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Merck KGaA, Darmstadt, Germany Receives European Medicines Agency Acceptance for Review of Marketing Authorization Application for Cladribine Tablets

Darmstadt, Germany, July 18, 2016 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced that the European Medicines Agency (EMA) has accepted for review the Marketing Authorization Application (MAA) of the investigational product, Cladribine Tablets for the treatment of relapsing-remitting multiple sclerosis (MS).

“Our submission of the Marketing Authorization Application for Cladribine Tablets demonstrates our continued commitment to fighting the devastating disease of multiple sclerosis,” said Luciano Rossetti, Head of Global R&D for the Biopharma business of Merck KGaA, Darmstadt, Germany. “Although there are multiple therapies available for relapsing-remitting MS, there is still a significant unmet medical need with a focus on efficacy, dosing, durability and safety. We believe that Cladribine Tablets, if approved, would have a first-of-its-kind dosing regimen and serve as an important therapeutic option for patients with relapsing-remitting MS.”

The MAA submission includes data from three Phase III studies, CLARITY, CLARITY EXTENSION and ORACLE-MS, and the Phase II ONWARD study. In these trials, Cladribine Tablets showed significantly reduced relapse rates, risk of disability progression and development of new MS lesions, as detected by MRI, versus placebo in patients with relapsing-remitting MS.^{1,2,3,4,5} Together with interim long-term follow-up data from the prospective registry, PREMIERE, the new MAA also includes



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follow-up consisting of over 10,000 patient years of exposure in total, with follow-up in some patients exceeding eight years.⁶

References

1. A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis. *New England Journal of Medicine*. <http://www.nejm.org/doi/full/10.1056/NEJMoa0902533> Accessed May 5, 2016.
2. Safety and Efficacy of Oral Cladribine in Patients with Relapsing-Remitting Multiple Sclerosis: Results from the 96 Week Phase IIIb Extension Trial to the CLARITY Study (P07.119). *Neurology*. http://www.neurology.org/content/80/7_Supplement/P07.119.short?sid=f809adbd-a031-410b-97ad-fe26ccbee454 Accessed May 5, 2016.
3. Effect of Oral Cladribine on Time to Conversion to Clinically Definite Multiple Sclerosis in Patients with a First Demyelinating Event (ORACLE MS): A Phase 3 Randomised Trial. *Lancet Neurology*. <http://www.ncbi.nlm.nih.gov/pubmed/24502830> Accessed May 5, 2016.
4. A Phase 2 Study of Cladribine Add-on to Interferon-beta (IFN-beta) Therapy in Multiple Sclerosis (MS) Subjects With Active Disease (ONWARD). *Clinical Trials* <https://clinicaltrials.gov/ct2/show/NCT00436826?term=cladribine&cond=%22Multiple+Sclerosis%22&rank=2> Accessed May 5, 2016.
5. Efficacy of Cladribine Tablets as Add-On to IFN-beta Therapy in Patients with Active Relapsing MS: Final Results from the Phase II ONWARD Study. American Academy of Neurology 2016 Meeting Abstracts. <http://www.abstractsonline.com/pp8/#!/4046/presentation/9728> Accessed May 10, 2016.
6. Current and Emerging Therapies for the Treatment of Multiple Sclerosis: Focus on Cladribine. *Journal of Central Nervous System Disease*. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3619698/> Accessed June 14, 2016

About Cladribine Tablets

Cladribine Tablets is an oral small molecule prodrug that selectively and periodically targets lymphocytes thought to be integral to the pathological process of MS. Cladribine Tablets is currently under clinical investigation and not approved for any use in the United States, Canada and Europe.

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 2.3 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 KGaA, Darmstadt, Germany, is a leading science and technology company in healthcare, life science and performance materials. Around 50,000 employees work to further develop technologies that improve and enhance life – from biopharmaceutical therapies to treat cancer or multiple sclerosis, cutting-edge systems for scientific research and production, to liquid crystals for smartphones and LCD televisions. In 2015, Merck KGaA, Darmstadt, Germany, generated sales of € 12.85 billion in 66 countries.

Founded in 1668, Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company. The founding family remains the majority owner of the publicly listed corporate group. Merck KGaA, Darmstadt, Germany, holds the global rights to the Merck name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.