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## News Release

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### **Merck KGaA Receives Refuse to File Letter from FDA on Cladribine Tablets New Drug Application**

Darmstadt, November 30, 2009 – Merck KGaA announced today that its US affiliate received a refuse to file letter from the US Food and Drug Administration (FDA) on the New Drug Application (NDA) for Cladribine Tablets, Merck Serono's proprietary investigational oral formulation of cladribine, as a therapy for relapsing forms of multiple sclerosis (MS).

"The company will work closely with the FDA to fully understand FDA's concerns and define a path forward for a successful resubmission of this application at the earliest point in time", said Elmar Schnee, Executive Board Member of Merck and head of the Merck Serono division. "We remain focused on delivering on our promise to transform the way people living with multiple sclerosis approach their therapy options."

Based on current regulations, once a NDA is submitted to the FDA, the Agency has 60 days to preliminarily review the NDA submission and assess whether the NDA is sufficiently complete to permit a substantive review. If it determines that the NDA is not sufficiently complete, the FDA issues a refuse to file letter to the applicant. Merck Serono plans to request a meeting with the FDA as soon as possible to discuss its comments on the NDA submission and to reach an understanding on what would be required for the Cladribine Tablets NDA to be accepted for review.

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### About Cladribine Tablets

Merck Serono'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.

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 its two-year extension 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.

### 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 more than 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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