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News Release

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Ontario Reimburses CIS Indication for REBIF®, a First-Line Treatment for Multiple Sclerosis

Rebif now reimbursed under Ontario Drug Benefit Program for treatment of patients with Clinically Isolated Syndrome (CIS)

Mississauga, ON, May 25, 2015 – Today, EMD Serono a Division of EMD Inc., Canada, a subsidiary of Merck KGaA, Darmstadt, Germany, announces that REBIF (interferon beta-1a), the company's disease-modifying drug used to treat relapsing forms of multiple sclerosis (MS) is now publicly reimbursed in Ontario for the treatment of Clinically Isolated Syndrome (CIS).

CIS, the earliest form of MS, is defined by a single demyelinating event, accompanied by an abnormal MRI scan with lesions typical of MS. Patients with CIS are at high risk of developing relapsing-remitting MS.

The efficacy of Rebif in the treatment of CIS has been successfully confirmed by data from the REFLEX study (Comi 2012). Results from the REFLEX study showed three-times weekly dosing of Rebif 44 mcg significantly delayed the onset, and reduced the risk, of both 2005 McDonald-criteria MS and Clinically Definite MS (CDMS) as defined by the Poser criteria, compared with placebo.

The 2-year cumulative probability of conversion to McDonald MS was reduced by 51% in patients treated with subcutaneous interferon beta-1a (three times a week ($p< 0.0001$, hazard ratio [HR] 0.49 [95% CI 0.38 0.64]) versus placebo. The 2-year rate of conversion to CDMS was 52% lower for interferon beta-1a three times a week ($p=0.0004$, HR 0.48 [95% CI 0.31–0.73]) than for placebo.

Results from the REFLEX study also showed that Rebif (three times a week) significantly improved magnetic resonance imaging (MRI) outcomes compared with placebo.(Comi 2012; De Stefano 2014) Rebif demonstrated a 81% reduction in combined active unique lesions per patient per scan ($p <0.001$) and a 92% reduction in Gadolinium enhancing lesions per patient per scan ($p <0.001$).

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Rebif received Health Canada approval for the treatment of relapsing remitting MS in 1998. Today, Rebif has a well-established and well-characterized profile with more than 1.5 million patient-years of experience.

“We have come to rely on the safety and efficacy of Rebif for many years for our patients, but were prevented from starting this medication when it means the most – at the earliest identifiable onset of the disease. We believe that initiating an effective medication like Rebif as early as possible in the disease course will offer patients the best chance of achieving a quality life with minimal relapses or progression.” says **Dr. Mark Freedman**, Professor of Medicine – Neurology, University of Ottawa and Director – MS Research Unit, The Ottawa Hospital and Senior Scientist, the Ottawa Hospital Research Institute.

“While the ultimate goal of the MS Society of Canada is to find a cure for multiple sclerosis, individuals living with MS and other demyelinating diseases need to have access to treatment options and support services to help manage their disease today,“ says **Yves Savoie**, President and CEO, MS Society of Canada. “It’s wonderful that Ontarians will now have another choice in the treatment of clinically isolated syndrome (CIS) and we encourage those who have been diagnosed with CIS and who are exploring treatment options to consult their healthcare team.”

“EMD Serono in Canada continuously works on enhancing our Rebif offering, taking advantage of the latest clinical and technological advances to meet patient needs," said **Rehan Verjee**, Managing Director of EMD Serono, Canada. "With today’s announcement, Ontarians diagnosed with CIS will not only have improved access to Rebif as a well-established first-line therapy, they will also gain access to a wide range of innovative services and devices to support them on their journey living with MS."

Support services and devices used in combination with Rebif in Canada include:

RebiSmart® -- RebiSmart is an electronic auto-injector for the self-administration of Rebif, using multidose cartridges, each of which contains one week's worth of medicine. Designed to address barriers to adherence, such as: fear, forgetfulness and fatigue, RebiSmart uses interactive, on-screen instructions and signals to guide patients through the process. Individually adjustable comfort settings give patients more flexibility with injection duration and depth.

Adherence Monitoring & Support -- RebiSmart is the first injection device available in MS that records the date, time and dosage of each injection so that an accurate dosing history can be discussed with a patient, allowing physicians to monitor and improve patient adherence to therapy. The latest version of RebiSmart enables this information to be sent wirelessly to a secure server where it can be more readily accessed by a patient’s health care team for the purposes of ongoing coaching.

dialogMS -- Patients prescribed Rebif also have access to dialogMS, a web-based software which allows patients with MS to engage in the management of their disease by allowing them to complete periodic health report questionnaires based on short forms of published instruments and standard scales, such as the Multiple Sclerosis Quality of Life Inventory (MSQLI) and the Multiple Sclerosis International Quality of Life (MusiQoL) questionnaires. dialogMS allows physicians and nurses to monitor trends in their patients' overall health status.

Momentum -- *Momentum* is EMD Serono, Canada's in-house patient support program, designed to provide patients with continuity of care from their initial diagnosis and prescription of Rebif to their ongoing treatment. *Momentum's* reimbursement team ensures patients receive access to their therapy within 7 days of being prescribed Rebif. Dedicated *Momentum* nurses provide training and conduct regular follow-ups throughout the first year of treatment and beyond to ensure optimal use of medication. As needed, patients also have 24/7 access to a nursing hotline for treatment-related questions, offered in more than 250 languages.

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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 beta is thought to help reduce inflammation. The exact mechanism is unknown.

Rebif, which was approved in Canada in 1998, 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.

In Canada, Rebif® can be administrated with the RebiSmart® electronic auto-injection device, the multidose injection pen RebiSlide™, or by manual injection.

Rebif should be used with caution in patients with a history of depression, liver disease 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.

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.

Multiple Sclerosis in Canada
Canada is known for having one of the highest prevalence of MS in the world. Currently, more than two million people are estimated to suffer with MS worldwide, including an estimated 100,000 Canadians.

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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,

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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.

About EMD Serono, Canada

EMD Serono, Canada, the Canadian biopharmaceutical business of Merck KGaA, Darmstadt, Germany, is a leading biopharma company focused exclusively on specialty care. 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.