EMD Serono and Pfizer Announce FDA Approval of Rebif® Rebidose® (interferon beta-1a)

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The majority of patients found Rebif Rebidose easy to use in a user trial

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EMD Serono, Inc., a subsidiary of Merck KGaA, Darmstadt, Germany, and Pfizer Inc. announced today that the U.S. Food and Drug Administration (FDA) approved Rebif® Rebidose® (interferon beta-1a), a single-use auto-injector for the self-administration of Rebif, a disease-modifying drug used to treat relapsing forms of multiple sclerosis (MS).

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"We are pleased to announce the FDA has approved Rebif Rebidose which provides people living with relapsing MS another option to meet their injection needs," said James Hoyes , president of EMD Serono, Inc. "The introduction of Rebif Rebidose underscores our commitment to the MS community and to our investment in the development of delivery devices to assist with ease of use and support those living with MS."

Rebif Rebidose was evaluated in a 12-week Phase IIIb multicenter, open-label, single-arm study for the self-administration of Rebif with respect to ease of use, patient satisfaction and acceptability, and functional reliability. In the trial, patients with relapsing MS, who were receiving Rebif 44 microgram three times weekly for more than 12 weeks, continued MS therapy using Rebif Rebidose for 12 weeks. The results of the Rebif

Rebidose user trial showed that the majority of patients found the device easy to use.

"Over the past two decades, treatment of relapsing MS has advanced and interferons such as Rebif have remained an established treatment option," said Liz Barrett , president, North America, Pfizer Specialty Care. "Rebif has a well-established safety profile with 18 years of clinical trial and patient experience. We are proud to offer another delivery option for Rebif with the approval of Rebif Rebidose in the United States."

Rebif Rebidose (interferon beta-1a) was designed with the objective to assist with ease of use and to offer patients an alternative delivery option. Rebif Rebidose will be available in a monthly pack in two different doses, 22 micrograms and 44 micrograms, and in a titration pack.

Rebif Rebidose will be available in the U.S. in early 2013. With this approval, all three delivery options of Rebif (prefilled syringes, Rebiject II and Rebif Rebidose) will be available in the U.S. to provide a range of options to meet the needs of patients treating their relapsing forms of MS with Rebif. Those living with MS can learn more about Rebif Rebidose and other Rebif product offerings by talking with their physician, calling MS LifeLines toll-free at 1-877-447-3243 or visit www.Rebif.com. For additional information about Rebif, please consult the Prescribing Information and Medication Guide.

About the Rebif® Rebidose®(interferon beta-1a)user trial

The user trial was a 12-week, phase IIIb, multicenter, open-label, single-arm study to evaluate Rebif Rebidose, for the self-administration of Rebif with respect to ease of use, patient satisfaction and acceptability, and functional reliability. Patients with relapsing MS, who were receiving Rebif 44 microgram three times weekly for more than 12 weeks, continued MS therapy using Rebif Rebidose for 12 weeks.

A total of 109 patients were enrolled in the study. Patients were between 18 and 65 years old with relapsing MS (McDonald criteria) and had received Rebif, 44 microgram three times weekly, consistently for 12 weeks or more prior to screening. Patients completed a user trial questionnaire at baseline and weeks 6 and 12.

The primary endpoint was the proportion of patients rating Rebif Rebidose as "easy to use" or "very easy to use" at week 12. Safety evaluation included the incidence of serious adverse events (AEs).

About Rebif® (interferon beta-1a)

Rebif is used to treat relapsing forms of MS to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS. Rebif is not approved for treatment of chronic progressive MS. Rebif is available in 22 mcg and 44 mcg prefilled, preassembled syringes and a titration pack.

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

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

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

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

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

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 there are approximately 400,000 people in the United States living with MS.

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, 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 KGaA 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 approximately 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 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.

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

About Pfizer Inc.

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the

discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also 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 about our commitments, please visit us at www.pfizer.com.

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