



Your Contact

Gangolf Schrimpf +49 6151 72-9591
Investor Relations +49 6151 72-3321

News Release

September 11, 2015

Merck KGaA, Darmstadt, Germany, Intends to Submit Cladribine Tablets to Treat Multiple Sclerosis for Registration in Europe

- **Letter of intent to apply for marketing authorization has been submitted to European Medicines Agency (EMA)**
- **Decision based on most recent data available from the Cladribine Tablets clinical program and newly performed analyses**

Darmstadt, Germany, September 11, 2015 – Merck KGaA, Darmstadt, Germany, a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials today announced that it intends to submit its investigational treatment Cladribine Tablets for the treatment of relapsing multiple sclerosis for registration in Europe. The decision follows the company's evaluation of new data and additional analyses of the compound's benefit-risk profile.

Merck KGaA, Darmstadt, Germany, has submitted a letter of intent to the EMA to file a Marketing Authorization Application (MAA) for Cladribine Tablets, which initiates a process to address a number of pre-submission requirements. The company's submission plan for other geographies is being further developed and executed.

"I applaud the company for its decision to move forward with Cladribine Tablets as demonstrated in its Letter of Intent to the European Medicines Agency," said Professor Giancarlo Comi, director of the Institute of Experimental Neurology (INSPE) and of the department of neurology at San Raffaele Hospital in Milan, Italy. "This decision is very positive for patients with multiple sclerosis because tailoring treatment to their individual

Merck KGaA

Frankfurter Strasse 250
64293 Darmstadt
Hotline +49 6151 72-5000
www.emdgroup.com

Head Media Relations -62445
Spokesperson: -9591 / -7144 / -6328
Fax +49 6151 72-3138
media.relations@emdgroup.com



News Release

needs is a key strategy for optimizing their care, and to achieve this we need to have access to more therapeutic options. While the options available to treating neurologists have grown over the years, Cladribine Tablets have the potential to offer a truly innovative addition to the armamentarium physicians have at their disposal to treat their patients."

"Time has brought additional data that allow a better characterization of the benefit-risk profile of Cladribine, and this has driven our decision to move forward with the registration process," said Belén Garijo, Member of the Executive Board of Merck KGaA, Darmstadt, Germany, and CEO Healthcare.

Merck KGaA, Darmstadt, Germany, wound down its clinical development program for Cladribine Tablets in 2011 after some regulatory authorities expressed concerns over the insufficient characterization of the drug's benefit-risk profile. Nevertheless, several large clinical trials were allowed to complete and additional safety information was also collected in a long-term registry.

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 two million patients 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.



Merck KGaA

Darmstadt · Germany

News Release

All Merck KGaA, Darmstadt, Germany, press releases are distributed by e-mail at the same time they become available on the EMD Group Website. In case you are a resident of the USA or Canada please go to www.emdgroup.com/subscribe to register again for your online subscription of this service as our newly introduced geo-targeting requires new links in the email. You may later change your selection or discontinue this service.

Merck KGaA of Darmstadt, Germany, is a leading company for innovative and top-quality high-tech products in healthcare, life science and performance materials. The company has six businesses – Biopharmaceuticals, Consumer Health, Allergopharma, Biosimilars, Life Science and Performance Materials – and generated sales of € 11.3 billion in 2014. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to foster the success of customers and to help meet global challenges. Merck KGaA, Darmstadt, Germany, is the world's oldest pharmaceutical and chemical company – since 1668, the company has stood for innovation, business success and responsible entrepreneurship. Holding an approximately 70% interest, the founding family remains the majority owner of the company to this day. Merck KGaA, Darmstadt, Germany holds the global rights to the Merck name and brand. The only exceptions are Canada and the United States, where the company operates as EMD Serono, EMD Millipore and EMD Performance Materials.