

News Release

September 14, 2009

Results of RebiSmart™ User Trial Presented at 25th ECTRIMS Congress Show Broad Patient Acceptance of the New Electronic Delivery Device for Relapsing Multiple Sclerosis Treatment Rebif®

- **The majority of patients found the electronic multidose device “suitable” or “very suitable” for self-injection and rated the device functions as “easy” or “very easy” to use**
- **RebiSmart™ has the potential to improve treatment adherence for multiple sclerosis patients**

Geneva, Switzerland, September 14, 2009 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today the results of the RebiSmart™ user trial, a Phase IIIb, multi-center, single-arm study assessing the suitability and ease of use of RebiSmart™, a new electronic, multi-dose device for self-injection of Rebif® in patients with relapsing multiple sclerosis (MS). Based on patient feedback after 12 weeks of use, 72% of patients rated the new RebiSmart™ device as “very suitable”/“suitable” for subcutaneous self-injection of Rebif® (primary endpoint). In addition, 95% of patients rated the device functions as “very easy”/“easy” to use, 59% found the device “much more”/“more” convenient than their current Rebif® injection device, 60% requested to keep RebiSmart™ rather than return to their previous injection device and 61% made use of the possibility to customize the comfort settings (secondary endpoints). A questionnaire assessing safety and tolerability endpoints (MS Treatment Concern

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Questionnaire (MSTCQ)) showed that flu-like symptoms, injection-site reactions and overall side-effects were largely unchanged compared with the Rebi® injection device used prior to entering the trial.

“These results show that multiple sclerosis patients find RebiSmart suitable and easy-to-use for self-injection,” said Dr. Virginia Devonshire, Assistant Professor of Neurology at the University of British Columbia in Vancouver, Canada, and the primary investigator for the RebiSmart user trial. “As it is the first electronic injection device in multiple sclerosis, it will be interesting to assess whether RebiSmart has the potential to encourage adherence to therapy and improve treatment outcomes in multiple sclerosis.”

“Merck Serono is committed to constantly improving the wellbeing of patients suffering from multiple sclerosis,” said Dr. Roberto Gradnik, Executive Vice President Commercial Europe at Merck Serono. “We are pleased to see that this innovative device was well-received by this group of patients.”

RebiSmart is approved in the European Union and already available in Germany, UK and Denmark, as well as in Canada. 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. The storage of the Rebi multi-dose cartridge at temperatures up to 25 °C for 2 weeks was approved by the European Commission in July 2009. RebiSmart is not yet available in the United States.

The RebiSmart user trial data were presented at the 25th Congress of the European Committee for the Treatment and Research in Multiple Sclerosis (ECTRIMS) held in Düsseldorf, Germany, from September 9-12, 2009.

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About the RebiSmart™ user trial

The RebiSmart™ user trial was an international, multicentre, single-arm, open-label, 12-week, Phase IIIb study to evaluate the suitability of the new device for self-injection of Rebif®, 44 microgram three times weekly, in patients with relapsing MS.

A total of 106 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 6 weeks or more prior to screening. The disease duration had to be of 3 months or more. At baseline, patients were trained in the use of the device and subsequently self-injected Rebif®, 44 microgram three times weekly, for 12 weeks. Assessments were performed at baseline and weeks 2, 4, 8 and 12.

The primary endpoint was the proportion of patients rating the device at week 12 as “very suitable”/“suitable”/“little suitable”/“not at all suitable” for self-injection of Rebif®. Secondary endpoints included subscale scores on the MS Treatment Concern Questionnaire and overall evaluation of the device based on a questionnaire. Safety endpoints included the incidence of serious adverse events (AEs). Local reactions at the injection site (including pain, swelling or redness; patient-reported) were recorded on the local tolerability form as part of regular physician follow up.

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® is now available in Germany, UK and Denmark as well as in Canada in two multidose cartridges [132 micrograms (three doses of 44 micrograms) and 66 micrograms (three doses of 22 micrograms)] for the use with the RebiSmart device.

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.

* 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 undergoing registration review in Europe, 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.



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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 KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. In the United States and Canada, EMD Serono operates through separately incorporated affiliates.

Merck Serono has leading brands serving patients with cancer (Erbix®[®], 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.

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 approximately 33,000 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 or www.merck.de