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News Release

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Merck KGaA, Darmstadt, Germany, Presents New Data on the Safety and Durable Efficacy of Cladribine Tablets and Advantages of Early Treatment with Rebif® at the 2016 ECTRIMS Congress

- **Two oral presentations and nine posters include new analyses on investigational Cladribine Tablets**
- **Real-world data assess the safety, tolerability and effectiveness of Rebif®**
- **Symposium highlights unmet needs among patients with MS and real-word issues**
- **Grant for Multiple Sclerosis Innovation (GMSI) award recipients will share in €1 million**

Darmstadt, Germany, September 12, 2016 – Merck KGaA, Darmstadt, Germany, a leading science and technology company, today announced key symposia and more than 30 presentations of clinical data on Cladribine Tablets, an investigational, oral, small molecule for the treatment of relapsing-remitting multiple sclerosis (RRMS), and Rebif® (interferon beta-1a), the company's high-dose, high-frequency interferon beta for relapsing forms of multiple sclerosis (MS), are scheduled for the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) taking place September 14-17, 2016, in London.

"We are committed to advancing patient care and offering therapeutic options that help address unmet medical needs for people with MS, with a focus on efficacy, dosing, durability and safety," said Luciano Rossetti, Global Head of Research & Development for the biopharma business of Merck KGaA, Darmstadt, Germany

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The company operates its biopharmaceutical business as EMD Serono in the U.S. and Canada. “We look forward to sharing additional data on Rebif® and Cladribine Tablets with the scientific community at this year’s ECTRIMS Congress.”

Oral presentations include a comparison of the CLARITY and the CLARITY EXTENSION studies, which sought to examine the duration of clinical outcome response to Cladribine Tablets, and results of the SOLAR study, which examined the effects of adding high-dose cholecalciferol (vitamin D3) to Rebif® therapy for patients with RRMS. Poster presentations will report on clinical and magnetic resonance imaging outcomes in patients treated with Cladribine Tablets or Rebif® and patient-reported outcomes in patients being treated with Rebif®. Several health economics outcomes research presentations will highlight key issues facing people with MS, including pregnancy outcomes.

In addition to data presentations, a satellite symposium sponsored by Merck KGaA, Darmstadt, Germany, “Reimagining the MS Treatment Journey,” will take place Wednesday, September 14, 18:45-19:45 BST in Hall A at the ExCel. The panel session will feature distinguished experts in MS who will debate whether unmet needs in MS care remain, consider what an ideal MS therapy might look like, and review current and potential future therapies.

On Thursday, September 15, Merck KGaA, Darmstadt, Germany, will hold its fourth annual Grant for Multiple Sclerosis Innovations (GMSI) Awards symposium. Up to €1 million will be awarded to one or more researchers to support work that aims to improve the understanding of MS for the ultimate benefit of patients. The symposium will take place in the South Gallery 19 at the ExCel from 19:30-20:30 BST.

For more information about the data to be presented, please review the ECTRIMS website. Also, visit Merck KGaA, Darmstadt, Germany’s booth at this year’s Congress to learn more about the company’s programs and commitment to advancing MS care.

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 Rebif®
Rebif® (interferon beta-1a) is a disease-modifying drug used to treat relapsing forms of multiple sclerosis (MS) and is similar to the interferon beta protein produced by the human body. The efficacy of Rebif® in chronic progressive MS has not been established. Interferon ß is thought to help reduce inflammation. The exact mechanism is unknown.
Rebif®, which was approved in Europe in 1998 and in the US in 2002, is registered in more than 90 countries worldwide. Rebif® has been proven to delay the progression of disability, reduce the frequency of relapses and reduce MRI lesion activity and area*.
Rebif® can be administrated with the RebiSmart® electronic auto-injection device (not approved in the US), or with the RebiDose® single-use disposable pen, or the manual multidose injection pen RebiSlide™. Rebif® can also be administered with the autoinjector Rebiject II® or by manual injection using ready-to-use pre-filled syringes. These injection devices are not approved in all countries.
In January 2012, the European commission approved the extension of the indication of Rebif® in early multiple sclerosis. The extension of the indication of Rebif® has not been submitted in the United States.
Rebif® should be used with caution in patients with a history of depression, liver disease, thyroid abnormalities and seizures. Most commonly reported side effects are flu-like symptoms, injection site disorders, elevation of liver enzymes and blood cell abnormalities. Patients, especially those with depression, seizure disorders, or liver problems, should discuss treatment with Rebif® with their doctors.

*The exact correlation between MRI findings and the current or future clinical status of patients, including disability progression, is unknown.

Rebif® (interferon beta-1a) is approved in the United States for relapsing forms of MS. RebiSmart®, an electronic device for self-injection of Rebif®, is also not approved in the United States. Cladribine Tablets is an investigational product and not approved for use in any indication in the United States.

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.

About Merck KGaA, Darmstadt, Germany
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 KGaA, Darmstadt, Germany, name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, MilliporeSigma and EMD Performance Materials.