News Release

Your Contact
Shikha Virdi 416-561-6276

December 4, 2017

EMD Serono Receives Health Canada Notice of Compliance for MAVENCLAD™ (cladribine tablets) for patients living with relapsing-remitting multiple sclerosis (RRMS)

Mississauga, Ontario, Dec. 4, 2017 -- EMD Serono, Canada, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany, in the U.S. and Canada, announced today that Health Canada has approved MAVENCLAD™ (cladribine tablets) as monotherapy for the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) to reduce the frequency of clinical exacerbations and delay the progression of disability. MAVENCLAD™ is generally recommended in MS patients who have had an inadequate response to, or are unable to tolerate, one or more therapies for multiple sclerosis. [1]

"MAVENCLAD is a unique and powerful new treatment for our patients that offers potent efficacy with only 20 days of oral treatment over two years." said Dr. Mark S. Freedman, Director, Multiple Sclerosis Research Unit at the Ottawa Hospital, Senior Scientist at The Ottawa Hospital Research Institute and investigator for the CLARITY study.

"Health Canada's approval of MAVENCLAD is a significant milestone for patients and for EMD Serono, Canada," said Gaby Murphy, President and Managing Director, EMD Serono, Canada. "MAVENCLAD offers a simple dosing schedule and sustained efficacy with minimal monitoring that we hope will improve the quality of life for patients living with relapsing-remitting multiple sclerosis (RRMS)."

EMD Serono

200-2695 North Sheridan Way
Mississauga, ON
L5K 2N6

News Release

MAVENCLAD is a simple oral treatment option that provides effective disease control with a maximum of up to 20 days of treatment over 2 years. Each treatment course consists of only two treatment weeks where one or two tablets are taken daily for four or five days. Patients completing two years of treatment are followed by observation for another two years.[2]

The Health Canada approval of MAVENCLAD is based on the safety and efficacy data from the pivotal phase III CLARITY[2,3] study. The clinical development program includes more than 10,000 patient years of data with over 2,700 patients included in the clinical trial programs[4] and up to 10 years of observation in some patients.

MAVENCLAD works by predominantly and temporarily depleting B & T lymphocytes followed by lymphocyte reconstitution, without continuous suppression of the immune system.[2]

About MAVENCLAD

In August 2017, the European Commission (EC) granted marketing authorization for MAVENCLAD (cladribine tablets) for the treatment of highly active relapsing multiple sclerosis (RMS) in the 28 countries of the European Union (EU) in addition to Norway, Liechtenstein and Iceland.

The clinical development program for MAVENCLAD (cladribine tablets) includes:

- The CLARITY (cladribine tablets Treating MS Orally) study: a two-year Phase III placebo-controlled study designed to evaluate the efficacy and safety of cladribine tablets as a monotherapy in patients with RRMS.
- The CLARITY extension study: a two-year Phase III placebo-controlled study following on from the CLARITY study, designed to evaluate the safety and efficacy of cladribine tablets over an extended administration for four years.
- The ORACLE MS (Oral Cladribine in Early MS) study: a two-year Phase III placebo-controlled study 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).
- The ONWARD (Oral Cladribine Added ON To Interferon beta-1a in Patients With Active Relapsing Disease) study: a Phase II placebo-controlled study 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.

- PREMIERE (Prospective Observational Long-term Safety Registry of Multiple Sclerosis Patients Who Have Participated in Cladribine Clinical Studies) study: interim long-term follow-up data from the prospective registry to evaluate the safety and efficacy of cladribine tablets. This includes more than 10,000 patient years of data with over 2,700 patients included in the clinical trial program, and more than 10 years of observation in some patients.

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. Canada has one of the highest rates of MS in the world with one in 340 people living with the disease. 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 EMD Serono, Canada
EMD Serono, Canada, is the Canadian biopharmaceutical business of Merck KGaA, Darmstadt, Germany. EMD Serono, Canada has integrated cutting-edge science, innovative products and devices, and industry-leading patient support and access programs. EMD Serono, Canada has deep expertise in neurology, fertility and endocrinology, as well as a robust pipeline of potential therapies in neurology, oncology, immunology and immuno-oncology. Today, EMD Serono, Canada has more than 100 employees across Canada with headquarters in Mississauga, Ontario.

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 2016, Merck KGaA, Darmstadt, Germany generated sales of € 15.0 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 name and brand. The only exceptions are the United States and Canada, where the company operates as EMD Serono, Millipore Sigma and EMD Performance Materials.

References:

[1] MAVENCLAD™ Product Monograph. November 2017
[2] Giovannoni G, Comi G, Cook S et al. A Placebo-Controlled Trial of Oral Cladribine for Relapsing Multiple Sclerosis. 2010 New England Journal of Medicine 362:416-426.

News Release

[3] Schreiner T, Miravalle A,. Current and Emerging Therapies for the Treatment of Multiple Sclerosis: Focus on Cladribine. Journal of Central Nervous System Disease. 2012; 4: 1–14

[4] Merck KGaA, Darmstadt, Germany data on file