

News Release

July 12, 2010

Merck Serono's Cladribine Tablets for MS Approved in Russia

- **First approval ever of an oral disease-modifying therapy for multiple sclerosis**
- **Cladribine Tablets will be marketed in Russia under the trade name Movectro®**
- **Russian launch expected early 2011**

Geneva, Switzerland, July 12, 2010 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today that the Russian Federal Service on Surveillance in Healthcare and Social Development has become the first government agency to grant marketing approval to Cladribine Tablets for the treatment of relapsing-remitting multiple sclerosis (MS). Cladribine Tablets will be available in Russia under the trade name Movectro®.

“This approval for Cladribine Tablets means that people with relapsing-remitting multiple sclerosis in Russia will benefit soon from this effective oral treatment”, said Elmar Schnee, President of Merck Serono. “This is an important milestone reinforcing Merck Serono’s leadership position and ongoing commitment to fight against the devastating disease of multiple sclerosis. We expect other regulatory approvals in the near future.”

Merck Serono initiated its global filings in mid-2009 and, to date has submitted regulatory applications for Cladribine Tablets in about 40 countries.

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“The availability of Cladribine Tablets in Russia will represent a key milestone for people with multiple sclerosis as this is the first approval of an orally-administered disease-modifying therapy for relapsing-remitting multiple sclerosis”, said Professor Alexey Boyko, Department of Neurology and Neurosurgery at the Russian State Medical University, Moscow. “This approval is an important step toward optimizing medical care in multiple sclerosis.”

“The approval of Cladribine Tablets will transform the way Russian patients with relapsing-remitting multiple sclerosis and physicians approach therapy options”, said Professor Gavin Giovannoni, Blizard Institute of Cell and Molecular Science, Barts and The London School of Medicine and Dentistry, London, United Kingdom, and principal investigator of the CLARITY study. “I hope that this new therapeutic option will also be available soon for people living with multiple sclerosis in other countries.”

Merck Serono will now apply for the listing of Cladribine Tablets within the Russian State Federal drug reimbursement program. The Company expects to launch Movectro® in Russia in early 2011

Russian registration was supported by the results from the CLARITY¹ study, the largest placebo-controlled Phase III clinical trial in relapsing-remitting MS completed to date. A total of 1,326 patients with relapsing-remitting MS were randomized at 155 centers in 32 countries, including 23 centers in Russia. The CLARITY study results, recently published in *The New England Journal of Medicine*², show that short-course treatment with Cladribine Tablets significantly reduced relapse rates (the primary endpoint), the risk of disability progression (a key secondary endpoint), and MRI measures of disease activity (other key secondary endpoints) at 96 weeks. Adverse events that were more frequent in the Cladribine Tablets groups included lymphopenia and herpes zoster.

¹ CLARITY: CLAdRiBine Tablets Treating MS Orally

² Giovannoni G et al. A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis; *N Engl J Med* 362:416, February 4, 2010

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About the CLARITY study design

The CLARITY study was a two-year (96-week), randomized, double-blind, placebo-controlled, international trial. It randomized 1,326 patients with relapsing-remitting MS according to the revised McDonald criteria. Study participants were randomized to one of three different treatment groups consisting of two different dose regimens of Cladribine Tablets or matching placebo tablets (1:1:1 ratio). Cladribine Tablets were given in two (3.5 mg/kg total dose) or four (5.25 mg/kg total dose) treatment courses in the first year, with each course consisting of once daily administration for four to five consecutive days (depending on patient weight), which means study patients took Cladribine Tablets for 8 to 20 days during the year. In the second year, two treatment courses were administered to all patient groups, meaning that patients took Cladribine Tablets for 8 to 10 days during the year.

The primary endpoint of the CLARITY study was the relapse rate over 96 weeks. Secondary endpoints included MRI endpoints, proportion of subjects relapse-free and disability progression at 96 weeks.

About Cladribine Tablets

Merck Serono's oral formulation of cladribine (Cladribine Tablets) is an investigational treatment for patients with relapsing-remitting multiple sclerosis (MS). Cladribine is a small molecule that may interfere with the behavior and the proliferation of certain white blood cells, particularly lymphocytes, which are thought to be involved in the pathological process of MS. Merck Serono has applied for marketing approval of Cladribine Tablets in the European Union, the United States and other regions.

The clinical development program for Cladribine Tablets includes:

- The CLARITY (CLAdRIbine Tablets Treating MS Orally) study and its extension: a two-year Phase III placebo-controlled trial designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients with relapsing-remitting MS and the CLARITY EXTENSION two-year Phase III study designed to provide data on the long-term safety and efficacy of extended administration of Cladribine Tablets for up to four years.
- The ORACLE MS (ORAI CLadribine in Early MS) study: a two-year Phase III placebo-controlled trial designed to evaluate the efficacy and safety of Cladribine Tablets as a monotherapy in patients at risk of developing MS (patients who have experienced a first clinical event suggestive of MS). This trial was announced in September 2008.
- The ONWARD (Oral Cladribine Added ON To Interferon beta-1a in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled trial designed primarily to evaluate the safety and tolerability of adding Cladribine Tablets treatment to patients with relapsing forms of MS, who have experienced breakthrough disease while on established interferon-beta therapy. This trial was announced in January 2007.

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 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.

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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 (Erbitux®, cetuximab), multiple sclerosis (Rebif®, interferon beta-1a), infertility (Gonal-f®, follitropin alfa), 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 more than € 1 billion, 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 € 7.7 billion in 2009, a history that began in 1668, and a future shaped by approximately 33,600 employees in 64 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