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

- Broadens access to Rebif® through expanded formulary coverage, including the CVS Caremark™ National Formulary
- Advances outcome assessments and scientific programs for relapsing MS patients

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

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

“We have also evolved our award-winning MS LifeLines® patient support service with the goal of providing a broad range of comprehensive assistance to people living with relapsing MS,” said Drew Young, Senior Vice President, Neurology and Immunology, EMD Serono. “Since reimbursement can often be complicated for

*IMS NPA data, June 2015 – October 2015; Patients who are new to therapy are defined as patients who have not received a prescription in at least the prior 12 months
patients to navigate, we are working to ensure that all eligible patients are aware of our comprehensive suite of patient support programs, including our reimbursement support.”

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

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

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

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

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

- **2016 Grant for MS Innovation**: EMD Serono is currently accepting proposals for the **2016 Grant for Multiple Sclerosis Innovation (GSMI) program**, which awards €1 million in funding with the aim of improving the understanding of MS for the ultimate benefit of those living with the disease. The submission deadline for 2016 proposals is February 8, 2016.

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

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

**About Rebif® (interferon beta-1a)**

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

**Important Safety Information**

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

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

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

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

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

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif-treated patients than in placebo-treated patients. Patients should be monitored for symptoms or signs of decreased blood counts. Monitoring of complete blood and differential white blood cell counts is also recommended.
Cases of thrombotic microangiopathy (TMA), some fatal, have been reported with interferon beta products, including Rebif, up to several weeks or years after starting therapy. Discontinue Rebif if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.

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

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

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


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

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

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About Merck KGaA, Darmstadt, Germany
Merck KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2014, Merck KGaA, Darmstadt, Germany, generated sales of € 11.3 billion in 66 countries. Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world’s oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the Merck KGaA, Darmstadt, Germany, name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.

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