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Two-Year Results From CLARITY Study With Cladribine Tablets In Multiple Sclerosis Published In The New England Journal Of Medicine

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EMD Serono, an affiliate of Merck KGaA, Darmstadt, Germany, announced the online publication of the results from the CLARITY(1) Phase III trial using Cladribine Tablets (EMD Serono's proprietary investigational oral formulation of cladribine) in *The New England Journal of Medicine*(2). The CLARITY study was a two-year (96-week), randomized, double-blind, placebo-controlled Phase III trial of Cladribine Tablets in 1,326 people with relapsing-remitting [multiple sclerosis](#) (MS).

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"The CLARITY trial represents an important step forward in multiple sclerosis research, and we are pleased that the results have been published in *The New England Journal of Medicine*," says Dr. Gavin Giovannoni, principal investigator of the CLARITY study and lead author on the publication, from Queen Mary University London, Blizard Institute of Cell and Molecular Science, Barts and the London School of Medicine and Dentistry, London, United Kingdom.

The authors report in the publication that the primary endpoint and key 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 international scientific meetings.

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

EMD 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.

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 its two-year extension 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 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 EMD Serono, Inc.

EMD Serono, Inc., an affiliate of Merck KGaA, Darmstadt, Germany, is a leader in the US biopharmaceutical arena, integrating cutting-edge science with unparalleled patient support systems to improve people's lives. The company has strong market positions in neurodegenerative diseases, with [Rebif®](#) (interferon beta-1a), as well as in endocrinology, with [Saizen®](#) (somatropin (rDNA origin) for injection) and [Serostim®](#) (somatropin (rDNA origin) for injection). EMD Serono is a leader in reproductive health, with [Gonal-f®](#) (follicle-stimulating hormone for injection), [Luveris®](#) (lutropin alfa for injection) and [Ovidrel®](#) Prefilled Syringe (choriogonadotropin alfa injection). With a clear focus on the patient and a leadership presence in the biopharmaceutical industry, EMD Serono's US footprint continues to grow, with more than 1000 employees around the country and fully integrated commercial, clinical and research operations in the company's home state of Massachusetts.

About Merck KGaA

Merck KGaA is a global pharmaceutical and chemical company with total revenues of euro 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.

References

- (1) CLARITY: CLAdRibine Tablets Treating MS Orally
- (2) Giovannoni G et al. A placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis

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