

## News Release

June 24, 2009

### **Merck Serono Launches RebiSmart™, First Electronic Injection Device For Delivery of Multiple Sclerosis Treatment Rebif®**

- **RebiSmart™ is designed to improve ease of handling and usage and introduces the potential for improved treatment adherence for multiple sclerosis patients**
- **First launch of RebiSmart™ together with recently approved multidose cartridges of the new formulation of Rebif® in the European Union and Canada**

Geneva, Switzerland, June 24, 2009 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today the launch of the innovative individually adjustable electronic injection device RebiSmart™ for the self-administration of Rebif® (interferon beta-1a), the company's disease-modifying drug used to treat relapsing forms of multiple sclerosis (MS). RebiSmart™ is the first device of its kind in this indication and was specifically designed for ease of handling and use. The unique features of RebiSmart™ also introduce the potential for improved treatment adherence, helping patients receive the full benefit from their treatment.

RebiSmart™ is used with Rebif® multidose cartridges, each of which contains one week's worth of medicine. Interactive, on-screen instructions and signals guide patients through the injection process, individually adjustable comfort settings give patients more flexibility with injection duration and depth, helping minimize discomfort and pain.

"Making injection more comfortable for the patient is important to ensure optimal treatment outcomes in multiple sclerosis," said Dr. Virginia Devonshire, Assistant Professor of Neurology at the University of British Columbia in Vancouver, Canada.

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“The first electronic injection device in MS is an innovative approach and could contribute to increasing patient adherence to therapy.”

RebiSmart™ is the first and only injection device in MS that records the date, time and dosage of each injection so that an accurate history of dosing can be viewed and discussed with the patient, allowing physicians to monitor and improve patient adherence to therapy. The dose history can be downloaded and viewed on a personal computer, thus also enabling the upload to patient registries in order to evaluate outcomes data in MS.

“The introduction of RebiSmart™ underscores our commitment to continuous advancements in multiple sclerosis treatments, in this case providing patients with an easy-to-use and innovative delivery system,” said Dr. Roberto Gradnik, Executive Vice President Commercial Europe at Merck Serono. “Patients and healthcare professionals were involved in the design of RebiSmart™, and their feedback was extremely valuable for developing an innovative device that really meets their needs.”

RebiSmart™ has been approved in Canada and the European Union. It was first launched in the United Kingdom and is also available in Canada now. Further launches will follow on a country-by-country basis. Two strengths of the multidose cartridge, 132 micrograms (three doses of 44 micrograms) and 66 micrograms (three doses of 22 micrograms), were approved by the European Medicines Agency (EMA) in January 2009. RebiSmart™ also facilitates use by patients starting treatment through its automatic pre-programmed titration setting. In May 2009, the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the EMA, issued a positive opinion for the storage of the multidose cartridge at temperatures up to 25 °C for 2 weeks.

For more information, please visit [www.rebismart.com](http://www.rebismart.com)

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### About Rebif®

Rebif® (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of multiple sclerosis (MS) and is similar to the interferon beta protein produced by the human body. The efficacy of Rebif® in chronic progressive MS has not been established. Interferons are thought to help modulate the body's immune system and reduce inflammation. The exact mechanism is unknown.

Rebif®, which was approved in Europe in 1998 and in the US in 2002, is registered in more than 80 countries worldwide. Rebif® has been proven to delay the progression of disability, reduce the frequency of relapses and reduce MRI lesion activity and area\*. Rebif® is available in a 22 micrograms and 44 micrograms ready-to-use pre-filled syringe and a titration pack (8.8 micrograms).

Rebif® should be used with caution in patients with a history of depression, liver disease and seizures. Most commonly reported side effects are flu-like symptoms, injection site disorders, elevation of liver enzymes and blood cell abnormalities. Patients, especially those with depression, seizure disorders, or liver problems, should discuss treatment with Rebif® with their doctors. For more information about Rebif®, please visit [www.ms lifelines.com](http://www.ms lifelines.com) for prescribing information.

\* The exact correlation between MRI findings and the current or future clinical status of patients, including disability progression, is unknown.

### About Merck Serono and multiple sclerosis

Merck Serono is a leader in multiple sclerosis (MS) with Rebif® (interferon beta-1a), a disease-modifying drug used to treat relapsing forms of MS, which is registered in more than 80 countries worldwide. Full prescribing information for this product can be obtained by contacting the Company or visiting its website. Additional therapeutic options are currently under development at Merck Serono, including 'Cladribine Tablets', currently in Phase III and potentially the first oral therapy for MS, as well as several products in early stage development. Merck Serono also is taking a leading role in developing an understanding of the role of genetics in MS.

### 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 more than 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 Merck Serono

Merck Serono is the division for innovative prescription pharmaceuticals of Merck, a global pharmaceutical and chemical group. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. Its North American business operates in the United States and Canada as EMD Serono.

Merck Serono has leading brands serving patients with cancer (Erbitux®, cetuximab), multiple sclerosis (Rebif®, interferon beta-1a), infertility (Gonal-f®, follitropin alpha), endocrine and metabolic disorders (Saizen® and Serostim®, somatropin), (Kuvan®, sapropterin dihydrochloride) as well as cardiometabolic diseases (Glucophage®, metformin), (Concor®, bisoprolol), (Euthyrox®, levothyroxine). Not all products are available in all markets.



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With an annual R&D expenditure of around € 1bn, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in autoimmune and inflammatory diseases.

### About Merck

Merck is a global pharmaceutical and chemical company with total revenues of € 7.6 billion in 2008, a history that began in 1668, and a future shaped by 32,700 employees in 60 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](http://www.merckserono.com) or [www.merck.de](http://www.merck.de)