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News Release

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Merck Submits Application for Cladribine Tablets as a Potential Oral Short-Course Multiple Sclerosis Therapy in the United States

Darmstadt, September 30, 2009 - Merck KGaA announced today the submission of a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for Cladribine Tablets, Merck's proprietary investigational oral formulation of cladribine, as a therapy for reducing relapses in people with relapsing forms of multiple sclerosis (MS). Cladribine Tablets has the potential to be the first orally administered disease-modifying therapy available for people living with relapsing MS, as all disease-modifying therapies currently approved for the treatment of MS are parenteral therapies.

"As a leader in the area of neurodegenerative diseases, we continue to focus on making a positive difference in the lives of people living with MS, and their families," said Fereydoun Firouz, President and CEO of EMD Serono, Inc., a US subsidiary of Merck. "If approved, short-course therapy with Cladribine Tablets could transform the way people approach their treatment options, and meet an unmet need as an oral, disease modifying drug available for MS. We look forward to working with the FDA during the course of the regulatory process."

The NDA submission is supported by results from the CLARITY^a study, a two-year, randomized, double-blind, placebo-controlled Phase III trial of Cladribine Tablets in people with relapsing-remitting MS. The NDA also shows that all primary and secondary endpoints of the CLARITY trial were met. The CLARITY data were presented at the 61st Annual Meeting of the American Academy of Neurology (AAN) in April 2009 and at other recent international scientific meetings.

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Merck KGaA

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Merck Serono submitted a marketing authorization application to the European Medicines Agency (EMA) for Cladribine Tablets in July 2009.

^a CLARITY: CLAdRIbine 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 relapse rate at 96 weeks. Secondary endpoints included MRI endpoints, proportion of subjects 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 has 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.

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.



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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.