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News Release

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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

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Merck KGaA

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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.



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