



News Release

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Merck KGaA: FDA Grants Priority Review to Cladribine Tablets for the Treatment of Relapsing Forms of Multiple Sclerosis

Darmstadt, Germany, July 28, 2010 – Merck KGaA announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the New Drug Application (NDA) for Cladribine Tablets as a therapy for relapsing forms of multiple sclerosis (MS).

The application also has been granted a Priority Review designation by the FDA, which means the review period for the NDA is reduced. The goal for completing a Priority Review is six months instead of the standard ten months. Priority Review is applied to drugs that have the potential to provide significant advances in treatment. A decision by the FDA is expected in Q4 2010.

“This is a critical milestone on the path to potential approval for short course therapy with Cladribine Tablets, moving us one step closer to meeting an unmet need as an oral, disease-modifying drug available for relapsing MS,” said Fereydoun Firouz, President and CEO of EMD Serono, Inc., the US affiliate of Merck. “Our commitment to people living with MS is to transform the way they approach their therapy options, and Priority Review for short-course therapy with Cladribine Tablets means we are moving closer to delivering on this promise. We look forward to working with the FDA throughout the regulatory process.”

The NDA is supported by results from the CLARITY¹ study, a two-year, randomized, double-blind, placebo-controlled Phase III trial of Cladribine Tablets in people with relapsing-remitting MS. The CLARITY study results were published in *The New England Journal of Medicine*² in February 2010.

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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

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.

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 patIEnts 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.

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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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.