

## News Release

July 23, 2009

### **Merck Serono Submits Application for Cladribine Tablets as Multiple Sclerosis Therapy in Europe**

Geneva, Switzerland, July 23, 2009 – Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today the submission of a marketing authorization application (MAA) to the European Medicines Agency (EMA) for Cladribine Tablets, Merck Serono's proprietary investigational oral formulation of cladribine, as a therapy for patients with relapsing-remitting multiple sclerosis (MS). Cladribine Tablets could become the first orally administered disease-modifying therapy available for patients with MS, as all disease-modifying therapies currently approved for the treatment of MS are injectable.

"The submission of Cladribine Tablets to the EMA brings us closer to the possibility of providing an oral short-course treatment to patients with multiple sclerosis and underscores our commitment to provide new options for the management of relapsing-remitting multiple sclerosis," said Roberto Gradnik, Executive Vice President Commercial Europe at Merck Serono. "We look forward to working with the EMA and the European Member States' authorities."

The MAA submission is supported by results from the CLARITY<sup>a</sup> study, a two-year, randomized, double-blind, placebo-controlled Phase III trial of Cladribine Tablets in patients with relapsing-remitting MS. The CLARITY data were presented at the 61<sup>st</sup> Annual Meeting of the American Academy of Neurology (AAN) in April 2009 and at the 19<sup>th</sup> Meeting of the European Neurological Society (ENS) in June 2009.



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Merck Serono is currently submitting new drug applications for Cladribine Tablets in several other countries, including the United States in the current quarter.

<sup>a</sup> CLARITY: CLAdRi bine Tablets Treating MS Orally

### About the CLARITY study

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 or four treatment courses in the first year, with each course consisting of once daily administration for four to five consecutive days, 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. The primary endpoint of the CLARITY study was the qualifying relapse rate at 96 weeks. Secondary endpoints included MRI endpoints, proportion of subjects qualifying relapse-free and disability progression at 96 weeks. Out of the 1,326 randomized patients, 90% of patients treated with Cladribine Tablets completed the study (92% in the lower total dose group and 89% in the higher total dose group) compared to 87% in the placebo group.

### About Cladribine Tablets

Merck Serono's proprietary oral formulation of cladribine (Cladribine Tablets) is currently being evaluated in Phase III as a 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.

The clinical development program for cladribine tablets includes:

- The CLARITY extension study: a two-year placebo-controlled extension of the CLARITY 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 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 and is ongoing.
- The ONWARD 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 and is ongoing.

Cladribine Tablets have been granted a fast track designation by the US Food and Drug Administration based on the need for an oral therapy in a subset of patients with relapsing forms of multiple sclerosis.

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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 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 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®<sup>®</sup>, 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 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)