

News Release

September 3, 2010

Merck Serono's Cladribine Tablets for MS Approved in Australia

Geneva, Switzerland, September 3, 2010 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today that the Australian Therapeutic Goods Administration (TGA) has approved Cladribine Tablets for the treatment of relapsing-remitting multiple sclerosis (MS)¹. Cladribine Tablets will be registered in Australia under the trade name Movectro[®].

“Approval of Cladribine Tablets in Australia is another step forward in our commitment to fight the devastating disease of multiple sclerosis by providing new therapeutic options meeting unmet needs,” said Elmar Schnee, President of Merck Serono. “Australia is the second country to approve Cladribine Tablets and we will continue our efforts to gain approval of Cladribine Tablets in other countries so that more patients can benefit from this oral disease-modifying therapy.”

Cladribine Tablets, also under the trade name Movectro[®], became the first oral MS treatment in the world to gain marketing authorization when health authorities in Russia approved it in July 2010. Merck Serono initiated global submissions for Cladribine Tablets in mid-2009 and to date has submitted regulatory applications for Cladribine Tablets covering about 40 countries.

¹ The indication approved by the TGA is: “Movectro is indicated for the treatment of relapsing-remitting multiple sclerosis for a maximum duration of two years.”

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About Cladribine Tablets

Merck Serono's oral formulation of cladribine (Cladribine Tablets) is an investigational treatment for patients with relapsing forms of 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 initiated global filings for Cladribine Tablets in mid-2009 and, to date has submitted regulatory applications for Cladribine Tablets covering about 40 countries. Cladribine Tablets was granted its first marketing approval in July 2010, in Russia.

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 (ORAL 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.
- The PREMIERE (Prospective observational long-term safEty registry of Multiple sclerosis patEnts who have participated in CladRibinE clinical trials) registry: an eight-year observational safety registry of patients who have participated in Cladribine Tablets clinical trials, designed to support the evaluation of the long-term safety of Cladribine Tablets 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 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 (Erbix[®], 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 40,000 (including Merck Millipore) 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