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EMD Serono: Phase III Trial of Cilengitide Did Not Meet Primary Endpoint in Patients With Newly Diagnosed Glioblastoma

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- Patients with newly diagnosed glioblastoma and methylated MGMT gene promoter status did not live significantly longer when treated with cilengitide plus chemoradiotherapy

Rockland, Massachusetts, February 25, 2013 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today that the Phase III CENTRICa trial of the investigational integrin inhibitor cilengitide did not meet its primary endpoint of significantly increasing overall survival when added to the current standard chemoradiotherapy regimen (temozolomide and radiotherapy). CENTRIC includes patients with newly diagnosed glioblastoma and methylated O⁶-methylguanine-DNA methyltransferase (MGMT) gene promoter status. The trial was planned and is being conducted in partnership with the European Organization for Research and Treatment of Cancer (EORTC). Detailed trial results will be submitted for presentation at the American Society of Clinical Oncology (ASCO) 2013 Annual Meeting and publication in a peer-reviewed journal.

most frequently reported adverse events the investigators considered to be attributed to cilengitide included nausea and fatigue.

CENTRIC is a randomized, controlled, multicenter, open-label Phase III trial. The trial evaluated the efficacy and safety of cilengitide in combination with temozolomide and radiotherapy in more than 500 patients from 23 countries worldwide with newly diagnosed glioblastoma and methylated MGMT gene promoter status. Patients whose tumors have an unmethylated MGMT gene promoter status are currently being evaluated in the Phase II, randomized, open-label, multicenter COREb trial.

"These results illustrate how challenging this disease remains, and that thorough clinical investigations like in this study are crucial before adopting new treatment strategies," said the lead investigator and president of the EORTC Professor Roger Stupp, Head of NeuroOncology, Department of Neurosurgery, University of Lausanne Medical Center, Lausanne, Switzerland and newly appointed director of the Zurich University Cancer Center. "Nevertheless, the unique collaboration between academia and industry was key in establishing molecular tumor characterization towards personalized medicine. And it allows for investigation of mechanisms of disease, and identifying novel targets and combinations for the future. We remain committed to addressing the needs of patients suffering from this rare disease and will continue to investigate other treatment options."

Dr. Annalisa Jenkins, Head of Global Drug Development and Medical for Merck Serono, a division of Merck KGaA, Darmstadt, Germany commented: "The results of CENTRIC are disappointing, especially for people who are fighting this devastating and difficult to treat cancer. Over the coming months, we intend to analyze the data sets and ensure appropriate public disclosure of key information that will serve future scientific research related to targeted therapies in oncology. For a complete picture, we will also evaluate the results of the currently ongoing Phase II CORE trial, which included only patients with an unmethylated MGMT gene promoter status. We remain committed to advancing our pipeline and developing new treatment options in oncology for patients with high medical need."

a.CENTRIC: Cilengitide in combination with Temozolomide and Radiotherapy In newly diagnosed glioblastoma Phase III randomized Clinical trial

About Cilengitide

Cilengitide is the first in a new class of investigational targeted anticancer therapies – the integrin inhibitors – to have reached Phase III clinical development. Cilengitide is thought to target certain integrins over-expressed or aberrantly expressed in many cancers that are involved in tumor cell growth and the formation of new tumor-related blood vessels in the tumor microenvironment.

Cilengitide is currently being investigated in glioblastoma – a very aggressive type of brain tumor – in a Phase III trial (CENTRIC) and in a Phase II trial (CORE). An additional Phase I/II trial is ongoing in non-small cell lung cancer (NSCLC). Further trials are being conducted by the U.S. National Cancer Institute (NCI). In the United States and Canada, cilengitide is being developed by EMD Serono, a subsidiary of Merck.

- The CENTRIC trial is a multicenter, randomized, controlled, open-label Phase III trial in patients with newly diagnosed glioblastoma and methylated MGMT gene promoter (M+) status. The study assessed the efficacy and safety of adding cilengitide to chemoradiotherapy (CRT; temozolomide [TMZ] and radiotherapy followed by TMZ), versus CRT alone. CENTRIC was planned and conducted in close partnership with the European Organisation for Research and Treatment of Cancer (EORTC).

- The CORE trial is a multicenter, randomized, controlled, open-label Phase II trial in patients with newly diagnosed glioblastoma and unmethylated MGMT gene promoter (M-) status. The study is assessing the safety and tolerability of two cilengitide dosing schedules added to CRT, versus that of CRT alone.

About MGMT Testing

The methylation status of methylguanine-DNA methyltransferase (MGMT) gene promoter is an important molecular factor in glioblastoma tumors. MGMT is thought to contribute to cellular DNA repair. Methylation of the gene promoter in the tumor tissue silences the expression of

Merck Serono is committed to the philosophy of personalized cancer care. The clinical trial program for cilengitide includes a companion diagnostic biomarker test, PredictMDx for Glioblastoma, produced by MDx Health, which identified the methylation status of the MGMT gene in patients. Patients whose tumors had methylated MGMT gene promoter status were included in the CENTRIC trial. Patients with unmethylated MGMT gene promoter status are currently being evaluated in the Phase II open-label multicenter CORE trial.

About EORTC

The aims of the European Organisation for Research and Treatment of Cancer (EORTC; www.eortc.org) are to develop, conduct, coordinate, and stimulate translational and clinical research in Europe to improve the management of cancer and related problems, aiming at increasing survival but also patient quality of life. Extensive and comprehensive research in this wide field is beyond the means of individual European hospitals, and can best be accomplished through the multidisciplinary multinational efforts of basic scientists and clinicians.

Over the past few years, numerous innovative agents have been discovered as a result of tremendous developments in the understanding of the molecular basis of cancer. Further clinical progress in cancer treatment will be accomplished mainly through the conduct of translational research projects, efficient drug development and the execution of large, prospective, randomized, multicenter cancer clinical trials. The EORTC promotes multidisciplinary cancer research in Europe and is linked to other leading biomedical research organizations around the world.

The aim of the EORTC is to facilitate the passage of experimental discoveries into state-of-the-art treatments by keeping to a minimum the time lapse between the discovery of new anti-cancer agents and the implementation of their therapeutic benefit for patients with cancer.

The ultimate goal of the EORTC is to improve the standards of cancer treatment and care, and personalized therapy. Innovative drugs and new regimens are being evaluated, and strategies of available drug treatments, surgery and radiotherapy being optimized and combined



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

For more information, please visit www.emdserono.com

About Merck KGaA

Merck is a global pharmaceutical and chemical company with total revenues of €10.3 billion in 2011, a history that began in 1668, and a future shaped by approx. 40,000 employees in 67 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

For more information, please visit www.merckserono.com or www.merckgroup.com.

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EMD Serono Announces Appeals Court Decision

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Rockland, MA, April 15, 2013 – A Pennsylvania appellate court recently decided that the collaboration agreement that EMD Serono Inc., a subsidiary of Merck KGaA, Darmstadt, Germany and Pfizer Inc. entered into in July 2002 for the co-promotion of the multiple sclerosis treatment Rebif® (interferon beta-1a) extends until December 31, 2015.

EMD Serono, which developed Rebif, had contended that the collaboration should end on December 31, 2013, based on the provisions of the agreement governing extension of the term, and had filed a complaint seeking a court declaration to that end. A lower court ruled that the agreement extends through 2015 and the appellate court affirmed that decision. EMD Serono has asked the appellate court to reconsider its ruling. Unless the court grants the request on or before June 7, it will be deemed denied.

EMD Serono remains committed to the success of Rebif and its efforts to promote Rebif. The decision will have no impact on patients or supply of Rebif and does not change the company's Rebif business plans and growth prospects in the US.



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

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MS LifeLines® Call Center Earns J.D. Power and Associates Re-Certification for Customer Service Excellence in Providing Support Services to the MS Community

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-Certification marks second consecutive year J.D. Power and Associates recognizes MS LifeLines for providing an outstanding customer service experience

Rockland, MA/New York, NY, May 28, 2013 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, and Pfizer Inc. announced today that the MS LifeLines® call center earned re-certification for customer service excellence in providing support services to the multiple sclerosis (MS) community through the prestigious J.D. Power and Associates Call Center Certification ProgramSM. This is the second consecutive year J.D. Power and Associates has recognized MS LifeLines with this certification after a thorough audit of customer satisfaction practices over several months in 2012.

For more than a decade, MS Lifelines has been committed to connecting with the MS community, listening to its needs and delivering individualized support to people living with MS, their families and their caregivers 24 hours a day, seven days a week.

Director, J.D. Power and Associates. "Our research indicated that in particular, customers were News Release very pleased with the level of courtesy and concern provided by MS LifeLines representatives, which is so critical when helping people cope with health-related issues."

To achieve certification, the MS LifeLines call center successfully passed a detailed audit of more than 100 practices across its call center operations and support functions. As part of its evaluation, J.D. Power and Associates also randomly surveyed MS LifeLines callers who recently contacted the call center. For certification status, the call center had to perform within the top 20 percent of customer service scores, which are based on benchmarks established in J.D. Power and Associates' cross-industry customer satisfaction research.

"We are honored to receive J.D. Power and Associates Call Center Certification program recognition for the MS LifeLines call center for a second straight year," said James Hoyes, President of EMD Serono, Inc. "We are proud to provide support to the MS community through MS LifeLines and are pleased that the customer service excellence provided by our call center specialists continues to be recognized."

MS LifeLines is an educational support service committed to the MS community in the United States. Its mission is to offer support to people with MS, which includes people taking or considering Rebif® (interferon beta-1a) for treatment of their relapsing MS, and the caregivers who support them. The web site, www.mslifelines.com, provides information on living well with MS. The MS LifeLines call center is located at EMD Serono's headquarters in Rockland, MA.

"The MS LifeLines' call center is central in our being able to provide individualized support and resources to the MS community, which also include our Nurse Support Network, MS LifeLines Ambassadors and patient education programs," said Liz Barrett, President, North America, Pfizer Specialty Care. "We look forward to continuing our commitment to excellence in the services we provide to the MS community."

At the heart of the MS LifeLines network is its call center, which has answered nearly 1.5 million in-bound calls to date. The call center includes patient enrollment specialists, patient support specialists, nurse support specialists and reimbursement specialists. Whenever News Release someone in the MS community needs to speak with a live person, support is available toll-free at 1-877-447-3243. The MS community can also visit MS LifeLines online at

- **Nurse Network:** MS LifeLines nurses are MS-certified. They are trained in the specialty of MS and certified by the International Organization of Multiple Sclerosis Nurses. They are available to conduct in-home injection training across the United States.
- **Reimbursement Specialists:** These professionals can help the relapsing MS community understand their insurance benefits and assist them in getting access to Rebif.
- **MS LifeLines Ambassadors:** EMD Serono and Pfizer recognize it can sometimes help to talk with someone about what it's like living with relapsing MS. MS LifeLines Ambassadors are individuals living with relapsing MS who share their stories with others in the community.
- **Local Patient Programs:** Thousands of local patient programs are conducted each year around the country to help people impacted by relapsing MS stay informed and connected with the MS community in their area. These local events feature informative talks with health care professionals and inspiring stories from MS LifeLines Ambassadors.
- **Talk MS:** This online talk show series features a variety of guests, including healthcare professionals, nurses and people living with relapsing MS. EMD Serono, Inc. and Pfizer Inc. continue to demonstrate a commitment to the multiple sclerosis community with MS LifeLines and other programs.

For J.D. Power and Associates 2012 Call Center Certification ProgramSM information, visit www.jdpower.com.

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

About Rebif® (interferon beta-1a)

Rebif is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the

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.

Users should demonstrate competency in all aspects of the injection prior to independent use. Patients with severe neurological deficits should not self-administer injections without assistance from a trained caregiver. Before taking Rebif, patients should tell their doctor if they have a history of depression, anxiety, trouble sleeping, liver disease, thyroid problems, blood cell count or bleeding problems, epilepsy, or are planning to become pregnant. Patients should tell their doctor about all medicines they take, including prescription and non-prescription medicines, vitamins and herbal supplements. Rebif and other medicines may affect each other causing serious side effects. Patients should talk to their doctor before taking any new medicines.

Possible side effects of Rebif include flu-like symptoms (fever, chills, sweating, muscle aches and tiredness), injection-site reactions, depression and anxiety, liver problems, abdominal pain, blood problems, thyroid problems and severe allergic reactions. Patients should let their doctor know if they have any of these symptoms or feel sad, tired, hot or cold, or experience hives, rashes, bruising, yellowing of the skin, or a change in body weight (gain or loss). This information is not intended to replace discussions with a doctor. For additional information about Rebif, please consult the Prescribing Information and Medication Guide at www.rebif.com and talk to a health care professional. Information is also available at www.mslifelines.com or call toll-free 1-877-44-REBIF (1-877-447-3243). Rebif is available by prescription only.

About EMD Serono, Inc.

EMD Serono is the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada - a leading science and technology company - focused exclusively on specialty

expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in oncology, immuno-oncology and immunology as R&D focus areas. Today, the business has 1,300 employees around the country with commercial, clinical and research operations based in the company's home state of Massachusetts. www.emdserono.com

About Merck KGaA, Darmstadt, Germany

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

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

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EMD Serono Announces Decision to Continue the Development of Tecemotide in Stage III Non-Small Cell Lung Cancer

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- ▶ **-The program will build upon the data from START* trial and explore potential in patients with Stage III NSCLC who have demonstrated stable disease or objective response after concurrent chemoradiotherapy**
- ▶ **-The Phase III START2 study will be conducted under a Special Protocol Assessment (SPA) with FDA**

Rockland, Massachusetts, September 25, 2013 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, today announced the decision to continue clinical development of its investigational MUC1 antigen-specific cancer immunotherapy tecemotide (also known as LBLP25) under a new Phase III trial called START2 for patients with unresectable, locally advanced Stage III non-small cell lung cancer (NSCLC). This announcement is based on the outcome of the START trial. The START trial did not meet the primary endpoint of improving overall survival (OS) in the overall patient population. Data from an exploratory analysis of a predefined subgroup of patients in the START trial, who received tecemotide after concurrent chemoradiotherapy (CRT), showed that these patients achieved a median OS of 30.8 months versus 20.6 months in patients treated with placebo (n=806; HR: 0.78; 95% CI 0.64–0.95;

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

Concurrent CRT is the current standard of care for these patients. The trial's primary endpoint is OS. The company also announced that it has received Scientific Advice from the European Medicines Agency (EMA) on the program, and has reached an agreement with the U.S. Food and Drug Administration (FDA) on a Special Protocol Assessment (SPA) for the Phase III international randomized trial.

"The results from the START trial provided insights into the potential clinical utility of tecemotide and raised a lot of interest in the scientific community. We haven't seen this type of clinically meaningful survival benefit with any other investigational therapies in unresectable Stage III NSCLC. Further investigation might help to better understand the potential role that tecemotide could play in successfully treating these patients," said Dr. Charles Butts, Cross Cancer Institute, University of Alberta, Edmonton, Canada, clinical investigator of the START trial and member of the corresponding steering committee.

Dr. Annalisa Jenkins, Head of Global Drug Development and Medical for Merck Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, said: "The START data delivered important insights that we believe justify further investigation in a new Phase III program. NSCLC is a devastating disease, and we are pleased to be able to continue supporting innovation in this important emerging field of immuno-oncology."

Tecemotide is an investigational MUC1 antigen-specific cancer immunotherapy designed to stimulate the body's immune system to identify and target cancer cells expressing the cell surface glycoprotein MUC1.1,2 MUC1 is expressed in many cancers, including NSCLC, and has multiple roles in tumor growth and survival.^{1,3}

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.⁴ NSCLC is the most common type of lung cancer, accounting for 80–85% of all lung cancers, and locally advanced or Stage III disease accounts for approximately 30% of patients with NSCLC.^{5,6} Unfortunately, at diagnosis, most patients have

*START: Stimulating Targeted Antigenic Responses To NSCLC

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About tecemotide

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

Merck KGaA obtained the exclusive worldwide rights for development and commercialization of tecemotide from Oncothyreon Inc., Seattle, Washington, U.S., in 2007, in an agreement replacing prior collaboration and supply agreements originally entered in 2001. In Japan, Merck

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

INSPIRE (tecemotide liposome vaccine trial In Asian NSCLC Patients: Stimulating Immune REsponse) is a Phase III, multicenter, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the efficacy, safety and tolerability of tecemotide in patients suffering from unresectable, locally advanced Stage IIIA or IIIB NSCLC who have had a response or stable disease after at least two cycles of platinum-based concurrent chemoradiotherapy. The design of INSPIRE is almost identical to the START trial. INSPIRE is enrolling approximately 420 unresectable, locally advanced Stage III NSCLC patients across China, Hong Kong, Korea, Singapore and Taiwan.

Tecemotide is currently under clinical investigation and has not been approved for use in the U.S., Europe, Canada, or elsewhere. Tecemotide has not been proven to be either safe or effective and any claims of safety and effectiveness can be made only after regulatory review of the data and approval of the labeled claims.

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EMD Serono Receives FDA Approval for Redesigned Fertility Pen

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-Gonal-f ® RFF* Redi-ject™ (follitropin alfa injection) incorporates updates and new features developed from patient and provider feedback

Rockland, Massachusetts, October 17, 2013 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today that the U.S. Food and Drug Administration (FDA) approved Gonal-f ® RFF* Redi-ject™ (follitropin alfa injection), a disposable pre-filled drug injector pen intended for the subcutaneous injection of a liquid formulation of Gonal-f ® RFF.

“EMD Serono is excited and proud to bring the Gonal-f ® RFF Redi-ject™ (follitropin alfa injection) to the market. This device was designed with key features based on feedback we received from Healthcare Professionals (HCPs), patients, and significant others,” said Craig Millian, Senior Vice President, Head of the US Fertility Franchise at EMD Serono. “Bringing the Gonal-f ® RFF Redi-ject™ to market aligns directly to our mission, which is to create, innovate, and advocate for people who want to have a child. EMD Serono has a long heritage of fertility expertise, and we will continue to invest in emerging science, patient-centric programs, and our existing product portfolio to achieve our goal of reducing barriers to treatment.”

*Revised Formulation Female

For more information about the GONAL-F® RFF Redi-ject™, please call Fertility Lifelines at 1-866-538-7879.

For information about Gonal-f ® RFF Redi-ject™, please visit emdserono.com for the Prescribing Information. Patients should consult their health care provider for additional information.

About Gonal-f ® RFF Redi-ject™ (follitropin alfa injection)

Gonal-f ® RFF Redi-ject™ (follitropin alfa injection) is indicated for: Induction of ovulation and pregnancy in oligoanovulatory women in whom the cause of infertility is functional and not due to primary ovarian failure, development of multiple follicles in ovulatory women as part of an Assisted Reproductive Technology (ART) cycle. Prior to initiation of treatment with Gonal-f ® RFF Redi-ject™: Women should have a complete gynecologic and endocrinologic evaluation and diagnose the cause of infertility. Primary ovarian failure and potential pregnancy should be excluded. Tubal patency should be demonstrated.

Gonal-f ® RFF Redi-ject™ is contraindicated in women who exhibit: Hypersensitivity to recombinant FSH preparations or one of their excipients, high levels of FSH indicating primary gonadal failure, pregnancy, uncontrolled non-gonadal endocrinopathies, sex hormone dependent tumors of the reproductive tract and accessory organs, tumors of pituitary gland or hypothalamus, abnormal uterine bleeding of undetermined origin, ovarian cyst or enlargement of undetermined origin, not due to polycystic ovary syndrome.

This product should only be prescribed by physicians specializing in fertility or reproductive health and only when appropriate monitoring facilities are available. The lowest effective dose should be used. Gonal-f ® RFF Redi-ject™ is a potent gonadotropin capable of causing Ovarian Hyperstimulation Syndrome (OHSS) with or without pulmonary or vascular complication and multiple births.

Serious systemic hypersensitivity reactions, including anaphylaxis, have been reported in the postmarketing experience with Gonal-f ® and Gonal-f ® RFF. Symptoms have included

instability and/or respiratory compromise occur, and discontinue further use.

In order to minimize the hazards associated with abnormal ovarian enlargement that may occur with Gonal-f ® RFF Redi-ject™ therapy, treatment should be individualized and the lowest effective dose should be used. Use of ultrasound monitoring of ovarian response and/or measurement of serum estradiol levels is important to minimize the risk of ovarian stimulation.

If the ovaries are abnormally enlarged on the last day of Gonal-f ® RFF Redi-ject™ therapy, hCG should not be administered in order to reduce the chance of developing Ovarian Hyperstimulation Syndrome (OHSS). Intercourse should be prohibited in women with significant ovarian enlargement after ovulation because of the danger of hemoperitoneum resulting from rupture of ovarian cysts.

OHSS is a medical entity distinct from uncomplicated ovarian enlargement and may progress rapidly to become a serious medical event. OHSS occurs after gonadotropin treatment has been discontinued and it can develop rapidly, reaching its maximum about 7 to 10 days following treatment. Cases of OHSS are more common, more severe, and more protracted if pregnancy occurs; therefore, women should be assessed for the development of OHSS for at least two weeks after hCG administration. If severe OHSS occurs, treatment must be stopped and the patient should be hospitalized and treated by a physician experienced in the management of this syndrome or in the management of fluid and electrolyte imbalances. During clinical trials with Gonal-f ® RFF, OHSS occurred in 7.2% of 83 women and 4.6% of 237 women treated with Gonal-f ® RFF for ovulation induction and during Assisted Reproductive Technology, respectively.

Serious pulmonary conditions (e.g., atelectasis, acute respiratory distress syndrome and exacerbation of asthma) have been reported in women treated with gonadotropins. In addition, thromboembolic events both in association with, and separate from OHSS have been reported in women treated with gonadotropins. Women with generally recognized risk factors for thrombosis, such as personal or family history, severe obesity, or thrombophilia, may have an increased risk of venous or arterial thromboembolic events, during or following treatment with gonadotropins. Sequelae of such reactions have included venous thrombophlebitis, pulmonary embolism, pulmonary infarction, cerebral vascular occlusion (stroke), and arterial occlusion resulting in loss of limb and rarely in myocardial infarctions. In rare cases, pulmonary complications and/or thromboembolic reactions have resulted in death. In women with

increased risk of thrombosis.

Ovarian torsion has been reported after treatment with gonadotropins. This may be related to OHSS, pregnancy, previous abdominal surgery, past history of ovarian torsion, previous or current ovarian cyst and polycystic ovaries. Damage to the ovary due to reduced blood supply can be limited by early diagnosis and immediate detorsion.

Multi-fetal gestation and births have been reported with all gonadotropin therapy including therapy with Gonal-f ® RFF.

During clinical trials with Gonal-f ® RFF, multiple births occurred in 20% of live births in women receiving therapy for ovulation induction and 35.1 % of live births in women undergoing ART.

The woman and her partner should be advised of the potential risk of multi-fetal gestation and birth before beginning therapy with Gonal-f ® RFF Redi-ject™.

The incidence of congenital malformations after some ART [specifically in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI)] may be slightly higher than after spontaneous conception. This slightly higher incidence is thought to be related to differences in parental characteristics (e.g., maternal age, maternal and paternal genetic background, sperm characteristics) and to the higher incidence of multi-fetal gestations after IVF or ICSI. There are no indications that the use of gonadotropins during IVF or ICSI is associated with an increased risk of congenital malformations.

Since infertile women undergoing ART often have tubal abnormalities, the incidence of ectopic pregnancy may be increased. Early confirmation of intrauterine pregnancy should be determined by β -hCG testing and transvaginal ultrasound.

The risk of spontaneous abortion (miscarriage) is increased with gonadotropin products. However, causality has not been established. The increased risk may be a factor of the underlying infertility.

There have been infrequent reports of ovarian neoplasms, both benign and malignant, in women who have had multiple drug therapy for controlled ovarian stimulation, however, a causal relationship has not been established.

and minimizing the risk of the OHSS and multiple gestation.

The most common adverse reactions ($\geq 5\%$) in ovulation induction include: headache, abdominal pain, and ovarian hyperstimulation. The most common adverse reactions ($\geq 5\%$) in ART include: abdominal pain, nausea, abdominal enlargement, headache, and injection site reactions (pain, bruising).

Advise patients to follow the Instructions for Use and not share the device or reuse needles.

Before prescribing Gonal-f® RFF Redi-ject™, please read the accompanying Prescribing Information.

About EMD Serono, Inc.

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

About Merck KGaA, Darmstadt, Germany

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

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the "Merck"



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EMD Serono and Open Monoclonal Technology Expand Collaboration

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-EMD Serono Acquires Unlimited Access to OmniRat® Human Antibody Platform

Rockland, Massachusetts October 24, 2013 – EMD Serono, a subsidiary of Merck KGaA, Darmstadt, Germany, and Open Monoclonal Technology, Inc. (OMT), a leader in the genetic engineering of animals for development of human therapeutic antibodies, today announced the expansion of the collaboration agreement they entered into in June 2012. Under the terms of the agreement, EMD Serono will make an upfront payment to secure unlimited access to the OmniRat® technology platform as well as success-based development milestones and royalties. Further details of the contract are not being disclosed.

"The expansion of our collaboration with OMT is reflective of its strong quality and the significant progress we've made together over the last 15 months," said Dr. Annalisa Jenkins, Executive Vice President and head of Global Research & Development forWKH biopharmaceutical division of Merck KGaA, Darmstadt, Germany. "This is a good example of our focus on exploring targeted partnerships with innovative companies such as OMT, with the goal of generating access to technologies that advance our capabilities in biotech development."

during the past 15 months. The expansion illustrates how OMT provides its partners with access to complementary platforms for discovery of superior antibodies against challenging targets in a cost-effective fashion.”

About Open Monoclonal Technology, Inc.

Open Monoclonal Technology, Inc. (OMT) is a leader in genetic engineering of animals for development of human therapeutic antibodies – naturally optimized human antibodies ® . OMT has created OmniRat®, the industry’s first fully human monoclonal antibody platform based on rats. The genetic engineering is the result of improved understanding of B cell development and a breakthrough approach to inactivation of endogenous rat antibody expression. OmniRat represents a novel and proprietary technology with unrestricted development options for fully human monoclonal antibodies. Along with Pfizer, OMT demonstrated that OmniRat animals have a complete immune system with a diverse antibody repertoire and generate antibodies with fully human idiotypes as well as wild-type animals make rat antibodies (Journal of Immunology 2013 Feb 15;190(4):1481-90). OMT’s antibody platforms have broad freedom to operate and use technology protected by new patents and patent applications.

For more information, please visit www.omtinc.net

About EMD Serono, Inc.

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

For more information, please visit www.emdserono.com

About Merck KGaA, Darmstadt, Germany

Merck KGaA, Darmstadt, Germany, is a global pharmaceutical, chemical and life science company with total revenues of € 11.2 billion in 2012, a history that began in 1668, and a future shaped by approx. 38,000 employees in 66 countries. Its success is characterized by innovations from entrepreneurial employees. The company's operating activities come under the umbrella of Merck KGaA, Darmstadt, Germany, in which the Merck family holds an approximately 70% interest and shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

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EMD Serono Announces Appointment of Paris Panayiotopoulos as President and Managing Director

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-Paris Panayiotopoulos to lead US operations of the biopharmaceutical division of Merck KGaA, Darmstadt, Germany

Rockland, Massachusetts, November 8, 2013 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today the appointment of Paris Panayiotopoulos as President and Managing Director of EMD Serono. In this capacity, he will be responsible for driving the strategic direction of the US commercial organization, as well as managing the operations of the US subsidiary.

Mr. Panayiotopoulos comes to EMD Serono from the company's Japan affiliate, Merck Serono, where he served as President and Managing Director since 2012.

"Paris is a strong customer and people oriented leader who brings a wealth of industry knowledge to this very important position for our organization," said Belén Garijo, MD,

performance and developing quality leadership teams. We are truly excited to have Paris take over this important and strategic role for the company.”

Mr. Panayiotopoulos joined Merck Serono, the biopharmaceutical division of Merck KGaA, Darmstadt, Germany in 2004 and has since held positions of increasing responsibility across multiple franchises and regions, including Director of Global Marketing, Global Commercial Team Leader, Head of Regional Operations and Head of the COO Office. Prior to this, Mr. Panayiotopoulos was at Eli Lilly & Co based in the UK.

“I am thrilled to have the opportunity to lead such a dedicated and driven organization in such a strategically important market for our Company,” said Mr. Panayiotopoulos. “I look forward to making great things happen with the talented employees of EMD Serono through our innovative, research-driven, specialty business to help patients live a better life.”

Mr. Panayiotopoulos has a BS in chemistry from the University College of London, and an MSc from Cranfield Business School of Management.

About EMD Serono, Inc.

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For more information, please visit www.emdserono.com

About Merck KGaA, Darmstadt, Germany

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

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

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EMD Serono's new spin - off TocopheRx to focus on infertility treatment

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- **Entrepreneur Partnership Program (EPP) to finance the 8th spin-off**
- **TocopheRx to accelerate development of investigational oral follicle-stimulating hormone agonists for treatment of infertility**

Rockland, Massachusetts December 2, 2013 –EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today the creation of TocopheRx, a Boston-based spin-off company resulting from the Entrepreneur Partnership Program (EPP) launched by the biopharmaceutical division of Merck KGaA, Darmstadt, Germany, in April 2012. TocopheRx, the 8th spin-off in the EPP will focus on the development of oral follicle-stimulating hormone (FSH) agonists for treatment of infertility, by advancing EMD Serono's preclinical program toward clinical testing. The affiliate of EMD Serono will initially invest \$3.2 million (approx. €2.4 million) in seed funding. MS Ventures, the corporate venture arm of the biopharmaceuticals division of Merck KGaA, Darmstadt, Germany, will manage the investment and will be represented on the company's board of directors.

FSH administration today is a standard hormonal treatment to help women and men with the unfulfilled desire to have children. TocopheRx strives to further investigate the potential role of

"The new company creation around EMD Serono's promising asset in the fertility space represents a unique opportunity to bring forward an innovative investigational product through externalization in a capital-efficient manner," said Belén Garijo, President and Chief Executive Officer of the biopharmaceutical division of Merck KGaA, Darmstadt, Germany. "It demonstrates our continued commitment to developing the next-generation of infertility treatments and required technologies, with the goal to improve the success rate of in vitro fertilization procedures."

The founders of TocopheRx are Stephen Palmer, Chief Scientific Officer at TocopheRx, Selva Nataraja, head of Biology, and Henry Yu, head of Medicinal Chemistry. Stephen Palmer was the head of the fertility research group at Merck Serono for 9 years, 2004-2013. Building on this highly experienced team combining scientific and drug discovery expertise with specific experience in the field of fertility, TocopheRx aims to bring a significant contribution to pharmaceutical approaches of infertility treatment. The seed financing will support the company to develop the asset from lead optimization to identification of a clinical candidate, and seek further financing and partnership opportunities for further development.

"Fertility research continues to be an important focus of R&D innovation. This seeding approach will enable us to further support the development of an oral FSH agonist, a promising early asset that we hope will help couples seeking fertility solutions," said Annalisa Jenkins, head of Global Research & Development for the biopharmaceutical division of Merck KGaA, Darmstadt, Germany.

Infertility is defined by the World Health Organization (WHO) as the inability of a couple to achieve conception or bring a pregnancy to term after a year or more of regular, unprotected sexual intercourse. It is estimated that over 70 million couples in the world are infertile. As the world leader in the treatment of infertility, EMD Serono has developed a comprehensive range of treatments designed to aid the estimated 1 in 10 couples of childbearing age who seek medical help for infertility.

TocopheRx is the 8th company financed in the context of the biopharmaceuticals division's EPP. Announced in April 2012 in the framework of the efficiency measures being taken by EMD Serono, the EPP is part of a € 30 million commitment to support the creation of spin-off and start-up companies focused on continuing activities and compounds that originated at EMD Serono. Initially, the program was aimed at reducing the impact on employment following the

Switzerland, but has been extended to former employees worldwide as well.

About TocopheRx

TocopheRx is a Boston based company developing novel therapies for treatment of infertility. The Company is a spin-off of the biopharmaceuticals division of Merck KGaA, Darmstadt, Germany, to further develop an oral FSH agonist toward clinical development and is seed financed by MS Ventures.

About MS Ventures

MS Ventures is the strategic corporate venture capital fund of the biopharmaceuticals division of Merck KGaA, Darmstadt, Germany. The fund was established in March 2009 and focuses primarily on early stage investments. MS Ventures has a strategic mandate and invests in companies that develop products and/ or technologies that could benefit patients in therapeutic areas relevant to the biopharmaceuticals division of Merck KGaA, Darmstadt, Germany.. MS Ventures has a total of EUR 140 million under management for strategic investments, investments through its Israel BioIncubator and for spin-offs from the organization. For more information, please visit www.ms-ventures.com.

About EMD Serono, Inc.

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EMD Serono's Redesigned Fertility Pen Available for Distribution in US

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- ▶ **Gonal-f® RFF* Redi-ject™ (follitropin alfa injection) was approved for use by the FDA on October 17, 2013**
- ▶ **-Gonal-f® RFF* Redi-ject™ incorporates updates and new features developed from patient and provider feedback**
- ▶ **-As of December 16 the device is available to patients in the United States**

Rockland, Massachusetts, December 16, 2013 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, announced today that Gonal-f® RFF Redi-ject™, a disposable pre-filled drug injector pen intended for the subcutaneous injection of a liquid formulation of Gonal-f® RFF, is now available in the U.S. for distribution. Gonal-f® RFF Redi-ject™ was approved by the U.S. Food and Drug Administration (FDA) on October 17, 2013.

"EMD Serono is excited that Gonal-f® RFF Redi-ject™ (follitropin alfa injection) is now available to patients and customers. This device was designed with feedback from Healthcare Professionals (HCPs), patients and significant others," said Craig Millian, Senior Vice President, Head of US Fertility and Endocrinology at EMD Serono. "EMD Serono has a long heritage of fertility expertise, and is committed to strengthening that legacy. Adding this device to our

The Gonal-f® RFF Redi-ject™ is available in three pen sizes: 300 IU, 450 IU and 900 IU.

*Revised Formulation Female Gonal-f® RFF Redi-ject™ has been available in wholesaler channels since December 9. It is anticipated that pharmacies will be fully stocked by December 16. To facilitate refills and supplementary orders for patients who have been trained on the Gonal-f® RFF Pen (not Rediject™), EMD Serono will maintain a small inventory of the Gonal-f® RFF Pen for a limited time.

For more information about the GONAL-F® RFF Redi-ject™, please call Fertility LifeLines at 1-866-538-7879.

For information about Gonal-f® RFF Redi-ject™, please visit fertilitylifelines.com. Patients should consult their health care provider for additional information.

About Gonal-f® RFF Redi-ject™ (follitropin alfa injection)

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

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

For use by physicians specializing in fertility treatment or reproductive health and only when appropriate monitoring facilities are available.

Gonal-f® RFF Redi-ject™ is a potent gonadotropin. The lowest effective dose should be used given risk of abnormal ovarian enlargement and Ovarian Hyperstimulation Syndrome (OHSS). Ultrasound monitoring of ovarian response and/or measurement of estradiol levels are

oliguria) develop, all gonadotropin treatment should be stopped, hCG should be withheld, and intercourse should be prohibited. OHSS can be severe and requires hospitalization and treatment of fluid and electrolyte imbalances. OHSS may occur with or without pregnancy. Refer to full prescribing information for complete disclosure.

Thromboembolic events both in association with, and separate from OHSS have been reported in women treated with gonadotropins. Women with generally recognized risk factors for thrombosis, such as personal or family history, severe obesity, or thrombophilia, may have an increased risk of venous or arterial thromboembolic events, during or following treatment with gonadotropins. Sequelae of such reactions have included venous thrombophlebitis, pulmonary embolism, pulmonary infarction, cerebral vascular occlusion (stroke), and arterial occlusion resulting in loss of limb and rarely in myocardial infarctions. In rare cases, pulmonary complications and/or thromboembolic reactions have resulted in death. In women with recognized risk factors, the benefits of ovulation induction and assisted reproductive technology need to be weighed against the risks.

Ovarian torsion has been reported after treatment with gonadotropins. This may be related to OHSS, pregnancy, previous abdominal surgery, past history of ovarian torsion, previous or current ovarian cyst and polycystic ovaries. Damage to the ovary due to reduced blood supply can be limited by early diagnosis and immediate detorsion.

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

Serious systemic hypersensitivity reactions, including anaphylaxis, have been reported in the postmarketing experience. Symptoms have included dyspnea, facial edema, pruritis, and urticaria. If an anaphylactic or other serious allergic reaction occurs, initiate appropriate therapy including supportive measures if cardiovascular instability and/or respiratory compromise occur, and discontinue further use.

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

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

characteristics) and to the higher incidence of multi-fetal gestations after IVF or ICSI.

The incidence of spontaneous abortion and ectopic pregnancy may be increased. Both benign and malignant ovarian neoplasms have been infrequently reported; causality has not been established.

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

The most common adverse reactions ($\geq 5\%$) in OI include: headache, abdominal pain, and ovarian hyperstimulation. The most common adverse reactions ($\geq 5\%$) in ART include: abdominal pain, nausea, abdominal enlargement, headache, and injection site reactions (pain, bruising).

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

HCP should refer to the full Prescribing Information for full disclosure.

About EMD Serono, Inc.

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

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Merck KGaA, Darmstadt, Germany, is a leading pharmaceutical, chemical and life science company with total revenues of € 11.2 billion in 2012, a history that began in 1668, and a future shaped by approx. 38,000 employees in 66 countries. Its success is characterized by innovations from entrepreneurial employees. The company's operating activities come under the umbrella of Merck KGaA, Darmstadt, Germany, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

About EMD Serono Fertility

EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company's US footprint continues to grow, with more than 850 employees around the country and fully integrated commercial, clinical, and research operations in the company's home state of Massachusetts. With a focus on specialized therapeutic areas, including reproductive health, neurology and metabolic endocrinology, the company is committed to growing existing therapeutic areas and entering into new ones by developing both biotherapeutic proteins and small molecules.

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EMD Serono, Inc. and the National MS Society Announce Recipients of Funding for Multiple Sclerosis Research

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- **EMD Serono and the National MS Society through Fast Forward provide funding of up to \$1.3 million in 2013 to accelerate early-stage research in MS**

Rockland, Mass./New York, NY, December 17, 2013 – EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, and the National Multiple Sclerosis Society through Fast Forward today announced the fourth group of recipients to receive funding through their collaboration, which is designed to accelerate innovation and commercial development of multiple sclerosis (MS) therapies.

The awards total approximately \$1.3 million and will be distributed from the Accelerating Innovation and Accelerating Commercial Development Funds created by EMD Serono and the National MS Society through Fast Forward to encourage early-stage drug discovery for MS. The Accelerating Innovation Program is open to academic institutions, non-profit research organizations and seed-stage for-profit commercial organizations. The other fund in the collaboration, the Accelerating Commercial Development Program is open to early-stage

EMD Serono and the National MS Society through Fast Forward distributed a call for proposals to fund projects directed towards the development of therapies to prevent, treat or reverse nervous system damage in MS. These priority research areas were determined by a joint steering committee comprised of Fast Forward staff and representatives from EMD Serono and Merck KGaA, Darmstadt, Germany.

The following organizations will receive funding:

- University of California, San Diego School of Medicine (Principal Researcher: Joan Heller Brown, Ph.D.) will receive \$285,000 over 18 months to perform research to identify a subset of G-protein coupled receptors (GPCRs) that activate astrocyte proliferation and inflammatory pathways through coupling to the G protein Gα12/13 and activation of RhoA.
- Emory University School of Medicine (Principal Researcher: Randy Hall, Ph.D.) will receive \$471,333 over 21 months to explore the importance of two orphan G protein-coupled receptors in the control of myelination.
- Euroscreen SA (Principal Researcher: Sébastien Hannedouche, Ph.D.) will receive \$501,657 over 12 months for the identification of ligands for up to five "orphan" GPCRs which may play pathogenic or protective roles in MS.

"We are pleased to announce the 2013 funding recipients whose work has the potential to broaden our knowledge and understanding of MS, and hopefully, result in new treatment options for people living with this disease," said Annalisa Jenkins, Global Head of Research and Development at Merck Serono, a division of Merck KGaA, Darmstadt, Germany. "Our ongoing collaboration with the National MS Society through Fast Forward reflects our sustained commitment to leveraging internal as well as external expertise in furthering scientific excellence in MS."

EMD Serono and the National MS Society entered into their collaboration in March 2009. As part of the up to \$19 million collaborative agreement, EMD Serono provides the majority of funding for the research awards, with the National MS Society contributing 10 percent of the total financing of the awards disseminated from each of the two funds.



Society. “We are pleased to have the opportunity to advance research through the continued collaboration with EMD Serono. We remain committed to being a driving force of research and treatment options to stop MS, restore function, and end MS forever, and we look forward to learning more from the results of these innovative projects.”

About Multiple Sclerosis

Multiple sclerosis, an unpredictable, often disabling disease of the central nervous system, interrupts the flow of information within the brain, and between the brain and body.

About the National Multiple Sclerosis Society and Fast Forward, LLC

The Society mobilizes people and resources to drive research for a cure and to address the challenges of everyone affected by MS. To fulfill this mission, the Society funds cutting-edge research, drives change through advocacy, facilitates professional education, collaborates with MS organizations around the world, and provides programs and services designed to help people with MS and their families move their lives forward. In 2013 alone, through its home office and 50-state network of chapters, the Society invested \$48.3 million to support 380 new and ongoing research projects around the world. The Society is dedicated to achieving a world free of MS. Join the movement at www.nationalMSSociety.org

Fast Forward, LLC was established by the National Multiple Sclerosis Society as part of a comprehensive approach to MS research and treatment, focusing on accelerating commercial development of promising research discoveries. Through Fast Forward, the Society connects university-based MS research with private-sector drug development and funds small biotechnology/pharmaceutical companies to develop innovative new MS therapies and repurpose FDA-approved drugs as new treatments for MS. For more information, please visit or more information, please visit www.nationalmssociety.org/fast-forward//index.aspx

About EMD Serono, Inc.



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

For more information, please visit www.emdserono.com

About Merck KGaA, Darmstadt, Germany

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