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Results from IMPROVE Study Show Therapeutic Effect of New Formulation of Rebif[®] at 16 Weeks in Patients with Multiple Sclerosis

- Study meets primary endpoint by demonstrating significant effect of new formulation of Rebif[®] on disease activity as measured by MRI after 16 weeks of treatment
- Data presented at late-breaking session of the World Congress on Treatment and Research in Multiple Sclerosis in Montreal, Canada

Geneva, Switzerland, September 22, 2008 - Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today that the ongoing IMPROVE (Investigating MRI Parameters with Rebif imprOVEd formulation) study met its primary endpoint. The primary objective of the study was to evaluate the efficacy of the new formulation of Rebif[®], compared to placebo, in patients with relapsing-remitting multiple sclerosis (RRMS) and active disease by means of magnetic resonance imaging (MRI) at the end of 16 weeks of treatment. The 16-week study results show that the mean number of combined unique active brain MRI lesions per patient was reduced by 69% in patients treated with the new formulation of Rebif[®] compared with those receiving placebo, a statistically significant result ($p < 0.001$). These data were presented at the late-breaking session of the World Congress on Treatment and Research in Multiple Sclerosis in Montreal, Canada.

"Patients who received Rebif[®] experienced far fewer new active brain MRI lesions than the placebo group after 16 weeks of treatment," said Dr. Mark Freedman, Professor of Neurology at the University of Ottawa, Director of the MS Research Clinic at the Ottawa Hospital, and an investigator of the IMPROVE trial. "These data demonstrate a

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significant effect of the new formulation of Rebif[®] on disease activity and provide further evidence of its benefit in treating patients with relapsing-remitting multiple sclerosis.”

The IMPROVE study is a two-arm, randomized, double-blind, controlled, multicenter, international Phase IIIb study to evaluate the efficacy, safety and tolerability of the new formulation of Rebif[®] in patients with RRMS according to the revised McDonald criteria and evidence of active disease. A total of 180 patients were randomized in a 2:1 ratio to receive either the new formulation of Rebif[®] 44 micrograms three times a week subcutaneously, or placebo for an initial period of 16 weeks. At the end of this initial 16-week treatment period, patients from the placebo group have been switched in a single-blinded fashion to treatment with the new formulation of Rebif[®] 44 micrograms three times a week subcutaneously for a period of 24 weeks (the physician assessing treatment response and side effects is blinded). Patients who were initially assigned to the new formulation of Rebif[®] group continue to receive active treatment for an additional period of 24 weeks. The duration of the whole treatment period is 40 weeks.

The primary endpoint of the study is the difference between the number of combined unique active MRI lesions at week 16 in the group treated with the new formulation of Rebif[®] versus the placebo group. Combined unique active MRI lesions are defined as an active lesion on T1 sequence with gadolinium or T2 sequence, or both, avoiding double counting. The primary endpoint mainly reflects inflammatory activity (gadolinium-enhancing T1 lesions), but also reflects disease progression (T2 lesions).

The primary efficacy analysis showed that, at week 16, the number of combined unique active brain lesions was significantly lower in patients treated with the new formulation of Rebif[®] than in patients who received a placebo ($p < 0.001$). The mean number of combined unique active brain lesions per patient was reduced by 69% in patients treated with the new formulation of Rebif[®] compared with those receiving placebo (0.7 versus 2.2). The median number of combined unique active brain lesions at week 16 was 0.0 in the group treated with the new formulation of Rebif[®] and 1.0 in the placebo group. Over half (53%) of patients treated with the new formulation of Rebif[®] had zero

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combined unique active brain lesions at week 16, compared to only 16.7% in the placebo group.

Results for the secondary and tertiary endpoints of the IMPROVE study will be available at the end of the 40-week treatment period.

The safety profile of the new formulation of Rebif[®] reported in this study is consistent with the known safety profile of Rebif[®]. No unexpected safety concerns were identified in this study.

The new formulation of Rebif[®] was approved in the European Union in August 2007 and in Canada in September 2007. It is now marketed in all EU countries and in Canada. The new formulation of Rebif[®] is not available in the United States.

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 for prescribing information.

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

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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 Rebif[®] can be obtained by contacting the Company or visiting its website. Additional therapeutic options are currently under development at Merck Serono, including oral cladribine, 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 nervous system and is the most common, non-traumatic, disabling, neurological disease in young adults. The World Health Organization estimates that up to 2.5 million people suffer from 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[®]), multiple sclerosis (Rebif[®]), infertility (Gonal-f[®]), endocrine and cardiometabolic disorders (Glucophage[®], Concor[®], Euthyrox[®], Saizen[®], Serostim[®]), as well as psoriasis (Raptiva[®]).

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 € 7.1 billion in 2007, a history that began in 1668, and a future shaped by 31,946 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.net or www.merck.de