the field of multiple sclerosis. We continue to focus on the careful execution of our ongoing Abili-T Trial in SPMS patients and look forward to our continued collaboration with EMD Serono."

**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, 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**

Merck KGaA, Darmstadt, Germany is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six

KGaA, Darmstadt, Germany employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. The company operates as EMD Serono, EMD Millipore and EMD Performance Materials in Canada and the United States.

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# EMD Serono Announces Strategic Collaboration with Illumina for Diagnostics in Oncology



**-- Collaboration strengthens company's position as a leader in precision medicine in oncology**

PR Newswire
ROCKLAND, Mass.

ROCKLAND, Mass., March 10, 2015 /PRNewswire/ -- EMD Serono today announced that the biopharmaceutical business of Merck KGaA, Darmstadt, Germany has entered into a collaboration with Illumina, Inc. to expand the development of a universal next-generation sequencing-based oncology diagnostic for clinical trials of targeted cancer therapies.

Under the terms of the agreement, the companies will work together to develop assays that detect and simultaneously measure multiple genetic variants in a single tumor sample in a clinical trial setting. Illumina's successful regulatory track record was an important consideration in the collaboration, as next-generation sequencing platforms cleared by a regulatory agency could accelerate the development of an assay and facilitate the registration of a companion diagnostic.

several diagnostics," said Susan Herbert, Head of Global Business Development at the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. "This collaboration will strengthen the position of our company as a global leader in precision medicine in oncology."

The collaboration will include development of the diagnostic, worldwide regulatory approvals and global commercialization.

"This agreement is another step forward in realizing the promise of precision medicine," said Richard Klausner, M.D., Illumina's Chief Medical Officer. "There is a clear need to expand genetically-based clinical trials as a key approach for developing better treatments for cancer. We are very excited to work with our new partner on this endeavor."

This collaboration complements existing partnerships with the biopharmaceutical business of Merck KGaA, Darmstadt, Germany in the area of diagnostics, including Life Technologies and Dako, allowing the company to choose from a wide variety of technologies in implementing a precision medicine strategy.

**About EMD Serono**

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**Merck Group**

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science

of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

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# The Biopharmaceutical Business of Merck KGaA, Darmstadt, Germany, and Intrexon Announce Agreement for the Development and Commercialization of CAR-T Therapy

EXPLORE MORE

- **Chimeric Antigen Receptor T-cell (CAR-T) therapy enhances R&D technology portfolio of Merck KGaA, Darmstadt, Germany, in immunooncology**
- **Collaboration and license agreement will focus on developing a next generation CAR-T platform to generate several drug candidates**

Darmstadt, Germany, March 30, 2015 – The biopharmaceutical business of Merck KGaA, Darmstadt, Germany, and Intrexon Corporation (NYSE:XON), today announced an exclusive strategic collaboration and license agreement to develop and commercialize Chimeric Antigen Receptor T-cell (CAR-T) cancer therapies. This collaboration advances the comprehensive, science-driven strategy of Merck KGaA, Darmstadt, Germany, to develop innovative therapies that modulate the immune system's natural ability to fight tumors.

"The collaboration with Intrexon underlies the focus of Merck KGaA, Darmstadt, Germany, on innovation, and enhances its R&D technology portfolio in immunooncology," says Belen Garijo,

significantly evolve the way cancer is treated."

CAR-T cells are genetically engineered T-cells with synthetic receptors that recognize a specific antigen expressed on tumor cells. When CAR-T cells bind to a target, an immunological attack against the cancer cells is triggered.

Utilizing Intrexon's cell engineering techniques and RheoSwitch® platform, the collaboration aims to develop leading-edge products that empower the immune system in a regulated manner to overcome the current challenges of CAR-T therapy.

The agreement provides Merck KGaA, Darmstadt, Germany exclusive access to Intrexon's proprietary and complementary suite of technologies to engineer T-cells with optimized and inducible gene expression, as recently strengthened by a license agreement with the University of Texas MD Anderson Cancer Center.

Intrexon will be responsible for all platform and product development until IND filing. Merck KGaA, Darmstadt, Germany will nominate targets of interest for which CAR-T products will be developed. Merck KGaA, Darmstadt, Germany will also lead the IND filing and pre-IND interactions, clinical development and commercialization. In addition, Intrexon has the opportunity to explore targets independently, granting Merck KGaA, Darmstadt, Germany opt-in rights during clinical development.

"Merck KGaA, Darmstadt, Germany is an ideal partner in CAR-T for us because of their long-term perspective, extraordinary character, worldwide reach and commitment to leadership in immuno-oncology," says Randal J. Kirk, Chairman and CEO of Intrexon. "We look forward to working together to benefit patients through the creation of a leading franchise in this very promising field."

Under the terms of the agreement, Intrexon will receive an upfront payment of $115 million. For the first two targets of interest selected by Merck KGaA, Darmstadt, Germany, Intrexon will receive research funding and is eligible to receive up to $826 million development, regulatory and commercial milestones, as well as tiered royalties on product sales. In addition, Intrexon is also eligible to receive further payments upon achievement of certain technology development milestones.

About EMD Serono

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# EMD Serono Appoints Frederick E. Munschauer M.D., FAAN to Vice President of Medical Affairs, Neurology and Immunology



**- Experienced leader and expert clinician to deliver strong outcomes for patients in the areas of Neurology and Immunology**

ROCKLAND, Mass., April 1, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceuticals subsidiary of Merck KGaA, Darmstadt, Germany, announced today the appointment of Frederick E. Munschauer to Vice President of Medical Affairs, Neurology and Immunology. In this capacity, he will lead the medical affairs activities for clinical, commercial and business development projects and collaborations for Rebif® (interferon beta-1a) as well as the company's Immunology and Neurology pipeline.

Dr. Munschauer joins EMD Serono from Biogen, bringing more than 30 years of knowledge in the area of neurology, specifically multiple sclerosis.

"Dr. Munschauer brings an exceptional level of expertise to our medical affairs team and we are confident that with his leadership will be able to deliver even stronger outcomes for patients,"

the needs for physicians and payers in clinical medicine will bring added value to our ongoing neurology and immunology research and development efforts."

"EMD Serono has been a proven leader in the area of multiple sclerosis, and I look forward to contributing to their broader neurology and immunology efforts to bring innovative solutions to patients," Munschauer said.

Prior to joining EMD Serono, Dr. Munschauer served most recently as Chief Medical Advisor at Biogen Idec. During his tenure at Biogen Idec he also served as Head, US Medical Affairs and Head, Global Medical Affairs. Dr. Munschauer joined industry after a career in academic medicine where he was Professor and Chair of Neurology at the University of New York, Buffalo, and Director of the Jacobs Neurological Institute. In this capacity he oversaw the financial, clinical, and research activities of all aspects of neurology with specific centers for MS, stroke, movement disorders, cognitive disorders, epilepsy, sleep disorders, neuroimaging, and pediatric neurology. He also led multidisciplinary clinical trial operations conducting Phase I – IV trials, established and oversaw training programs for medical students, residents, fellow, and post-doctoral students, and created a stroke and vascular disease center of clinical research excellence, including both acute and preventive interventions. Dr. Munschauer has also held leadership roles on the National Board of Directors of the National MS Society, the Consortium of MS Centers, and the NY State MS Consortium.

Dr. Munschauer holds a Medical Degree from McGill University, Montreal, Quebec, and completed an internship and residency in internal medicine and a residence in neurology at The Johns Hopkins Hospital, Maryland. He also completed a fellowship in neurological and neurosurgical intensive care at The National Hospital for Nervous Disease, London, UK. Additionally, Dr. Munschauer received a B.S.E., Electrical Engineering, Mechanical Engineering, from Duke University, Durham, NC a M.Sc., Mechanical Engineering, Massachusetts Institute of Technology, Cambridge, MA.

As part of the global biopharmaceuticals business of Merck KGaA, Darmstadt, Germany, EMD Serono has ongoing MS clinical programs, including ATX-MS-1467, an investigational therapy for RRMS, and imilecleucel-T, an investigational therapy for Secondary Progressive MS (SPMS). (The company has an option agreement for the development and commercial licensing of imilecleucel-T.) In Discovery, its Immunology group will evaluate opportunities with the goal of advancing new immune-based therapies for MS and other immune diseases. EMD Serono

EMD Serono's well-established treatment for relapsing MS, Rebif® (interferon beta-1a), has been used by patients for more than a decade and is registered in more than 90 countries around the world. The company continues to advance its understanding of the clinical benefit of Rebif (interferon beta-1a) including real world evidence through ongoing and newly implemented Phase IV and investigator initiated studies. EMD Serono remains committed to the MS community by providing education and support to people living with relapsing MS, through our MS LifeLines program, as well as through our grants program which funds and supports promising advancements in MS.

**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 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

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 Launches 11th Edition of The EMD Serono Specialty Digest™ at Annual Meeting of The Academy of Managed Care Pharmacy

EXPLORE MORE

ROCKLAND, Mass., April 6, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceuticals subsidiary of Merck KGaA, Darmstadt, Germany, today announced the launch of the 11th edition of the EMD Serono Specialty Digest™ at the 27th Annual Meeting of The Academy of Managed Care Pharmacy (AMCP) in San Diego, CA. The Digest is an educational resource that provides market data on health plans' management of specialty pharmaceuticals in 2014 and identifies common trends occurring across plans. The Digest is available to those who request a copy at http://www.specialtydigest.emdserono.com.

The 11th edition of the EMD Serono Specialty Digest™ includes data from 70 commercial health plans across the country, representing more than 100 million covered lives. This year's Digest has been enhanced to reflect current opportunities, challenges, and solutions to specialty drug management, including new topics regarding benefit design, medical provider reimbursement and management, and analysis of the top therapy categories driving specialty drug costs (oncology, immune modulators, multiple sclerosis and hepatitis C).

specialty pharmacy network contract rate, and traditional utilization management. This year's Digest highlights a new focus on coordinating strategies across the pharmacy and medical benefits, directing members to the lowest cost site of care, measuring the value of therapy, realigning provider incentives, educating members about their health care choices, and reducing administrative burden through the adoption of vendor partnerships and new technologies.

"The 11th edition of the EMD Serono Specialty Digest highlights some important trends in specialty drug management today as well as expectations for management in the future," said Allene Diaz, Senior Vice President, Managed Markets, EMD Serono. "As a leader in specialty care, we are committed to partnering with our customers to improve patient outcomes and trust that the Specialty Digest will provide valuable information on how to attain this goal."

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

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

**About EMD Serono**

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**Merck KGaA, Darmstadt, Germany**

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# Global Strategic Partners Merck KGaA, Darmstadt, Germany, and Pfizer Finalize Agreement to Co-Promote XALKORI® (crizotinib)

EXPLORE MORE

**-In the second and third quarters of 2015, Merck KGaA, Darmstadt, Germany, and Pfizer will begin co-promoting XALKORI in the United States, Canada, Japan and five European Union countries (France, Germany, Italy, Spain and the United Kingdom)**

**-In the United States and Canada, XALKORI will be co-promoted by EMD Serono, the US and Canadian biopharmaceutical businesses of Merck KGaA, Darmstadt, Germany**

**-Co-promotion of XALKORI allows the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer to establish a combined oncology sales organization in key markets for the program**

Darmstadt, Germany, and New York, US, April 7, 2015 – Merck KGaA, Darmstadt, Germany, and Pfizer Inc, New York, US, today announced the finalization of the copromotion agreement allowing the companies to co-promote Pfizer's anaplastic lymphoma kinase (ALK) inhibitor XALKORI® (crizotinib). This agreement showcases the alliance's commitment to establishing a combined oncology sales organization in key markets in advance of the potential launch of avelumab*-based treatment regimens in the future.

positive advanced non-small cell lung cancer (NSCLC) treatment settings. To date, globally more than 8,000 patients have been treated with XALKORI, including those who received XALKORI in clinical trials.

Under the agreement, XALKORI will be co-promoted in two waves, the first of which will begin in the second and third quarters of 2015 in the United States, Canada, Japan and five European Union countries (France, Germany, Italy, Spain and the United Kingdom). In the United States and Canada, XALKORI will be co-promoted by EMD Serono, the US and Canadian biopharmaceutical businesses of Merck KGaA, Darmstadt, Germany. The second wave will begin in 2016 and includes China and Turkey.

In 2015, Merck KGaA, Darmstadt, Germany, will receive a reimbursement associated with its promotion of XALKORI, followed by an 80 percent (Pfizer), 20 percent (Merck KGaA, Darmstadt, Germany) profit sharing on the product starting in 2016. The copromotion term will last through December 31, 2020 for the United States, Canada, Japan, France, Germany, Italy, Spain and the United Kingdom, and from January 1, 2016 through December 31, 2021 in China and Turkey. Pfizer will report the sales of XALKORI in countries where it is co-promoted with Merck KGaA, Darmstadt, Germany.

"We are proud and excited to share the legacy of XALKORI, a medicine that changed the treatment paradigm for patients with ALK-positive metastatic NSCLC, with Merck KGaA, Darmstadt, Germany," said Liz Barrett, President and General Manager, Pfizer Oncology. "Through our co-promotion of XALKORI, we will establish a best-in-class global sales organization that will be exceptionally prepared for the potential launches of our future oncology medicines."

"As we progress our robust program to co-develop and co-commercialize avelumab, the co-promotion agreement is an exciting milestone for the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer, allowing us to establish our combined oncology sales organization in key markets for the program," said Dr. Andrew Schiermeier, Head of Global Oncology and General Manager for the Alliance for Merck KGaA, Darmstadt, Germany, adding: "For Merck KGaA, Darmstadt, Germany, this agreement is particularly important as it accelerates the establishment of our United States and Canada oncology sales organization ahead of our potential avelumab launches and positions us for future success in this market."

commercialize avelumab, an investigational anti-PD-L1 monoclonal antibody, to accelerate the development of immuno-oncology medicines for patients with cancer. The immuno-oncology alliance will also advance Pfizer's PD-1 antibody.

*Avelumab is the proposed International Nonproprietary Name (INN) for the anti-PD-L1 monoclonal antibody (MSB0010718C)

About Non-small Cell Lung Cancer

Globally, lung cancer is the most common cause of cancer-related deaths in men and the second most common in women, responsible for almost twice as many deaths as both breast and prostate cancer combined1 . Non-small cell lung cancer is the most common type of lung cancer, accounting for 85 to 90 percent of all lung cancers2 . Locally advanced and metastatic disease account for approximately 35 to 40 percent3 and 70 percent4 of patients, respectively with NSCLC.

About XALKORI® (crizotinib)

XALKORI is a kinase inhibitor indicated in the US for the treatment of patients with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The US indication is not limited to any specific line of therapy. In the EU, XALKORI is indicated for the treatment of adults with previously treated ALK-positive advanced NSCLC. XALKORI has received approval in more than 80 countries.

XALKORI® Important Safety Information

Hepatotoxicity: Drug-induced hepatotoxicity with fatal outcome occurred in 0.2% of patients treated with XALKORI across clinical trials (n=1225). Transaminase elevations generally occurred within the first 2 months of treatment. Monitor with liver function tests including ALT and total bilirubin every 2 weeks during the first 2 months of treatment, then once a month and as clinically indicated. Permanently discontinue for ALT or AST elevation greater than 3 times ULN

Pneumonitis: Severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis can occur in patients treated with XALKORI. Across clinical trials (n=1225), 2.5% of XALKORI-treated patients had any grade ILD, 0.9% of patients had Grade 3 or 4, and 0.5% had fatal cases. These cases generally occurred within 2 months after the initiation of treatment. Monitor patients for pulmonary symptoms indicative of pneumonitis. Exclude other causes and permanently discontinue XALKORI in patients with drug related pneumonitis.

QT Interval Prolongation: QTc prolongation can occur in patients treated with XALKORI. Across clinical trials (n=1225), QTc prolongation (all grades) was observed in 2.7% of patients and QTc greater than 500 ms on News Release 4 at least 2 separate ECGs occurred in 1.4% of patients. Avoid use of XALKORI in patients with congenital long QT syndrome. Consider periodic monitoring with electrocardiograms and electrolytes in patients who have a history of or predisposition for QTc prolongation, or who are taking medications that prolong the QT interval. Permanently discontinue XALKORI in patients who develop QTc greater than 500 ms or greater than or equal to 60 ms change from baseline with Torsade de pointes, polymorphic ventricular tachycardia, or signs/symptoms of serious arrhythmia, otherwise temporarily suspend and dose reduce XALKORI as indicated.

Bradycardia: Symptomatic bradycardia can occur in patients receiving XALKORI. Across clinical trials, bradycardia with a heart rate less than 50 beats per minute occurred in 11% of patients treated with XALKORI (n=1174). Monitor heart rate and blood pressure regularly. Avoid using XALKORI in combination with other agents known to cause bradycardia to the extent possible. Permanently discontinue for lifethreatening bradycardia due to XALKORI; however, if associated with concomitant medications known to cause bradycardia or hypotension, hold XALKORI until recovery to asymptomatic bradycardia or to a heart rate of 60 bpm or above. If concomitant medications can be adjusted or discontinued, restart XALKORI at 250 mg once daily with frequent monitoring. Otherwise temporarily suspend and resume or dose reduce XALKORI as indicated.

Embryofetal Toxicity: XALKORI can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving XALKORI. If the patient or their partner becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus.

reactions were reported in 37.2% patients treated with XALKORI. The most frequent serious adverse reactions reported in patients treated with XALKORI were pneumonia (4.1%), pulmonary embolism (3.5%), dyspnea (2.3%), and ILD (2.9%). Fatal adverse reactions in XALKORI-treated patients occurred in 9 (5%) patients, consisting of: acute respiratory distress syndrome, arrhythmia, dyspnea, ILD, pneumonia, pneumonitis, pulmonary embolism, respiratory failure, and sepsis. Common adverse reactions occurring in ≥25% included vision disorder (diplopia, photophobia, photopsia, vision blurred, visual acuity reduced, visual impairment, vitreous floaters), diarrhea, nausea, vomiting, constipation, edema, decreased appetite, fatigue, upper respiratory infection, and dysgeusia. Grade 3 or 4 events occurring at a higher incidence with XALKORI than with chemotherapy and at greater than 2% incidence were syncope (3%), QT prolongation (3%), and pulmonary embolism (5%). Elevation of ALT of any grade occurred in 76% of patients and grade 3 or 4 in 17% of patients. Neutropenia of any grade occurred in 49% of patients and grade 3 or 4 in 12% of patients. Lymphopenia of any grade occurred in 51% of patients and grade 3 or 4 in 9% of patients. Renal cysts occurred in 4% and neuropathy in 19% of patients treated with XALKORI.

Drug Interactions: Exercise caution with concomitant use of moderate CYP3A inhibitors. Avoid grapefruit or grapefruit juice which may increase plasma concentrations of crizotinib. Avoid concomitant use of strong CYP3A inducers and inhibitors. Dose reduction may be needed for coadministered drugs that are predominantly metabolized by CYP3A.

Nursing Mothers: Given the potential for serious adverse reactions in nursing infants, consider whether to discontinue nursing or discontinue XALKORI. Hepatic Impairment: XALKORI has not been studied in patients with hepatic impairment. As crizotinib is extensively metabolized in the liver, hepatic impairment is likely to increase plasma Crizotinib concentrations. Use caution in patients with hepatic impairment.

Renal Impairment: Administer XALKORI at a starting dose of 250 mg taken orally once daily in patients with severe renal impairment (CLcr<30 mL/min) not requiring dialysis. No starting dose adjustment is needed for patients with mild and moderate renal impairment.

For more information and full prescribing information, please visit www.XALKORI.com.

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

US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an investigational anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The companies will collaborate on up to 20 high priority immuno-oncology clinical development programs, including combination trials, many of which are expected to commence in 2015.

Pfizer Inc.: Working together for a healthier world®

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

Merck KGaA, Darmstadt, Germany

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt,

Performance Materials.

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

Pfizer Disclosure Notice

The information contained in this release is as of April 7, 2015. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about an agreement between Pfizer and Merck KGaA, Darmstadt, Germany, to co-promote Pfizer's XALKORI in certain markets as well as about the companies' immuno-oncology alliance involving avelumab and Pfizer's anti-PD-1 antibody and clinical development plans, including their potential benefits, that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the success of the co-promotion arrangement and whether the companies will realize the anticipated benefits of the co-promotion arrangement; the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates as well as the possibility of unfavorable study results; risks associated with interim data, including the risk that the final results of the Phase I study for avelumab and/or additional clinical trials may be different from (including less favorable than) the interim data results and may not support further clinical development; the risk that clinical trial data are subject to differing interpretations, and, even when we view data as sufficient to support the safety and/or effectiveness of a product candidate, regulatory authorities may not share our views and may require additional data or may deny approval altogether; whether and when drug applications may be filed in any jurisdictions for any potential product candidates or combination therapies; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by

competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

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# Alise Reicin Joins the Biopharmaceutical Business of Merck KGaA, Darmstadt, Germany as Head of Global Clinical Development



**- Reicin brings extensive experience in R&D as a senior leader in biopharma**
**- Reicin will serve as a member of the R&D Executive Leadership Team**

(1)

ROCKLAND, Mass., April 16, 2015 /PRNewswire/ -- EMD Serono today announced the US biopharmaceutical business of Merck KGaA, Darmstadt, Germany, appointed Alise Reicin, MD, as Senior Vice President, Head of Global Clinical Development.  Dr. Reicin brings extensive research and early/late clinical development expertise, including experience in Oncology and Immunology. She is an accomplished pharmaceutical executive with strong leadership ability, having served as a Vice President in various capacities across R&D at MSD (Merck Sharp & Dohme) for the last 10 years.

In her role as Head of Global Clinical Development, Reicin will oversee the Clinical Development organization, including the Clinical Development Therapeutic Areas; Evidence Value and

biopharmaceutical business of Merck KGaA, Darmstadt, Germany's portfolio of pipeline programs.

"We are honored to have Alise join us," says Luciano Rossetti, Head of Global Research and Development. "Her impressive experience across diverse areas of clinical research and operations will bring significant value to our organization. She is an accomplished executive whose leadership will serve to significantly advance our clinical development efforts and our strong commitment to enhance our R&D operating model."

Reicin's experience complements the R&D strategy of the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, which focuses on the core therapeutic areas of oncology, immuno-oncology and immunology with several high-priority programs in late development, such as evofosfamide (TH-302) and avelumab (anti-PD-L1), as well as a number of promising early-stage assets.

In the past, Alise served as Vice President, Project and Pipeline Leadership, Oncology Franchise at MSD. In this capacity, she led MSD's PD-1 program and oversaw the initial development and filing activities worldwide, including the first approval in the US.  She also managed program leaders across early and late oncology product development teams. During her tenure at MSD, she held roles of increasing responsibility in R&D, including Vice President and Therapeutic Area Head (Bone, Respiratory, Immunology and Endocrinology); Vice President, Research & Early Development (Bone, Respiratory, Immunology and Endocrinology Franchise Integrator); Vice President, Strategic Realization Office; Vice President and Therapeutic Area Head (Clinical Immunology & Analgesia); and Head of a Transformation Task Force for late clinical development.

Before joining MSD, Reicin was a faculty member at Columbia Medical School, and a physician and researcher at Columbia Presbyterian Hospital.

Reicin has a degree in biochemistry from Barnard College of Columbia University. She received her Medical Degree from Harvard Medical School, where she was enrolled in the Health Sciences and Technology program with MIT (Massachusetts Institute of Technology).

Billerica, MA.

**EMD Serono**

EMD Serono, 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

**Merck KGaA, Darmstadt, Germany**

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany, holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

Cory Tromblee
Phone: 781.681.2393

Photo - http://photos.prnewswire.com/prnh/20150415/198968

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# EMD Serono Highlights Scientific Commitment to MS with Data Presented at the AAN Annual Meeting



**- Data analyses in relapsing MS highlight MRI outcomes and 'no evident disease activity' (NEDA) measure for Rebif® (interferon beta-1a) vs. Avonex® (interferon beta-1a)**

(1)

ROCKLAND, Mass., April 16, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceuticals business of Merck KGaA, Darmstadt, Germany, announced today that data about Rebif® (interferon beta-1a), the company's high-dose, high-frequency interferon for relapsing forms of multiple sclerosis, will be presented at the American Academy of Neurology's 67th Annual Meeting, taking place from April 18 - 25, in Washington, D.C.

Data from 13 abstracts to be presented at AAN assess the clinical effect of Rebif on NEDA and MRI outcomes, among other measures. The data also explore trends in treatment adherence among patients treated with self-injectables versus oral therapies, and barriers to adherence in those living with MS.

said Dr. Rick Munschauer, Vice President, Medical Affairs, Neurology and Immunology, EMD Serono. "These data presented at AAN continue to advance our understanding of the important clinical effects of Rebif."

In addition to Rebif, EMD Serono is engaged in strategic research collaborations funding promising neurology research with leading academic and healthcare institutions. The company also has ongoing MS clinical study programs, including a Phase I study of ATX-MS-1467, an investigational therapy for relapsing remitting multiple sclerosis (RRMS), and a Phase IIb study of imilecleucel-T, an investigational therapy for Secondary Progressive MS (SPMS), an area of high unmet medical need. The company has an option agreement with Opexa Therapeutics, Inc. for the development and commercial licensing of imilecleucel-T.

The following abstracts have been accepted for presentation at the 67th AAN Annual Meeting:

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| **Title** | **Lead author** | **Abstract/ Poster #** | **Presentation date/time (CDT)** | **Session** | **Room/ Details** |
|---|---|---|---|---|---|
| Effect of Age and Sex on Cost of Multiple Sclerosis–Related Relapse Defined by Inpatient Stays | Chris M. Kozma | *P1.136* | *April 20, 2015 2:00 pm* | Poster Session I: MS and CNS Inflammatory Diseases: Symptoms, Specific Symptomatic Treatment, Co-morbidities, and Costs (2:00-6:30 pm) | Hall E |
| Quality of Life Perceptions | Barbara Teter | *P1.113* | *April 20, 2015 2:00 pm* | Poster Session I: Neuroepidemiology: | Hall E |

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| Clinical Relapse Reduction Metrics in Patients Treated with Subcutaneous Interferon beta-1a Given Three Times a Week (collaboration with New York State MS Consortium (NYSMSC) | | | | Diseases (2:00-6:30 pm) | |
| Relationship between Cognitive Status and Perception of Ease of Use of an Electronic Autoinjector for Subcutaneous Interferon Beta-1a | Ajay Gupta | *P3.225* | *April 21, 2015 2:00 pm* | Poster Session III: MS and CNS Inflammatory Diseases: Tools for Clinical Assessment and Therapeutic Response (2:00-6:30 pm) | Hall E |
| Post-Marketing | Meredith Y. Smith | *P3.268* | *April 21, 2015 2:00 pm* | Poster Session III: MS and CNS | Hall E |

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| beta-1a SC in Patients with Multiple Sclerosis Treated in the US: a Retrospective Cohort Study | | | | Treatment Efficacy, Safety and Tolerability (2:00-6:30 pm) | |
| An Assessment of Adherence Among MS Patients Newly Initiating Treatment with a Self-injectable vs Oral Disease-Modifying Drug | Julie C. Locklear | *P3.281* | *April 21 2015, 2:00 pm* | Poster Session III: MS and CNS Inflammatory Diseases: Treatment Efficacy, Safety and Tolerability (2:00-6:30 pm) | Hall E |
| A Pragmatic Literature Review of Network Meta-Analyses of Disease-Modifying Drugs in the | Amy Phillips | *P3.232* | *April 21, 2015 2:00 pm* | Poster Session III: MS and CNS Inflammatory Diseases: Tools for Clinical Assessment and Therapeutic Response (2:00-6:30 pm) | Hall E |

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| An Exploratory Analysis of Predictors of Disease-Modifying Drug Adherence Using Data from a Panel Survey of Patients with Multiple Sclerosis | Julie C.Locklear | *P3.217* | *April 21, 2015 2:00 pm* | Poster Session III: MS and CNS Inflammatory Diseases: Tools for Clinical Assessment and Therapeutic Response (2:00-6:30 pm) | Hall E |
| Early Effects of Interferon beta-1a SC tiw Versus Interferon beta-1a IM qw on MRI Outcomes in Patients with Relapsing MS in the EVIDENCE Study | Anthony T. Reder | *P7.257* | *April 23, 2015 2:00 pm* | Poster Session VII: MS and CNS Inflammatory Diseases: Clinical Trials (2:00-6:30 pm) | Hall E |
| No Evidence of Disease | Patricia Coyle | *P7.220* | *April 23, 2015 2:00 pm* | Poster Session VII: MS and CNS | Hall E |

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| Relapsing MS Treated with Interferon beta-1a SC tiw Versus Interferon beta-1a IM qw in the EVIDENCE Study | | | | Trials (2:00-6:30 pm) | |
| No Evidence of Disease Activity in Patients with Relapsing MS Treated with Interferon Beta-1a SC tiw versus Interferon Beta-1a IM qw: Subgroup Analyses of the EVIDENCE Study | Juanzhi Fang | *P7.271* | *April 23, 2015 2:00 pm* | Poster Session VII: MS and CNS Inflammatory Diseases: Clinical Trials (2:00-6:30 pm) | Hall E |
| 1-Year Efficacy and Tolerability Results for IFN beta-1a | Mark Cascione | *P7.242* | *April 23, 2015 2:00 pm* | Poster Session VII: MS and CNS Inflammatory Diseases: Clinical | Hall E |

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| and Predictive Value of 6-Month MRI: Exploratory Analysis of PRISMS Data in Patients with RRMS | | | | | |
| Early Onset and Predictive Value of MRI Measures Among Patients Receiving Interferon beta-1a SC tiw for RRMS: Post Hoc Analyses of PRISMS-2 Data | David Li | *P7.254* | *April 23, 2015 2:00 pm* | Poster Session VII: MS and CNS Inflammatory Diseases: Clinical Trials (2:00-6:30 pm) | Hall E |
| Development of Chronic Black Holes (CBH) Predicts Long Term Disability: Post-Hoc Analysis of | Tony Traboulsee | *P7.251* | *April 23, 2015 2:00 pm* | Poster Session VII: MS and CNS Inflammatory Diseases: Clinical Trials (2:00-6:30 pm) | Hall E |

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| Imaging (MRI) Data in the PRISMS Study (collaboration with Merck Serono, Global Medical) | | | | | |

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

Avonex® (interferon beta-1a) is a registered trademark of Biogen Inc.

**About Rebif® (interferon beta-1a)**
Rebif (interferon beta-1a) is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS.

**Important Safety Information**
Before beginning treatment, you should discuss the potential benefits and risks associated with Rebif with your healthcare provider.

Rebif can cause serious side effects. Tell your healthcare provider right away if you have any of the symptoms listed below while taking Rebif.

- Behavioral health problems including depression and suicidal thoughts. You may have mood problems including depression (feeling hopeless or feeling bad about yourself), and thoughts of hurting yourself or suicide
- Liver problems or worsening of liver problems including liver failure. Symptoms may include nausea, loss of appetite, tiredness, dark colored urine and pale stools, yellowing of your skin or the white part of your eye, bleeding more easily than normal, confusion, and

- Serious allergic and skin reactions. Symptoms may include itching, swelling of your face, eyes, lips, tongue or throat, trouble breathing, anxiousness, feeling faint, skin rash, hives, sores in your mouth, or skin blisters and peels
- Injection site problems. Symptoms at the injection site may include redness, pain, swelling, color changes (blue or black), and drainage of fluid.
- Blood problems. Rebif can affect your bone marrow and cause low red and white blood cell, and platelet counts. In some people, these blood cell counts may fall to dangerously low levels. If your blood cell counts become very low, you can get infections and problems with bleeding and bruising. Your healthcare provider may ask you to have regular blood tests to check for blood problems
- Seizures. Some people have had seizures while taking Rebif

Rebif will not cure your MS but may decrease the number of flare-ups of the disease and slow the occurrence of some of the physical disability that is common in people with MS.

Do not take Rebif if you are allergic to interferon beta, human albumin, or any of the ingredients in Rebif.

Before you take Rebif, tell your healthcare provider if you have or have had any of the following conditions:

- mental illness, including depression and suicidal behavior
- liver problems, bleeding problems or blood clots, low blood cell counts, seizures (epilepsy), or thyroid problems
- drink alcohol
- you are pregnant or plan to become pregnant. It is not known if Rebif will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with Rebif.
- you are breastfeeding or plan to breastfeed. It is not known if Rebif passes into your breast milk. You and your healthcare provider should decide if you will use Rebif or breastfeed. You should not do both.

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

The most common side effects of Rebif include:

reducers. For many people, these symptoms lessen or go away over time. Symptoms may include muscle aches, fever, tiredness, and chills
- stomach pain
- change in liver blood tests

For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional.

**About EMD Serono**

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For more information, please visit www.emdserono.com

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# Global Strategic Partners Merck KGaA, Darmstadt, Germany, and Pfizer Initiate Phase III Study with Avelumab* in Patients with Stage IIIb/IV Non-Small Cell Lung Cancer



- **-First of several registration trials expected to start in 2015 for the alliance between Merck KGaA, Darmstadt, Germany, and Pfizer**
- **-Initiation and first patient treated in Phase III clinical study recruiting across approximately 290 sites in more than 30 countries**
- **-The primary endpoint of the study is overall survival (OS) in patients with programmed death-ligand 1 positive (PD-L1+) stage IIIb/IV non-small cell lung cancer (NSCLC) who have experienced disease progression after receiving a prior platinum-containing doublet therapy**

Darmstadt, Germany, and New York, US, April 20, 2015 – Merck KGaA, Darmstadt, Germany, and Pfizer Inc, New York, US, today announced the initiation and first patient treated in the international Phase III study (EMR 100070-004) designed to assess the efficacy and safety of the investigational cancer immunotherapy avelumab (MSB0010718C), compared with docetaxel, in

The Phase III study is an open-label, multicenter, 1:1 randomized clinical trial where patients with stage IIIb/IV NSCLC will receive either avelumab or docetaxel, regardless of PD-L1 status.

Approximately 650 patients will participate across 290 sites in more than 30 countries in North America, South America, Asia, Africa and Europe. In North America, clinical trials on behalf of Merck KGaA, Darmstadt, Germany, will be conducted by EMD Serono, the company's US and Canadian biopharmaceutical businesses. The study is part of the JAVELIN clinical trial program for avelumab.

The primary endpoint of the study is overall survival (OS) in patients with programmed deathligand 1 positive (PD-L1+) stage IIIb/IV NSCLC who have experienced disease progression after receiving a prior platinum-containing doublet therapy. Secondary endpoints will be assessed across the entire study population regardless of PD-L1 status and include OS; overall response rate (ORR); progression-free survival (PFS); and patient-reported outcomes.

"New and innovative treatment strategies are urgently needed to improve overall survival for patients with NSCLC, and we are investigating avelumab as a potential treatment option for patients with this very difficult-to-treat disease," said Dr. Luciano Rossetti, Global Head of R&D of the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. "The treatment of the first patient in the Phase III trial is an important milestone for our immuno-oncology alliance."

"This trial marks the first of several registration studies we are planning to initiate this year together, and underscores our commitment to accelerating the development of medications for patients with cancer," said Dr. Mace Rothenberg, Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer for Pfizer Oncology. "Through this alliance, we will have the opportunity to combine the promising anti-PD-L1 antibody, avelumab, with our combined portfolios of approved and investigational oncology therapies, which may provide an exciting opportunity to potentially broaden the use of immunotherapy for patients with cancer."

The JAVELIN clinical trial program also includes an international Phase II trial to investigate avelumab in patients with metastatic Merkel cell carcinoma; an international Phase I trial to investigate avelumab in patients with metastatic or locally advanced solid tumors, and a Phase I trial to investigate avelumab in Japanese patients with metastatic or locally advanced solid tumors with an expansion part in Asian patients with gastric cancer. The Phase I program for avelumab includes more than 840 patients treated across multiple tumor types, including

*Avelumab is the proposed International Nonproprietary Name (INN) for the anti-PD-L1 monoclonal antibody (MSB0010718C)

About Non-Small Cell Lung Cancer

Globally, lung cancer is the most common cause of cancer-related deaths in men and the second most common in women, responsible for almost twice as many deaths as both breast and prostate cancer combined1 . NSCLC is the most common type of lung cancer, accounting for 85 to 90 percent of all lung cancers 2 . Locally advanced and metastatic disease account for approximately 35 to 40 percent3 and 70 percent4 of patients, respectively with NSCLC.

Avelumab

Avelumab (also known as MSB0010718C) is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody. By inhibiting PD-L1 interactions, avelumab is thought to enable the activation of T-cells and the adaptive immune system. By retaining a native Fc-region, avelumab is thought to engage the innate immune system and induce antibodydependent cell-mediated cytotoxicity (ADCC). In November, 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

JAVELIN Clinical Trial Program for Avelumab

JAVELIN is an expansive international clinical trial program exploring the use of PD-L1 inhibition with avelumab to treat multiple types of cancer. The JAVELIN clinical trial program includes a Phase III study designed to assess the efficacy and safety of avelumab compared with docetaxel in patients with stage IIIb/IV NSCLC who have experienced disease progression after receiving a prior platinum-containing doublet therapy; an international Phase II open-label multicenter trial to investigate the clinical activity and safety of avelumab in patients with metastatic Merkel cell carcinoma; an international Phase I open-label, multiple ascending dose trial to investigate the safety, tolerability, pharmacokinetics, biological and clinical activity in patients with metastatic or locally advanced solid tumors; and a Phase I trial to investigate the tolerability, safety,

cancer.

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

US Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc, New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an investigational antiPD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The companies will collaborate on up to 20 high priority immuno-oncology clinical development programs, including combination trials, many of which are expected to commence in 2015.

Pfizer Inc.: Working together for a healthier world®

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

Merck KGaA, Darmstadt, Germany

businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

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

Pfizer Disclosure Notice The information contained in this release is as of April 20, 2015. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's and Merck KGaA, Darmstadt, Germany's immunooncology alliance involving anti-PD-L1 and anti-PD-1 therapies, clinical development plans and a target indication for avelumab (MSB0010718C) for treatment of patients with stage IIIb/IV NSCLC who have experienced disease progression after receiving a prior platinum-containing doublet therapy (the "Target Indication") that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical study commencement and completion dates as well as the possibility of unfavorable study results; risks associated with interim data, including the risk that the final results of the Phase I study for avelumab and/or additional clinical trials may be different from (including less favorable than) the interim data results and may not support further clinical development; the risk that clinical trial data are subject to differing interpretations, and, even when we view data

altogether; whether and when drug applications may be filed in any jurisdictions for any potential product candidates or combination therapies, including the Target Indication; whether and when any such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefitrisk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of any of such product candidates or combination therapies, including the Target Indication; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

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



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# Remembering Thorsten Eickenhorst, MD, PhD



**March 30, 1962 - April 18, 2015**

Thorsten Eickenhorst, MD, Chief Medical Officer and Senior Vice President, EMD Serono, passed away peacefully in his sleep on April 18, 2015. With his passing, EMD Serono, Merck KGaA, Darmstadt, Germany, and the international medical community lost an esteemed colleague and friend. Dr. Eickenhorst was appointed Chief Medical Officer and Senior Vice President of EMD Serono in July 2012.

During his tenure at the company, Dr. Eickenhorst made significant contributions as a member of the US Executive Team as well as Global Development and Medical Leadership Teams. He has been a leader in advancing the company's scientific and medical efforts on behalf of patients and physicians across our therapeutic areas. A respected member of the international medical community, Dr. Eickenhorst's dedication and work has substantially contributed to bringing solutions to patients in need, particularly those living with multiple sclerosis. He leaves a legacy of lasting impact.

He served as Vice President of Clinical Development, Vice President, Global Head of Medical Affairs, and Vice President, US Medical Affairs. Prior to Biogen he held increasing levels of responsibility in business development, clinical research and medical affairs at Amgen and Schwartz pharmaceuticals both in Europe and the United States. A native of Germany, Dr. Eickenhorst received a B.Sc. from the University of Antwerp and completed his medical education and Ph.D in microbiology at Freie Universität Berlin. He was a trained urological surgeon. He subsequently also completed an MBA at the University of Toronto.

Dr. Eickenhorst is survived by his wife, Shelley George, MD, his daughter, Natalie, and his mother, Edelgard.

Our thoughts and prayers are with his family and friends during this difficult time.

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# EMD Serono Initiates Co-Promotion of XALKORI® (crizotinib) with Pfizer in the United States



**- Marks first commercial oncology milestone for EMD Serono through the global strategic alliance between Merck KGaA, Darmstadt, Germany and Pfizer**
**- Expands on EMD Serono strategy and deep expertise in addressing unmet needs in specialty care**

ROCKLAND, Mass., May 6, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced it has begun co-promoting Pfizer's anaplastic lymphoma kinase (ALK) inhibitor XALKORI® (crizotinib) as part of its global strategic alliance with Pfizer. The initiation of field-based commercialization efforts for XALKORI illustrates the company's dedication to oncology, and to bringing important treatment options for challenging cancers to patients.

"The XALKORI co-promotion between EMD Serono and Pfizer marks our first entry into the U.S. oncology market, further delivers on our EMD Serono strategy in specialty care and, most importantly, extends our work to help patients and their families battling serious diseases," said Paris Panayiotopoulos, President and Managing Director at EMD Serono. "As our pipeline

EMD Serono has extensive expertise in specialty care and is backed by a global organization with deep oncology experience, which positions the Company well to bring oncology treatments to patients in the U.S. Along those lines, the Company is establishing a strong sales force for XALKORI based in U.S. markets with premier cancer centers, deepening EMD Serono's engagement with the clinical oncology community.

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer, but has many subtypes and can be difficult to treat. XALKORI is approved in the U.S. for the treatment of patients with metastatic NSCLC whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. XALKORI is the first ALK inhibitor approved in the U.S., Japan and the European Union (EU) and is supported by two positive global randomized trials in the first- and second-line ALK-positive advanced NSCLC treatment settings. More than 8,000 patients have been treated worldwide with XALKORI, including those who received the treatment in clinical trials.

This co-promotion relationship is part of the larger, global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer to jointly develop and commercialize avelumab, an investigational anti-PD-L1 monoclonal antibody, to accelerate the development of immuno-oncology medicines for patients with cancer. The immuno-oncology alliance will also advance Pfizer's PD-1 antibody.

Outside of the scope of its alliance with Pfizer, EMD Serono has a diversified oncology and immuno-oncology pipeline which includes multiple, high-priority projects currently in development to optimize patient outcomes in challenging cancers that have significant unmet patient need.

**About Non-small Cell Lung Cancer**

Globally, lung cancer is the most common cause of cancer-related deaths in men and the second most common in women, responsible for almost twice as many deaths as both breast and prostate cancer combined. Non-small cell lung cancer is the most common type of lung cancer, accounting for 85 to 90 percent of all lung cancers. Locally advanced and metastatic disease account for approximately 35 to 40 percent and 70 percent of patients, respectively with NSCLC.

non-small cell lung cancer whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The U.S. indication is not limited to any specific line of therapy.

**XALKORI® Important Safety Information**

Hepatotoxicity: Drug-induced hepatotoxicity with fatal outcome occurred in 0.2% of patients treated with XALKORI across clinical trials (n=1225). Transaminase elevations generally occurred within the first 2 months of treatment. Monitor with liver function tests including ALT and total bilirubin every 2 weeks during the first 2 months of treatment, then once a month and as clinically indicated. Permanently discontinue for ALT or AST elevation greater than 3 times ULN with concurrent total bilirubin elevation greater than 1.5 times ULN (in the absence of cholestasis or hemolysis), otherwise temporarily suspend and dose reduce XALKORI as indicated.

Pneumonitis: Severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis can occur in patients treated with XALKORI. Across clinical trials (n=1225), 2.5% of XALKORI-treated patients had any grade ILD, 0.9% of patients had Grade 3 or 4, and 0.5% had fatal cases. These cases generally occurred within 2 months after the initiation of treatment. Monitor patients for pulmonary symptoms indicative of pneumonitis. Exclude other causes and permanently discontinue XALKORI in patients with drug related pneumonitis.

QT Interval Prolongation: QTc prolongation can occur in patients treated with XALKORI. Across clinical trials (n=1225), QTc prolongation (all grades) was observed in 2.7% of patients and QTc greater than 500 ms on at least 2 separate ECGs occurred in 1.4% of patients. Avoid use of XALKORI in patients with congenital long QT syndrome. Consider periodic monitoring with electrocardiograms and electrolytes in patients who have a history of or predisposition for QTc prolongation, or who are taking medications that prolong the QT interval. Permanently discontinue XALKORI in patients who develop QTc greater than 500 ms or greater than or equal to 60 ms change from baseline with Torsade de pointes, polymorphic ventricular tachycardia, or signs/symptoms of serious arrhythmia, otherwise temporarily suspend and dose reduce XALKORI as indicated.

Bradycardia: Symptomatic bradycardia can occur in patients receiving XALKORI. Across clinical trials, bradycardia with a heart rate less than 50 beats per minute occurred in 11% of patients treated with XALKORI (n=1174). Monitor heart rate and blood pressure regularly. Avoid using

associated with concomitant medications known to cause bradycardia or hypotension, hold XALKORI until recovery to asymptomatic bradycardia or to a heart rate of 60 bpm or above. If concomitant medications can be adjusted or discontinued, restart XALKORI at 250 mg once daily with frequent monitoring. Otherwise temporarily suspend and resume or dose reduce XALKORI as indicated.

Embryofetal Toxicity: XALKORI can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving XALKORI. If the patient or their partner becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus.

Adverse Reactions: Safety was evaluated in a phase 3 study in patients with ALK-positive metastatic NSCLC randomized to XALKORI (n=172) or chemotherapy (n=171). Serious adverse reactions were reported in 37.2% patients treated with XALKORI. The most frequent serious adverse reactions reported in patients treated with XALKORI were pneumonia (4.1%), pulmonary embolism (3.5%), dyspnea (2.3%), and ILD (2.9%). Fatal adverse reactions in XALKORI-treated patients occurred in 9 (5%) patients, consisting of: acute respiratory distress syndrome, arrhythmia, dyspnea, ILD, pneumonia, pneumonitis, pulmonary embolism, respiratory failure, and sepsis. Common adverse reactions occurring in ≥25% included vision disorder (diplopia, photophobia, photopsia, vision blurred, visual acuity reduced, visual impairment, vitreous floaters), diarrhea, nausea, vomiting, constipation, edema, decreased appetite, fatigue, upper respiratory infection, and dysgeusia. Grade 3 or 4 events occurring at a higher incidence with XALKORI than with chemotherapy and at greater than 2% incidence were syncope (3%), QT prolongation (3%), and pulmonary embolism (5%). Elevation of ALT of any grade occurred in 76% of patients and grade 3 or 4 in 17% of patients. Neutropenia of any grade occurred in 49% of patients and grade 3 or 4 in 12% of patients. Lymphopenia of any grade occurred in 51% of patients and grade 3 or 4 in 9% of patients. Renal cysts occurred in 4% and neuropathy in 19% of patients treated with XALKORI.

Drug Interactions: Exercise caution with concomitant use of moderate CYP3A inhibitors. Avoid grapefruit or grapefruit juice which may increase plasma concentrations of crizotinib. Avoid concomitant use of strong CYP3A inducers and inhibitors. Dose reduction may be needed for co-administered drugs that are predominantly metabolized by CYP3A.

Hepatic Impairment: XALKORI has not been studied in patients with hepatic impairment. As crizotinib is extensively metabolized in the liver, hepatic impairment is likely to increase plasma Crizotinib concentrations. Use caution in patients with hepatic impairment.

Renal Impairment: Administer XALKORI at a starting dose of 250 mg taken orally once daily in patients with severe renal impairment (CLcr<30 mL/min) not requiring dialysis. No starting dose adjustment is needed for patients with mild and moderate renal impairment.

For more information and full prescribing information, please visit www.XALKORI.com.

**About EMD Serono**

EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, is a leading U.S. biopharma 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.

**Merck KGaA, Darmstadt, Germany**

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

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# Rebif® (interferon beta-1a) Data at CMSC Annual Meeting Highlights Clinical and MRI Predictors for Long Term Outcomes



**- Analyses in relapsing MS evaluate early predictors of clinical response, one-year efficacy and tolerability of Rebif (interferon beta-1a), among other outcomes**

(1)

ROCKLAND, Mass., May 21, 2015 /PRNewswire/ -- EMD Serono, Inc., the U.S. biopharmaceuticals business of Merck KGaA, Darmstadt, Germany, announced today that data about Rebif® (interferon beta-1a), the company's high-dose, high-frequency interferon beta for relapsing forms of multiple sclerosis, will be presented at the 2015 Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC), taking place from May 27-30 in Indianapolis, Indiana.

Data from 11 abstracts to be presented assess the efficacy of Rebif (interferon beta-1a) on MRI and clinical outcomes, and evaluate early predictors of no evidence of disease activity (NEDA) response, among other measures. The data also explores real-world evidence in MS,

"EMD Serono continues to evaluate the patient outcomes of Rebif, more specifically the important role it plays in the lives of those living with MS," said Dr. Rick Munschauer, Vice President, Medical Affairs, Neurology and Immunology, EMD Serono. "Our scientific and medical presence at this year's CMSC Annual Meeting is aimed at enhancing the understanding of our product and its effect on key measures in MS to help optimize patient care."

In addition to Rebif, EMD Serono is engaged in strategic research collaborations funding promising neurology research with leading academic and healthcare institutions. The company also has ongoing MS clinical study programs, including a Phase I study of ATX-MS-1467, an investigational therapy for relapsing remitting multiple sclerosis (RRMS), and a Phase IIb study of imilecleucel-T, an investigational therapy for Secondary Progressive MS (SPMS), an area of high unmet medical need. The company has an option agreement with Opexa Therapeutics, Inc. for the development and commercial licensing of imilecleucel-T.

The following abstracts have been accepted for presentation at the 2015 Annual Meeting of the CMSC:

| **Title** | **Lead author** | **Abstract/ Poster #** | **Presentation date/time (EST)** |
|---|---|---|---|
| Predictive Value of MRI Measures in Patients with Relapsing Multiple Sclerosis Receiving IFN β-1a SC tiw or IFN β-1a IM qw: *Post Hoc* Analyses of EVIDENCE Data | Anthony Reder | Poster #DX68 | Friday, May 29, 2015, 12:30- 1:30 PM |
| User Trial Questionnaire and Quality of Life Responses in Patients with | Bruce Hughes | Poster #DX36 | Friday, May 29, 2015, |

| | | | |
|---|---|---|---|
| Study | | | |
| Tolerability Results from Year 1 of the PRISMS-2 Two-Year Randomized Controlled Trial of IFN β-1a SC tiw Compared with Placebo | Amy Perrin Ross | Poster #DX64 | Friday, May 29, 2015, 12:30- 1:30 PM |
| Clinical and MRI Benefits of IFN Beta-1a 44 µg SC tiw Treatment over 1 Year in Patients with RMS: Subgroup Analyses of the PRISMS Study | Mark Cascione` | Poster #DX14 | Friday, May 29, 2015, 12:30- 1:30 PM |
| Predictive Value of Early MRI Measures in Patients with RRMS Receiving IFN β-1a SC tiw or Placebo: *Post Hoc* Analyses of PRISMS Data | Mark Cascione | Poster #DX48 | Friday, May 29, 2015, 12:30- 1:30 PM |
| Clinical and MRI Efficacy of IFN β-1a SC tiw in MS Patients with More Advanced Disease (EDSS 4.0–6.0) | Mark S. Freedman | Poster #DX26 | Friday, May 29, 2015, 12:30- 1:30 PM |
| Development of chronic black holes (CBH) predicts long term disability: post-hoc analysis of magnetic resonance imaging (MRI) data in the PRISMS study | Anthony Traboulsee | Poster #DX75 | Friday, May 29, 2015, 12:30- 1:30 PM |

| | | | |
|---|---|---|---|
| Patients with Multiple Sclerosis (MS) Receiving Disease-Modifying Drug (DMD) Therapy | Molly Frean | Poster #DX24 | 29, 2015, 12:30- 1:30 PM |
| Predictors of Adherence Using Panel Survey Data from Multiple Sclerosis Patients Currently Treated with High-Dose High-Frequency Interferons | Chris M Kozma | Poster #DX45 | Friday, May 29, 2015, 12:30- 1:30 PM |
| An Assessment of Adherence Among Multiple Sclerosis Patients Newly Initiating Treatment with a Self-Injectable Versus Oral Disease-Modifying Drug | Michael Munsell | Poster #DX54 | Friday, May 29, 2015, 12:30- 1:30 PM |
| A Descriptive Analysis of Time to First Treatment with Disease-Modifying Drugs in Newly Diagnosed Patients with Multiple Sclerosis | Natalie C Edwards | Poster #DX20 | Friday, May 29, 2015, 12:30- 1:30 PM |

**About Rebif® (interferon beta-1a)**

Rebif (interferon beta-1a) is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS.

**Important Safety Information**

Before beginning treatment, you should discuss the potential benefits and risks associated with Rebif with your healthcare provider.

- Behavioral health problems including depression and suicidal thoughts. You may have mood problems including depression (feeling hopeless or feeling bad about yourself), and thoughts of hurting yourself or suicide
- Liver problems or worsening of liver problems including liver failure. Symptoms may include nausea, loss of appetite, tiredness, dark colored urine and pale stools, yellowing of your skin or the white part of your eye, bleeding more easily than normal, confusion, and sleepiness. During your treatment with Rebif you will need to see your healthcare provider regularly and have regular blood tests to check for side effects
- Serious allergic and skin reactions. Symptoms may include itching, swelling of your face, eyes, lips, tongue or throat, trouble breathing, anxiousness, feeling faint, skin rash, hives, sores in your mouth, or skin blisters and peels
- Injection site problems. Symptoms at the injection site may include redness, pain, swelling, color changes (blue or black), and drainage of fluid.
- Blood problems. Rebif can affect your bone marrow and cause low red and white blood cell, and platelet counts. In some people, these blood cell counts may fall to dangerously low levels. If your blood cell counts become very low, you can get infections and problems with bleeding and bruising. Your healthcare provider may ask you to have regular blood tests to check for blood problems
- Seizures. Some people have had seizures while taking Rebif

Rebif will not cure your MS but may decrease the number of flare-ups of the disease and slow the occurrence of some of the physical disability that is common in people with MS.
Do not take Rebif if you are allergic to interferon beta, human albumin, or any of the ingredients in Rebif.

Before you take Rebif, tell your healthcare provider if you have or have had any of the following conditions:

- mental illness, including depression and suicidal behavior
- liver problems, bleeding problems or blood clots, low blood cell counts, seizures (epilepsy), or thyroid problems
- drink alcohol
- you are pregnant or plan to become pregnant. It is not known if Rebif will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with Rebif.
- you are breastfeeding or plan to breastfeed. It is not known if Rebif passes into your breast milk. You and your healthcare provider should decide if you will use Rebif or breastfeed. You

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

The most common side effects of Rebif include:

- flu-like symptoms. You may have flu-like symptoms when you first start taking Rebif. You may be able to manage these flu-like symptoms by taking over-the-counter pain and fever reducers. For many people, these symptoms lessen or go away over time. Symptoms may include muscle aches, fever, tiredness, and chills
- stomach pain
- change in liver blood tests

For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional.

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exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

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Logo - http://photos.prnewswire.com/prnh/20140902/141783

SOURCE EMD Serono

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# EMD Serono Continues its Entry into Oncology with the Key Appointments of David Trexler to Senior Vice President of Oncology Commercial and Zhen Su, MD, MBA to Vice President of Medical Oncology



(2)

ROCKLAND, Mass., May 28, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced two critical management appointments to lead its entry into oncology. EMD Serono's diversified oncology and immuno-oncology pipeline includes multiple, high-priority projects currently in development to optimize patient outcomes in challenging cancers that have significant unmet patient need.

David Trexler, Senior Vice President of Oncology Commercial, will lead the strategy of the EMD Serono oncology franchise and will be responsible for maximizing growth opportunities by building a performance-driven oncology team focused on customer and patient centricity.

EMD Serono from Eisai, Inc., where he served as Senior Vice President of the Americas Oncology Business Unit. At Eisai, Mr. Trexler successfully led the oncology sales and marketing teams, expanding Eisai's reach in strategic markets across the Americas. Mr. Trexler previously held senior leadership roles at Mylan Bertek Pharmaceuticals and Sanofi-Aventis Pharmaceuticals.

Dr. Zhen Su, Vice President of Oncology Medical, will lead the medical strategy and team for the franchise. A physician executive with more than 15 years of experience, Dr. Su has strong clinical expertise in oncology, immuno-oncology and urology. He has held positions in academic and pharmaceutical medicine, including general management, clinical development, medical affairs and business development. Prior to EMD Serono, Dr. Su served as Associate Vice President and Global Head of Jevtana® (cabazitaxel) at Sanofi. Prior to joining industry, Dr. Su held several academic positions, including Assistant Professor of Surgery at Duke University, where he also received his fellowship in oncology. He has deep ties to the oncology community, having worked with leading oncologists at organizations across the country. Dr. Su earned his MD degree from the Technical University of Dresden, Germany and completed his MBA training at the University of Toronto, Canada.

"This is an exciting time for the oncology franchise of EMD Serono as we initiated our commercial presence in the United States and continue to advance our pipeline," said Paris Panayiotopoulos, President and Managing Director of EMD Serono. "Our long-standing commitment and focus on specialty care is a driving force behind our expansion in oncology. The experience and passion that David and Zhen possess aligns perfectly with our commitment to address challenging cancers, champion patient care and forge a new path in oncology management."

Earlier this month, the company announced the launch of the co-promotion of XALKORI® (crizotinib) with Pfizer. This co-promotion is part of a larger global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer to jointly develop and commercialize avelumab*, an investigational anti-PD-L1 monoclonal antibody, to accelerate the development of immuno-oncology medicines for patients with cancer. The immuno-oncology alliance will also advance Pfizer's anti-PD-1 antibody.

its investigational compound evofosfamide (previously known as TH-302), administered in combination with gemcitabine, for the treatment of previously untreated patients with metastatic or locally advanced unresectable pancreatic cancer. This is the second indication for this compound to receive Fast Track designation from the FDA, following the granting of the designation for the development of evofosfamide in combination with doxorubicin for the treatment of advanced soft tissue sarcoma to the company's co-development partner, Threshold Pharmaceuticals, in November 2014. Evofosfamide is currently under evaluation in two Phase III trials: one in combination with doxorubicin versus doxorubicin alone in patients with locally advanced unresectable or metastatic soft tissue sarcoma (the TH-CR-406 trial), and the other in combination with gemcitabine versus gemcitabine and placebo in patients with locally advanced unresectable or metastatic pancreatic cancer (the MAESTRO trial).

*Avelumab is an investigational agent. Avelumab is the proposed International Nonproprietary Name (INN) for the anti-PD-L1 monoclonal antibody (MSB0010718C).

**About XALKORI® (crizotinib)**

XALKORI is a kinase inhibitor indicated in the U.S. for the treatment of patients with metastatic non-small cell lung cancer whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The U.S. indication is not limited to any specific line of therapy. XALKORI® is a registered trademark of Pfizer Inc.

**XALKORI® Important Safety Information**

Hepatotoxicity: Drug-induced hepatotoxicity with fatal outcome occurred in 0.2% of patients treated with XALKORI across clinical trials (n=1225). Transaminase elevations generally occurred within the first 2 months of treatment. Monitor with liver function tests including ALT and total bilirubin every 2 weeks during the first 2 months of treatment, then once a month and as clinically indicated. Permanently discontinue for ALT or AST elevation greater than 3 times ULN with concurrent total bilirubin elevation greater than 1.5 times ULN (in the absence of cholestasis or hemolysis), otherwise temporarily suspend and dose reduce XALKORI as indicated.

Pneumonitis: Severe, life-threatening, or fatal interstitial lung disease (ILD)/pneumonitis can occur in patients treated with XALKORI. Across clinical trials (n=1225), 2.5% of XALKORI-treated patients had any grade ILD, 0.9% of patients had Grade 3 or 4, and 0.5% had fatal cases. These cases generally occurred within 2 months after the initiation of treatment. Monitor

QT Interval Prolongation: QTc prolongation can occur in patients treated with XALKORI. Across clinical trials (n=1225), QTc prolongation (all grades) was observed in 2.7% of patients and QTc greater than 500 ms on at least 2 separate ECGs occurred in 1.4% of patients. Avoid use of XALKORI in patients with congenital long QT syndrome. Consider periodic monitoring with electrocardiograms and electrolytes in patients who have a history of or predisposition for QTc prolongation, or who are taking medications that prolong the QT interval. Permanently discontinue XALKORI in patients who develop QTc greater than 500 ms or greater than or equal to 60 ms change from baseline with Torsade de pointes, polymorphic ventricular tachycardia, or signs/symptoms of serious arrhythmia, otherwise temporarily suspend and dose reduce XALKORI as indicated.

Bradycardia: Symptomatic bradycardia can occur in patients receiving XALKORI. Across clinical trials, bradycardia with a heart rate less than 50 beats per minute occurred in 11% of patients treated with XALKORI (n=1174). Monitor heart rate and blood pressure regularly. Avoid using XALKORI in combination with other agents known to cause bradycardia to the extent possible. Permanently discontinue for life-threatening bradycardia due to XALKORI; however, if associated with concomitant medications known to cause bradycardia or hypotension, hold XALKORI until recovery to asymptomatic bradycardia or to a heart rate of 60 bpm or above. If concomitant medications can be adjusted or discontinued, restart XALKORI at 250 mg once daily with frequent monitoring. Otherwise temporarily suspend and resume or dose reduce XALKORI as indicated.

Embryofetal Toxicity: XALKORI can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving XALKORI. If the patient or their partner becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus.

Adverse Reactions: Safety was evaluated in a phase 3 study in patients with ALK-positive metastatic NSCLC randomized to XALKORI (n=172) or chemotherapy (n=171). Serious adverse reactions were reported in 37.2% patients treated with XALKORI. The most frequent serious adverse reactions reported in patients treated with XALKORI were pneumonia (4.1%), pulmonary embolism (3.5%), dyspnea (2.3%), and ILD (2.9%). Fatal adverse reactions in XALKORI-treated patients occurred in 9 (5%) patients, consisting of: acute respiratory distress syndrome, arrhythmia, dyspnea, ILD, pneumonia, pneumonitis, pulmonary embolism,

impairment, vitreous floaters), diarrhea, nausea, vomiting, constipation, edema, decreased appetite, fatigue, upper respiratory infection, and dysgeusia. Grade 3 or 4 events occurring at a higher incidence with XALKORI than with chemotherapy and at greater than 2% incidence were syncope (3%), QT prolongation (3%), and pulmonary embolism (5%). Elevation of ALT of any grade occurred in 76% of patients and grade 3 or 4 in 17% of patients. Neutropenia of any grade occurred in 49% of patients and grade 3 or 4 in 12% of patients. Lymphopenia of any grade occurred in 51% of patients and grade 3 or 4 in 9% of patients. Renal cysts occurred in 4% and neuropathy in 19% of patients treated with XALKORI.

Drug Interactions: Exercise caution with concomitant use of moderate CYP3A inhibitors. Avoid grapefruit or grapefruit juice which may increase plasma concentrations of crizotinib. Avoid concomitant use of strong CYP3A inducers and inhibitors. Dose reduction may be needed for co-administered drugs that are predominantly metabolized by CYP3A.

Nursing Mothers: Given the potential for serious adverse reactions in nursing infants, consider whether to discontinue nursing or discontinue XALKORI.

Hepatic Impairment: XALKORI has not been studied in patients with hepatic impairment. As crizotinib is extensively metabolized in the liver, hepatic impairment is likely to increase plasma Crizotinib concentrations. Use caution in patients with hepatic impairment.

Renal Impairment: Administer XALKORI at a starting dose of 250 mg taken orally once daily in patients with severe renal impairment (CLcr<30 mL/min) not requiring dialysis. No starting dose adjustment is needed for patients with mild and moderate renal impairment.

For more information and full prescribing information, please visit www.XALKORI.com.

**About Evofosfamide**

Evofosfamide (previously known as TH-302) is an investigational hypoxia-activated prodrug that is thought to be activated under severe tumor hypoxic conditions, a feature of many solid tumors. Areas of low oxygen levels (hypoxia) in solid tumors are due to insufficient blood vessel supply. Similarly, the bone marrow of patients with hematological malignancies has also been shown, in some cases, to be severely hypoxic.

Evofosfamide is currently under evaluation in two Phase III trials: one in combination with doxorubicin versus doxorubicin alone in patients with locally advanced unresectable or

metastatic pancreatic cancer (the MAESTRO trial). Both Phase III trials are being conducted under Special Protocol Assessment (SPA) agreements with the FDA. The FDA and the European Commission have granted evofosfamide Orphan Drug designation for the treatment of STS and pancreatic cancer. The FDA has also granted Fast Track designation for evofosfamide for both STS and pancreatic cancer. Evofosfamide is also being investigated in a Phase II trial for the treatment of non-squamous non-small cell lung cancer, and in earlier-stage clinical trials of other solid tumors and hematological malignancies.

Merck KGaA, Darmstadt, Germany, signed a global license and co-development agreement for evofosfamide with Threshold Pharmaceuticals, Inc. in February 2012, with an option for Threshold to co-commercialize in the U.S.

Evofosfamide is currently under clinical investigation and has not been approved for use in the U.S., Europe, Canada, or elsewhere. Evofosfamide has 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.

**Avelumab**

Avelumab (also known as MSB0010718C) is an investigational fully human anti-PD-L1 IgG1 monoclonal antibody. By inhibiting PD-L1 interactions, avelumab is thought to enable the activation of T-cells and the adaptive immune system. By retaining a native Fc-region, avelumab is thought to engage the innate immune system and may induce antibody-dependent cell-mediated cytotoxicity (ADCC). In November, 2014, Merck KGaA, Darmstadt, Germany, and Pfizer announced a strategic alliance to co-develop and co-commercialize avelumab.

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

Immuno-oncology is a top priority for Merck KGaA, Darmstadt, Germany, and Pfizer Inc. The global strategic alliance between Merck KGaA, Darmstadt, Germany, and Pfizer Inc, New York, US, enables the companies to benefit from each other's strengths and capabilities and further explore the therapeutic potential of avelumab, an investigational anti-PD-L1 antibody initially discovered and developed by Merck KGaA, Darmstadt, Germany. The immuno-oncology alliance will jointly develop and commercialize avelumab and advance Pfizer's PD-1 antibody. The companies will collaborate on up to 20 high priority immuno-oncology clinical development programs, including combination trials, many of which are expected to commence in 2015.

leading U.S. biopharma 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.

**Merck KGaA, Darmstadt, Germany**
Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

Cory Tromblee
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# Merck KGaA, Darmstadt, Germany, as Pioneer in Assisted Reproductive Treatments, Takes Leading Role in Fertility Technologies, Announces a Global Collaboration Agreement with Genea Biomedx

EXPLORE MORE

**- Merck KGaA, Darmstadt, Germany is a leading company in the growing market of fertility technologies to support standardization and improve fertility outcomes**
**- Company receives global marketing and commercialization rights for three key innovative technologies, as well as pipeline of future products**
**- Investing into innovation beyond drugs is currently seen as a key lever for improving outcomes**
**- In the United States and Canada, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, operates as EMD Serono**

ROCKLAND, Mass., May 28, 2015 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials today announced a global collaboration agreement with the fertil

Germany, a global market leader in drugs for Assisted Reproductive Treatment (ART), receives global marketing and commercialization rights to Genea Biomedx's product portfolio. This comprises Gavi, Geri and Gems product lines for use in the IVF laboratories which are expected to receive CE mark in Europe shortly, as well as a joint development pipeline. Gavi, Geri and Gems are not cleared for use in the U.S.

Gavi is a fully-automated vitrification instrument, focusing on lab processes that could reduce potential errors and possibly increase laboratory efficiency in cryopreservation of embryos and in the future for oocytes (eggs). Geri is a benchtop incubator fitted with a time-lapse camera to capture images of embryos as they develop and individually controlled incubation chambers per patient to potentially reduce disruptive events to the early-stage embryo. Gems is the latest generation of Genea's culture media for embryo cultivation.

The collaboration is part of the company's strategy to continue to provide fertility solutions to its customers to increase success rates. With the global rights to these three product lines and future developments, Merck KGaA, Darmstadt, Germany is expanding its market position, offering key potentially outcome improving technologies to support standardization, automation and objectivity. To further strengthen this position, Merck KGaA, Darmstadt, Germany, will closely collaborate with Genea Biomedx to jointly develop other innovative technology products and services, and have formed a development hub to pave the way for further improvements for the patient.

"As a pioneer in reproductive health, we are continuously seeking to extend our product portfolio to bring innovative science and services to the fertility community," explained Belén Garijo, Member of the Executive Board of Merck KGaA, Darmstadt, Germany and CEO Healthcare. "There is significant need for improved technologies in fertility treatment, since the majority of issues in ART are beyond drug therapy. The key priority of our Fertility Technologies unit is to advance our fertility portfolio beyond drugs and to enable innovation in technologies and services. Entering a global partnership with Genea will allow us to introduce innovative technologies in the ART market, further aiming to improve outcomes throughout the in vitro fertilization process. We are dedicated to help patients realize their dream of creating a family."

"Advancing the science of fertility treatment to improve outcomes and success rates for patients worldwide is Genea's mission and we are excited that this agreement helps us continue to bring that aim to fruition," said Tomas Stojanov CEO of Genea. "This is just the beginning of a unique collaboration between our two companies which will deliver innovative, high-

The collaboration showcases both companies' commitment to improve fertility treatment. Both Merck KGaA, Darmstadt, Germany, and Genea Biomedx have a strong heritage in fertility treatment and will build on this expertise to invent and develop innovative fertility technologies. The collaboration is effective from May 1, 2015. Financial details of the agreement are not being disclosed.

**About Genea Biomedx**

Genea Biomedx creates and manufactures practical, accessible and precise fertility technologies that help standardise and automate fertility treatment. Its unique relationship with Genea Fertility means that Genea Biomedx is a manufacturer that truly understands the customers' perspective. As a result Genea Biomedx has developed the world's first automated vitrification instrument, and has other projects well advanced in the product pipeline.

**About Gavi, Geri and Gems**

- Gavi – will be the world's first automated vitrification instrument; Vitrification is a process used in IVF to preserve human egg cells (oocytes) or embryos by cooling them to deep sub-zero degrees. Approaching the process in an innovative way, Gavi uses an automated, standardized protocol aiming to provide consistent results in blastocyst vitrification.
- Geri - a benchtop incubator with individually controlled incubation chambers per patient to minimize disruptive events to the early-stage embryo. It also incorporates a time-lapse camera to capture images of embryos as they develop.
- Gems - the latest generation of Genea's culture media for embryo cultivation.

**About EMD Serono**

EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, is a leading U.S. biopharma 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.

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# Merck KGaA, Darmstadt, Germany, Illumina and Genea Form the Global Fertility Alliance for Excellence in Assisted Reproductive Treatment



**- Global Fertility Alliance will identify and work on improvements of fertility-related laboratory processes**

ROCKLAND, Mass., June 8, 2015 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials, today announced the formation of the Global Fertility Alliance, a new collaboration to advance excellence in fertility technologies and processes within the assisted reproductive treatment (ART) laboratory. The alliance is a partnership between the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, Illumina Inc., San Diego, US, a leader in developing and commercializing systems for analysis of genetic variation and function, and Genea Limited, Sydney, Australia, which develops innovative fertility technologies.

"We are the global leader in the field of fertility drugs and committed to supporting the success and improvement in ART by going beyond drugs with innovative technologies," explained Meeta Gulyani, Head of Global Strategy and Franchises at the biopharmaceutical business of Merck

will ensure a consistently high level of performance between different centers and countries."

The alliance aims to improve the consistency in ART worldwide and addresses the need for more standardization of fertility processes within the ART laboratory. The three companies will launch their initiative at the 31st Annual Meeting of the European Society of Human Reproduction and Embryology (ESHRE) in Lisbon, Portugal, on 13 June 2015. This is another important step for EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, towards establishing global standards in the growing market of fertility technologies.

With the establishment of the alliance, EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, Illumina and Genea emphasize their desire to help improve fertility outcomes by contributing to the standardization of technologies and protocols in ART labs. Currently, variation in practices and techniques can lead to inconsistent results and outcomes. Recognizing the importance of innovation in ART technologies the alliance aims to enhance progress and innovation in three ways. Firstly, the founding members aim to foster integration of multiple, leading fertility technologies. Secondly, building on this, the alliance will aim to collaborate with leading health care professionals and medical societies to develop global standards. And finally, as technologies in the fertility space are rapidly advancing, the alliance will also develop educational resources for health care professionals worldwide. These efforts will include training curricula and workshops as well as access to model labs, symposia and events at medical meetings.

Illumina's Senior Vice President and General Manager of Reproductive and Genetic Health, Tristan Orpin, also highlighted the significance of the alliance for the reproductive biology community: "Illumina has a strong commitment to improving in vitro fertilization (IVF) outcomes through the use of industry leading genomics but appreciates that there are many factors that impact ART outcomes. Founding the Global Fertility Alliance together with the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, and Genea represents an exciting opportunity for us to share our knowledge and experience with the wider community and to help bring alignment and higher consistency to ART practices worldwide. Having already partnered with the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in other treatment areas, we are confident this collaboration of innovators in the fertility field will deliver a significant positive impact for health care professionals, fertility labs, and most importantly their patients."

Global Fertility Alliance for excellence in ART will drive automation and standardization in the field and support health care professionals in providing their patients with the best possible outcomes."

In order to rapidly progress the initiative, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, Illumina and Genea will actively contribute to the alliance and establish a board of representatives, which will meet regularly. At the same time, the companies invite new members, who demonstrate a consistent commitment to driving technology innovation and improving ART results, to join the alliance.

In the United States and Canada, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, operates as EMD Serono

**About Genea**

Genea is a fertility pioneer, researching, developing and introducing breakthrough techniques and technologies in assisted reproductive treatment for almost 30 years. Genea is a strongly interconnected group of three companies:

Genea Fertility has clinics across Australia, as well as in New Zealand and Thailand.

Genea Biomedx creates and manufactures practical, accessible and precise fertility technologies that help standardise and automate fertility treatment. Its unique relationship with Genea Fertility means that Genea Biomedx is a manufacturer that truly understands the customers' perspective. As a result Genea Biomedx has developed the world's first automated vitrification instrument, and has other projects well advanced in the product pipeline.

Genea Biocells develops unique disease-specific and unaffected human pluripotent stem cell platforms, differentiated cells, including the first robust skeletal muscle differentiation platform; culture media and small molecule libraries for use in research, drug development and cell therapy. Genea Biocells partners with scientists in industry and academia to advance innovative projects using chemical biology and stem cell-driven approaches.

**About Illumina**

technologies, serving customers in the research, clinical and applied markets. Our products are used for applications in the life sciences, oncology, reproductive health, agriculture and other emerging segments.

**About EMD Serono**

EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, is a leading U.S. biopharma 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.

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# EMD Serono Announces EUR 1.2 million Grant for Fertility Innovation (GFI) for 2015 / 16



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

ROCKLAND, Mass., June 17, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced its strong support of the Grant for Fertility Innovation (GFI) fund with grants totaling up to € 1.2 million for the years 2015 / 2016. The announcement was made during the 31st annual meeting of the European Society of Human Reproduction and Embryology (ESHRE) currently taking place in Lisbon.

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 six years, approximately 750 applications to GFI were received from over 50 countries around the world; from this year's applications, six projects from five countries were awarded a grant for a total of € 1.2 million.

Hildemann, Global Chief Medical Officer and Head of Global Medical and Drug Safety at the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. "We are excited by the growing number of high quality applications each year, reflecting significant opportunity for continued research and scientific advancement in fertility, where there is still unmet need."

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

- **Clinical translation of a new procedure for embryo evaluation based on miRNAs profiling from spent blastocyst culture media: prospective multicenter study:** *Antonio Capalbo - Genera Reproductive Medicine centres, Rome (ITALY)*
- **Glycomarker Panel for Prediction of IVF Outcome***: Tracey Edgell - Hudson Institute of Medical Research, Clayton (AUSTRALIA)*
- **Improved diagnostic of in-vitro-fertilization using miRNome and microvesicles from early stage embryos**: *Andreas Keller - Clinical Bioinformatics Center Saarland University, Saarbrücken (GERMANY)*
- **Embryo derived trypsin: A novel and simple marker of embryo viability:** *Nick Macklon - University of Southampton* (UK)
- **Identification of novel markers of human oocyte aging via non-invasive RNA sequencing analysis of cumulus cells:** *Pasquale Patrizio - Yale Fertility Center, New Haven (USA)*
- **Exoxomes/microvesicles release as a non-invasive method to assess embryo activity***: Paola Vigano - San Raffaele Scientific Institute, Milan (ITALY)*

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employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany, holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

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SOURCE EMD Serono

# EMD Serono Appoints Scott Filosi as Senior Vice President of Managed Markets



**- Filosi brings 20 years of market access experience to the EMD Serono leadership team**

ROCKLAND, Mass., Sept. 9, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, announced today the appointment of Scott Filosi as Senior Vice President of Managed Markets. Filosi brings extensive specialty pharmaceutical experience with a focus on managed markets, global business development and market access for biologics. He has led national and regional accounts teams including federal, field reimbursement, contracting and health outcomes.

As Senior Vice President of Managed Markets, Filosi will be responsible for developing and executing Managed Markets marketing, sales, and contracting strategies to ensure optimal market access and pull through for EMD Serono products for patients, as well as reimbursement strategies for the oncology portfolio. He is also responsible for leading specialty pharmacy patient adherence and retention programs.

"Mr. Filosi brings to us a successful track record of driving operational growth and performance for mid-sized specialty pharmaceutical market access teams," said Gary Zieziula, Chief Commercial Officer of EMD Serono. "He's well-positioned to lead a strong managed markets

Prior to joining EMD Serono, Filosi was the Head of U.S. Market Access and Pricing and the Head of Established Brands in the U.S., and led business operations for Canada and Mexico at UCB Pharma. In this role, he had full Profit and Loss (P&L) responsibility for the established brands and led contracting, access, distribution, reimbursement, access strategy, health outcomes and channel forecasting.

Previous to UCB, Filosi was Vice President of Global Business Development at i3 Innovus where he led the U.S. and EU business development model design and implementation for health outcomes. Prior to joining i3 Innovus, Filosi spent six years with Boehringer Ingelheim and 13 years with Johnson & Johnson in a variety of commercial and sales roles.

Filosi holds a B.S. in Marketing and Business Administration from University of Massachusetts.

**About EMD Serono**

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EMD Millipore and EMD Performance Materials.

Cory Tromblee
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# New Rebif® (interferon beta-1a) Data at ECTRIMS Highlights the Importance of Disability and Imaging Predictors for Long Term Outcomes



**- Data include post-hoc assessments of controlled studies in relapsing MS of predictive scores for disease activity and disability progression, as well as a cost-effectiveness analysis of Rebif® (interferon beta-1a) vs Avonex® (interferon beta-1a) based on the 'no evident disease activity' (NEDA) measure**

**- The new data presented underscore company's commitment to impacting patient care and adherence**

ROCKLAND, Mass., Sept. 24, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced that data about Rebif® (interferon beta-1a), the company's high-dose, high-frequency interferon beta for relapsing forms of multiple sclerosis will be presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), taking place October 7-10 in Barcelona, Spain. The new data will help healthcare professionals and patients to make informed therapeutic treatment decisions and better understand the impact of Rebif in patients with relapsing forms of MS.

Hildemann, Senior Vice President, Chief Medical Officer, and head of Global Medical Affairs and Global Drug Safety at the biopharmaceuticals business of Merck KGaA, Darmstadt, Germany. "We will present real-world data that will help us understand more fully the patient journey and aim to optimize MS patient care, including data on the comparative cost-effectiveness of Rebif."

The following abstracts have been accepted for presentation at ECTRIMS 2015:

| **Title** | **Lead Author** | **Abstract Number** | **Presentation Date/Time (CEST)** |
|---|---|---|---|
| Predictive value of early MRI measures for long-term disease activity in patients with relapsing-remitting multiple sclerosis receiving IFN beta-1a SC tiw or IFN beta-1a IM qw: post hoc analyses of the EVIDENCE study | K.P. Coyle (Stony Brook, United States) | 2107 | Poster Sessions 09.10.2015, 15:30 – 17:00 |
| Predictive value of EDSS worsening and relapse/active T2 lesions on outcomes among patients receiving IFN beta-1a SC tiw for RRMS: post hoc analyses of PRISMS data over 4 years | M. Cascione (Tampa, United States) | 2034 | Poster Sessions 09.10.2015, 15:30 – 17:00 |
| Factors associated with continuation of treatment with IFN beta-1a given subcutaneously three times a week: a US retrospective cohort study | M. Sabido-Espin (Darmstadt, Germany) | 597 | Poster Sessions 08.10.2015, 15:45 – 17:00 |
| The impact of age, gender, and geographic region on the prevalence of common comorbidities in | J.C. Locklear (Rockland, | 1745 | Poster Sessions |

| | | | |
|---|---|---|---|
| | | | 17:00 |
| Development of a composite, administrative claims-based measure of disease severity among patients with multiple sclerosis receiving disease-modifying drug therapy | A.L. Phillips (Rockland, United States) | 1776 | Poster Sessions 09.10.2015, 15:30 – 17:00 |
| Cost-effectiveness of 44 mcg subcutaneous interferon beta-1a (scIFNbeta-1a) and 30 mcg intramuscular interferon beta-1a (imIFNbeta-1a) using clinical endpoints of disease activity | A.L. Phillips (Rockland, United States) | 1831 | Poster Sessions 09.10.2015, 15:30 – 17:00 |
| Factors associated with early disease-modifying drug (DMD) treatment initiation in newly diagnosed patients with multiple sclerosis (MS) | A.L. Phillips (Rockland, United States) | 1853 | Poster Sessions 09.10.2015, 15:30 – 17:00 |
| An evaluation of adherence between patients with multiple sclerosis newly initiating treatment with a self-injectable or an oral disease-modifying drug | J.C. Locklear (Rockland, United States) | 1933 | Poster Sessions 09.10.2015, 15:30 – 17:00 |

The full abstract are available at http://www.professionalabstracts.com/ectrims2015/iplanner/

Avonex® is a registered trademark of Biogen, Inc.

**About Rebif® (interferon beta-1a)**

with MS.

**Important Safety Information**

Before beginning treatment, you should discuss the potential benefits and risks associated with Rebif with your healthcare provider.

Rebif can cause serious side effects. Tell your healthcare provider right away if you have any of the symptoms listed below while taking Rebif.

- Behavioral health problems including depression and suicidal thoughts. You may have mood problems including depression (feeling hopeless or feeling bad about yourself), and thoughts of hurting yourself or suicide
- Liver problems or worsening of liver problems including liver failure. Symptoms may include nausea, loss of appetite, tiredness, dark colored urine and pale stools, yellowing of your skin or the white part of your eye, bleeding more easily than normal, confusion, and sleepiness. During your treatment with Rebif you will need to see your healthcare provider regularly and have regular blood tests to check for side effects
- Serious allergic and skin reactions. Symptoms may include itching, swelling of your face, eyes, lips, tongue or throat, trouble breathing, anxiousness, feeling faint, skin rash, hives, sores in your mouth, or skin blisters and peels
- Injection site problems. Symptoms at the injection site may include redness, pain, swelling, color changes (blue or black), and drainage of fluid.
- Blood problems. Rebif can affect your bone marrow and cause low red and white blood cell, and platelet counts. In some people, these blood cell counts may fall to dangerously low levels. If your blood cell counts become very low, you can get infections and problems with bleeding and bruising. Your healthcare provider may ask you to have regular blood tests to check for blood problems
- Seizures. Some people have had seizures while taking Rebif

Rebif will not cure your MS but may decrease the number of flare-ups of the disease and slow the occurrence of some of the physical disability that is common in people with MS.

Do not take Rebif if you are allergic to interferon beta, human albumin, or any of the ingredients in Rebif.

Before you take Rebif, tell your healthcare provider if you have or have had any of the following conditions:

or thyroid problems
- drink alcohol
- you are pregnant or plan to become pregnant. It is not known if Rebif will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with Rebif.
- you are breastfeeding or plan to breastfeed. It is not known if Rebif passes into your breast milk. You and your healthcare provider should decide if you will use Rebif or breastfeed. You should not do both.

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

The most common side effects of Rebif include:

- flu-like symptoms. You may have flu-like symptoms when you first start taking Rebif. You may be able to manage these flu-like symptoms by taking over-the-counter pain and fever reducers. For many people, these symptoms lessen or go away over time. Symptoms may include muscle aches, fever, tiredness, and chills
- stomach pain
- change in liver blood tests

For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional.

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Erin Marie Beals
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# EMD Serono Announces Pioneering Researchers Awarded with $1.1 Million Through Grant for Oncology Innovation Initiative



**- Global winners selected by internationally renowned oncologists and researchers for pushing the boundaries of creativity and science to explore innovative research in the personalized treatment of solid tumors**

ROCKLAND, Mass., Sept. 28, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced the winners of the 2015 Grant for Oncology Innovation (GOI), who will receive grants totaling $1.1 million.

This year's winners are:

- Dr. Roberto Chiarle, University of Turin, Italy, for his proposal to elucidate the molecular mechanisms underlying relapse in a subset of patients with non-small cell lung cancer, following anaplastic lymphoma kinase (ALK)-targeted tyrosine kinase inhibitor (TKI) therapy. Around half of patients treated with ALK-TKI therapy will relapse without explanation, meaning they are not able to benefit from additional lines of targeted therapy.

for personalized cancer-specific vaccines to generate T-cell responses in human tumors.

- Dr. Rodrigo Dienstmann, Vall d'Hebron Institute of Oncology, Spain, for his proposal to analyze clinical and gene expression data, and translating the findings to inform the design of early clinical trials into therapies that target intracellular signals on which colorectal cancers depend.

"We are proud to present the Grant for Oncology Innovation to these outstanding researchers and their teams, and offer our sincere congratulations. Their groundbreaking work helps us better understand solid tumor biology, pushing us closer to personalized cancer therapies that could one day change patients' lives," said Belen Garijo, Member of the Executive Board and CEO of the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. "We hope this grant supports their continued pioneering work in this critical area of research."

The 2015 winners were formally announced at an awards ceremony coinciding with the 2015 European Cancer Congress (ECC) 2015 in Vienna, Austria. Winners were selected by an international Scientific Steering Committee comprised of leading oncologists and researchers.

The GOI was created to support researchers who are breaking new ground with innovative projects by providing the potential to advance research in the increasingly important area of personalized treatment of solid tumors. The grant was launched in September 2013 at the European Cancer Congress (ECCO-ESMO-ESTRO) in Amsterdam.

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 are all awarded annually.

For more information on the GOI and details of how to apply for the 2016 award, please visit: www.grantforoncologyinnovation.org

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CONTACT: Cory Tromblee, Phone: 781.681.2393

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# EMD Serono Advances Medical and Scientific Leadership and Entry into Oncology, Appointing Joseph Leveque, M.D. as U.S. Chief Medical Officer

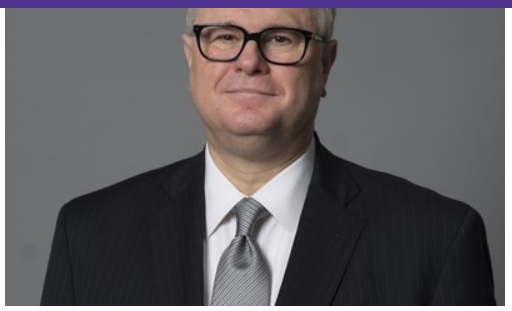


**- Leveque brings more than 20 years of medical experience to the EMD Serono leadership team**

(1)

ROCKLAND, Mass., Sept. 29, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, announced today the appointment of Joseph Leveque, M.D. as U.S. Chief Medical Officer. In this role, Dr. Leveque will be responsible for working with the regulatory, medical and development teams to enhance EMD Serono's clinical presence in the U.S. and to drive the execution of key medical initiatives.

Dr. Leveque brings more than 20 years of experience in the areas of strategic leadership, advancing medical and clinical programs, as well as life cycle management. He has served as the medical lead in a number of biopharmaceutical roles, and has wide industry expertise across therapeutic areas, with a focus in oncology and immuno-oncology.



our specialty care focus in neurology, oncology, fertility, and endocrinology and bringing our pipeline forward," said Paris Panayiotopoulos, President and Managing Director of EMD Serono. "In the U.S., Dr. Leveque will collaborate closely with our global medical and R&D organizations, and will play a key role in advancing our commitment to innovation and bringing new therapeutic options to patients, particularly those with difficult to treat diseases."

Dr. Leveque will report to Steven Hildemann, Global Chief Medical Officer and Head of Global Medical Affairs and Drug Safety for the biopharma business of Merck KGaA, Darmstadt, Germany and will be a member of the Global Medical Affairs and EMD Serono U.S. Leadership Teams.

Most recently, Dr. Leveque was at Bristol-Myers Squibb, where he served as the head of U.S. Medical for Oncology. At Bristol-Myers Squibb, Dr. Leveque was responsible for providing strategic leadership and management for marketed and near-term pipeline oncology assets. Previous to Bristol Myers Squibb, Dr. Leveque has also held medical affairs leadership positions at Onyx Pharmaceuticals, Inc., Cephalon and Amgen, Inc.

Dr. Leveque holds an M.D. from University of Texas and his MBA from Wharton Business School.

He will be based in Rockland, Massachusetts.

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Photo - http://photos.prnewswire.com/prnh/20150929/271785

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# EMD Serono Joins Industry Leaders for The Economist Events' War On Cancer Forum in Boston

EXPLORE MORE

ROCKLAND, Mass., Sept. 29, 2015 /PRNewswire/ -- EMD Serono today announced that Merck KGaA, Darmstadt, Germany, is a platinum sponsor of The Economist Events' Health Care Forum: War on Cancer. The event brings together policymakers, oncology experts, researchers and pharmaceutical and insurance executives to engage in important dialogue on advancing cancer research and care through collaboration on September 29, 2015 in Boston.

"Over the last 10 years, the survival rates in many types of cancers as well as the number of potential oncology treatments in development have risen steadily, but cancer is a resilient enemy," said Paris Panayiotopoulos, President and Managing Director of EMD Serono. "The Economist Events' 'War on Cancer' Forum brings together key stakeholders with the goal of fostering collaboration and helping us identify new solutions that can one day benefit patients."

The American Cancer Society estimates that there will be more than 1.6 million new cancer cases diagnosed and nearly 590,000 cancer deaths in the U.S. this year. Five-year survival rates for many cancers are improving due, in part, to improved prevention, screening and therapy. However, there are still unmet needs, particularly in rare and difficult-to-treat cancers

altering people's behaviors for improved health, among other topics.

The Economist Events' War on Cancer forum is part of a global event series, the first of which took place in Hong Kong in March, with the final conference to be held in London in October. The Boston event will be chaired by *The Economist's* healthcare correspondent Natasha Loder.

For more information, click here. Join the conversation and connect with speakers and attendees on Twitter via #WarOnCancer.

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# EMD Serono Announces Grant for Growth Innovation at ESPE in Barcelona



**- Grants awarded to coincide with the 54th European Society for Paediatric Endocrinology (ESPE) Meeting**
**- Investment supports innovative projects for the advancement of science and medical research in the field of growth**

DARMSTADT, Germany, Oct. 4, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced the recipients of the Grant for Growth Innovation (GGI) for 2015. The awards were handed over during the official award ceremony yesterday evening at the 54th European Society for Paediatric Endocrinology (ESPE) Meeting currently taking place in Barcelona, Spain.

Seventy applications were received from 21 countries, an increase of more than fifteen percent compared to the number of entries last year. The applications were reviewed by an independent Scientific Steering Committee composed of internationally renowned endocrinologists and chaired by Professor Christian Strasburger, Head of Clinical Endocrinology at the Charite Universitatsmedizin Berlin. Following a rigorous selection process two awards have been made to innovative projects which seek to advance understanding in the field of growth. The winning projects are based in the United Kingdom and the United States, and are as follows:

"Effect of insulin sensitisation on Insulin-Like Growth Factor-I levels in response to Growth Hormone treatment in children born small for gestational age."

**Edward List, PhD**
Edison Biotechnology Institute, Ohio University, Athens, OH, USA
"Experimental use of an alternative form of growth hormone."

"We are committed to supporting the advancement of science and medical research in the field of growth to deliver better outcomes for those living with growth hormone disorders. Following a successful debut last year, we are delighted that we had more entries from more countries for this year's Grant for Growth Innovation awards," said Professor Steven Hildemann, Global Chief Medical Officer and Head of Global Medical Affairs and Global Drug Safety at the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. "Supporting those who are pioneering new research in growth disorders through the Grant for Growth Innovation reflects our belief that innovation is the cornerstone in releasing potential in the treatment of these diseases."

Notes to editors
Photos of the awards ceremony are available.

**About the Grant for Growth Innovation (GGI)**
EMD Serono initiated the GGI program to support the advancement of understanding of the field of growth. A total grant of up to €400,000 per year divided between up to three research proposals will be awarded to one or more selected projects. Each application was blinded and evaluated by an independent 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

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Cory Tromblee
Phone: 781.681.2393

SOURCE EMD Serono

# EMD Serono Announces Recipients of the Third Annual €1 Million Grant for Multiple Sclerosis Innovation

EXPLORE MORE

**- Four research grants awarded out of 146 applications, highlighting continuing commitment to multiple sclerosis**

ROCKLAND, Mass., Oct. 8, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced the recipients of the third annual Grant for Multiple Sclerosis Innovation (GMSI) at the 31st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) being held in Barcelona, Spain.

Four recipients, from The Netherlands, Finland, Italy, and the UK, will share the overall €1 million grant to support their research:

- *Dynamics of M1/M2 polarization of microglia in multiple sclerosis: a PET imaging study:* Helga E de Vries, Professor in Neuro-immunology, MS Centre Amsterdam, Dept. Molecular Cell Biology and immunology, VU University Medical Center, The Netherlands.
- *Role of microglia in the pathogenesis of progressive multiple sclerosis:* Laura Airas, Associate Professor, University of Turku, Finland.

of Neuroscience, Italy.

- *Molecular markers of multiple sclerosis disease progression:* Gabriele De Luca, Associate Professor of Clinical Neurology, Nuffield Department of Clinical Neurosciences, University of Oxford, UK.

The GMSI was launched in October 2012 with the aim of improving the understanding of MS for the ultimate benefit of those living with the disease. This year researchers from across the globe were invited to submit proposals describing promising translational research projects, resulting in 146 proposals.

"At EMD Serono, our long-term commitment to MS patients is evident in our medical research and development programs. The Grant for Multiple Sclerosis Innovation is another manifestation of our commitment and the interest in advancing the science behind MS is clear from the number of proposals this year," says Steven Hildemann, Chief Medical Officer, and head of Global Medical Affairs and Global Drug Safety at the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. "I am impressed by the breadth, depth, and quality of the proposals, and it is further confirmation that there continues to be a deep interest within the scientific community to gain further understanding of the disease."

The call for proposals, for the 2016 GMSI was made by EMD Serono at today's Symposium. 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. More information about the GMSI can be found at the following website: www.grantformultiplesclerosisinnovation.org

**About multiple sclerosis**

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

**About EMD Serono**

EMD Serono, a subsidiary of Merck KGaA, Darmstadt, Germany, is a leading US biopharmaceutical company focused exclusively on specialty care. For more than 40 years, EMD

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**

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.

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SOURCE EMD Serono

# EMD Serono announces publication of PRISMS-15 yr follow-up study in patients using Rebif® (interferon beta-1a), focused on factors influencing outcomes in RRMS

EXPLORE MORE

ROCKLAND, Mass., Oct. 12, 2015 /PRNewswire/ -- EMD Serono, the U.S. biopharmaceutical business of Merck KGaA, Darmstadt, Germany, today announced that the *Journal of Neurology, Neurosurgery and Psychiatry (JNNP)* published 15 year follow-up data for Rebif® (interferon beta-1a), the company's high-dose, high-frequency interferon beta for relapsing forms of multiple sclerosis from PRISMS (Prevention of Relapses and Disability by Interferon beta-1a Subcutaneously in Multiple Sclerosis) trial. The published data highlights outcomes from an exploratory study of the relationship between cumulative exposure to subcutaneous (sc) interferon (IFN) beta-1a treatment and other possible prognostic factors with clinical outcomes in relapsing–remitting multiple sclerosis (RRMS).

"The publication of the PRISMS-15 study in JNNP offers the MS medical community a retrospective single visit assessment in a subset of RRMS patients from the PRISMS trial with varying exposure to Rebif," said Dr. Rick Munschauer, Vice President, Medical Affairs, Neurology and Immunology, EMD Serono.

also has ongoing MS clinical study programs, including a Phase I study of ATX-MS-1467, an investigational therapy for relapsing remitting multiple sclerosis (RRMS), and a Phase IIb study of imilecleucel-T, an investigational therapy for Secondary Progressive MS (SPMS), an area of high unmet medical need. The company has an option agreement with Opexa Therapeutics, Inc. for the development and commercial licensing of imilecleucel-T.

*Kappos L, et al. J Neurol Neurosurg Psychiatry 2015;0:1–6. doi:10.1136/jnnp-2014-310024*

**About Rebif® (interferon beta-1a)**

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

**Important Safety Information**

Before beginning treatment, you should discuss the potential benefits and risks associated with Rebif with your healthcare provider.

Rebif can cause serious side effects. Tell your healthcare provider right away if you have any of the symptoms listed below while taking Rebif.

- Behavioral health problems including depression and suicidal thoughts. You may have mood problems including depression (feeling hopeless or feeling bad about yourself), and thoughts of hurting yourself or suicide
- Liver problems or worsening of liver problems including liver failure. Symptoms may include nausea, loss of appetite, tiredness, dark colored urine and pale stools, yellowing of your skin or the white part of your eye, bleeding more easily than normal, confusion, and sleepiness. During your treatment with Rebif you will need to see your healthcare provider regularly and have regular blood tests to check for side effects
- Serious allergic and skin reactions. Symptoms may include itching, swelling of your face, eyes, lips, tongue or throat, trouble breathing, anxiousness, feeling faint, skin rash, hives, sores in your mouth, or skin blisters and peels
- Injection site problems. Symptoms at the injection site may include redness, pain, swelling, color changes (blue or black), and drainage of fluid.
- Blood problems. Rebif can affect your bone marrow and cause low red and white blood cell, and platelet counts. In some people, these blood cell counts may fall to dangerously low levels. If your blood cell counts become very low, you can get infections and problems with

- Seizures. Some people have had seizures while taking Rebif

Rebif will not cure your MS but may decrease the number of flare-ups of the disease and slow the occurrence of some of the physical disability that is common in people with MS.

Do not take Rebif if you are allergic to interferon beta, human albumin, or any of the ingredients in Rebif.

Before you take Rebif, tell your healthcare provider if you have or have had any of the following conditions:

- mental illness, including depression and suicidal behavior
- liver problems, bleeding problems or blood clots, low blood cell counts, seizures (epilepsy), or thyroid problems
- drink alcohol
- you are pregnant or plan to become pregnant. It is not known if Rebif will harm your unborn baby. Tell your healthcare provider if you become pregnant during your treatment with Rebif.
- you are breastfeeding or plan to breastfeed. It is not known if Rebif passes into your breast milk. You and your healthcare provider should decide if you will use Rebif or breastfeed. You should not do both.

Tell your healthcare provider about all medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

The most common side effects of Rebif include:

- flu-like symptoms. You may have flu-like symptoms when you first start taking Rebif. You may be able to manage these flu-like symptoms by taking over-the-counter pain and fever reducers. For many people, these symptoms lessen or go away over time. Symptoms may include muscle aches, fever, tiredness, and chills
- stomach pain
- change in liver blood tests

For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional.

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SOURCE EMD Serono

# Merck KGaA, Darmstadt, Germany, Appoints Laszlo Radvanyi as Head of Global Immuno-Oncology Research



**Radvanyi brings more than 25 years of experience in immuno-oncology R&D**

DARMSTADT, Germany, Nov. 2, 2015 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced the appointment of Laszlo Radvanyi, PhD, as Senior Vice President, Head of Research in Immuno-Oncology. Radvanyi brings extensive immuno-oncology expertise to the role, having spent 10 years conducting research on tumor infiltrating lymphocytes (TILs) and more than 25 years studying cellular and molecular immunology.

As the Head of Research in Immuno-Oncology for Merck KGaA, Darmstadt, Germany, Radvanyi will focus on leading the discovery of oncology therapies that leverage the natural ability of the body's immune system to fight cancer, as well as identifying biomarkers with the aim to deliver personalized treatments for patients. Radvanyi will contribute to shaping Merck KGaA, Darmstadt, Germany's immuno-oncology R&D strategy and driving its leadership position in the field.

oncology research is very impressive. His expertise and fresh perspective will add significant value to our early-stage immuno-oncology portfolio including combination and biomarker strategies for avelumab and other clinical candidates, as we endeavour to bring new therapeutic options to patients living with cancer."

The research efforts of Merck KGaA, Darmstadt, Germany in immuno-oncology led to the discovery and progression of its lead anti-PD-L1 candidate avelumab* into clinical development; currently it is being studied in more than 15 types of cancer.

Prior to joining Merck KGaA, Darmstadt, Germany, Radvanyi served as Chief Scientific Officer at Lion Biotechnologies based in Tampa, Florida, where he was responsible for developing novel technologies to produce next-generation TILs for tumor indications including lung, cervical and breast cancer. In this role, he was instrumental in driving the company's metastatic melanoma TIL program into clinical development in the first TIL therapy trial performed outside an academic center.

Earlier in his career, he served as Professor of melanoma and breast medical oncology at MD Anderson Cancer Center in Houston, Texas, where he conducted clinical studies on TIL therapy in metastatic melanoma. In this role, he also conducted basic and translational research to identify relevant T-cell therapy biomarkers, enhance the anti-tumor function of expanded T-cells, and improve the manufacturing methods for eventual commercialization of T-cell therapies. His work there also spanned into the area of T-regulatory cells where he identified new Treg biomarkers associated with clinical responses to melanoma immunotherapy. He also established and led an Immunomonitoring Core facility at MD Anderson Cancer Center for over 9 years.

Radvanyi has a bachelor's degree in biology, a master's degree in botany, and a PhD in clinical biochemistry with a focus on immunology, all from the University of Toronto. Among his postdoctoral appointments was as a Cancer Research Institute (CRI) fellow in the Department of Immunology and Immunogenetics at the Joslin Diabetes Center at Harvard Medical School with Drs. Diane Mathis and Christophe Benoist.

Radvanyi has published more than 100 peer-reviewed and invited research articles and serves as an adjunct member of faculty in the Department of Immunology at H. Lee Moffitt Cancer Center in Tampa, Florida.

November 2, 2015. He will be based in Billerica, Massachusetts.

The biopharmaceutical business of Merck KGaA, Darmstadt, Germany, operates as EMD Serono in the U.S.

*Avelumab is the proposed International Nonproprietary Name (INN) for the anti-PD-L1 monoclonal antibody (MSB0010718C)

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1,100 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts.

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# Merck KGaA, Darmstadt, Germany, Named as Top Employer by Science Magazine



**- Company makes Top 20 Employer list for second year in a row**

DARMSTADT, Germany, Nov. 3, 2015 /PRNewswire/ -- Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced it was named one of the top 20 employers in the biopharmaceutical industry by *Science* magazine, a leading peer-reviewed international scientific publication. Merck KGaA, Darmstadt, Germany, ranked 17th among biotechnology and pharmaceutical companies worldwide. This is the second year in a row the Company has been named to the Top Employer list, improving from its position of number 20 in 2014. The biopharmaceutical business of Merck KGaA, Darmstadt, Germany, operates as EMD Serono in the United States.

Merck KGaA, Darmstadt, Germany, is proud of the innovation that exists within its R&D organizations across all business areas, and the commitment of employees to deliver that innovation to our stakeholders, including patients in need around the world. The people of Merck KGaA, Darmstadt, Germany, are fundamental to its success, and this recognition is a compliment to their dedication and contributions.

Each year, Science Careers commissions a survey to identify the top employers in the biotechnology and pharmaceutical industry and to determine the characteristics that best

In selecting the best companies, respondents yet again chose "innovative leader" as the top-driving characteristic. A top employer is also defined as an organization that "treats employees with respect," "has loyal employees," "is socially responsible," and has a "work culture aligned" with employees' values.

The 2015 survey included a way for respondents to rank the biggest advantages to working in the biopharma industry. Workers voted "innovation" solidly as #1, followed by "working with smart colleagues" and "excellent compensation and benefits" as a close #2 and #3, respectively.

Merck KGaA, Darmstadt, Germany, ranked highly across the categories of social responsibility, having loyal employees, and having a work culture aligned with employees' values.

*Science* Magazine's annual Top Employer feature became available in print and online October 29, 2015 and includes detailed survey results for the top 20 companies overall.

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

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SOURCE Merck KGaA

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