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News Release

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Merck: Regulatory Update on Cladribine Tablets

- **Following recent feedback from FDA and previous feedback from EMA Merck has decided to no longer pursue the global approval process of Cladribine Tablets**
- **Merck will focus resources on other projects bringing benefit to patients with multiple sclerosis**
- **The benefit/risk profile of Cladribine Tablets is unchanged - Ongoing clinical trials will continue**
- **One-time charge of EUR 20 million to be recorded in the second quarter**

Darmstadt, Germany, June 22, 2011 – Merck KGaA announced today that following feedback from regulatory authorities the company has decided to no longer pursue the global approval process of Cladribine Tablets for the treatment of relapsing-remitting multiple sclerosis (MS). Based on discussions with the U.S. Food and Drug Administration (FDA) at the end-of-review meeting for the Cladribine Tablets new drug application, Merck believes that data from ongoing clinical trials are very unlikely to address the FDA requirements and will not provide a basis for approval. Overall the FDA feedback was consistent with the feedback previously received from the European Medicines Agency (EMA). Attempting to fulfill the FDA and the EMA requirements would necessitate the initiation of a new clinical trial program which would take several years to complete.

“Considering the time it would take to complete a new clinical trial program and the significant risk that even a new program would not result in data sufficient for Cladribine Tablets’ approval, and taking into account the changing competitive landscape, we

Page 1 of 4

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News Release

have decided to not pursue further the worldwide approval process of Cladribine Tablets and to focus resources on other projects bringing benefit to patients with multiple sclerosis,” said Dr. Stefan Oschmann, member of the Executive Board and head of the Merck Serono division. “We will continue our research and development activities and will actively pursue in-licensing opportunities to further strengthen our pipeline in multiple sclerosis, and we will also continue our product enhancement, educational and patient support activities around Rebit[®], to address relevant medical needs for patients with this devastating disease.”

“We are extremely grateful for the strong support we have received from patients and from physicians during the whole clinical development of Cladribine Tablets,” said Dr. Bernhard Kirschbaum, Merck Serono’s head of Research and Development. “We intend to complete the core 96-week duration of the ongoing clinical trials with Cladribine Tablets in order to provide study participants with the opportunity to continue the trials and to add knowledge for the scientific community.”

Merck’s decision is not based on a change of the benefit/risk profile of Cladribine Tablets, which remains the same. Merck intends to complete the core 96-week treatment period of the CLARITY¹ extension, ORACLE MS² and ONWARD³ clinical trials. Merck also intends to proceed with the ongoing PREMIERE⁴ registry which follows patients who have participated in Cladribine Tablets studies. The company is in the process of informing regulatory agencies and work closely with them to ensure appropriate follow-up of patients. The company is also in the process of informing investigators and providing them instructions for the next steps of the studies. Patients involved in studies who have questions should contact their study investigator.

Merck intends to withdraw applications from regulatory review in the limited number of countries where procedures are ongoing. In Australia and Russia, where Cladribine Tablets are approved and available under the trade name Movectro[®], Merck intends to withdraw the product from the market and will discuss the timelines and other details



News Release

with the local regulatory agencies to determine the best solutions for patients currently on Movectro therapy.

The decisions on Cladribine Tablets announced today will result in a one-time charge of EUR 20 million which will be recorded in the second quarter financial statements.

¹ CLARITY: CLAdRIbine Tablets treating MS orally

² ORACLE MS: ORAI CLadribine in Early MS

³ ONWARD: Oral Cladribine added oN to interferon beta-1a in patients With Active Relapsing Disease

⁴ PREMIERE: PRospective observational long-term safEty registry of Multiple sclerosis patlEnts who have participated in CladRibinE clinical trials

About Cladribine Tablets

Merck'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. Cladribine Tablets were approved in Russia in July 2010 and in Australia in September 2010 as a treatment of relapsing-remitting 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 the CLARITY EXTENSION two-year Phase III study 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.

- The PREMIERE (PRospective observational long-term safEty registry of Multiple sclerosis patlEnts who have participated in CladRibinE clinical trials) registry: a long-term observational safety registry of patients who have participated in Cladribine Tablets clinical trials, designed to support the evaluation of the long-term safety of Cladribine Tablets in MS.

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 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 is a global pharmaceutical and chemical company with total revenues of EUR 9.3 billion in 2010, a history that began in 1668, and a future shaped by more than 40,000 employees in 67 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.