

7 April 2020 | Darmstadt, Germany

## **COMPANY STATEMENT**

### **Merck KGaA Darmstadt, Germany statement on Rebif® (interferon beta-1a) donation to the World Health Organization for the SOLIDARITY trial**

As a company dedicated to human progress and to making a lasting difference on patients' lives, Merck KGaA Darmstadt, Germany is fully committed to contributing to solutions related to global health crises such as COVID-19.

As part of the global effort to investigate potential therapeutics for COVID-19 and our support of independent research, Merck KGaA Darmstadt, Germany is donating 290,000 units of its interferon beta-1a (Rebif®) to the World Health Organization for use in their global SOLIDARITY trial. The SOLIDARITY trial investigates several potential therapeutics for the treatment of COVID-19 and currently has received expressions of interest from over 70 countries. This complements our previously announced donation for the international DISCOVERY trial sponsored by the French INSERM institute (Institut National de la Santé et de la Recherche Médicale).

Rebif® (interferon beta-1a, solution for subcutaneous injection in pre-filled syringe) is indicated for the treatment of relapsing multiple sclerosis. To date, Rebif® is not approved by any regulatory authority for the treatment of COVID-19 or for use as an antiviral agent.

We continue to work closely with global and national health authorities to respond to the needs of patients impacted by COVID-19.

For additional information on the DISCOVERY trial please visit <https://presse.inserm.fr/en/launch-of-a-european-clinical-trial-against-covid-19/38737/>; for more information on the SOLIDARITY trial please visit: <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---18-march-2020>

#### **About Rebif® (interferon beta-1a)**

Rebif (interferon beta-1a) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. It is used to decrease the frequency of relapses and delay the occurrence of some of the physical disability that is common in people with MS. The efficacy and safety of Rebif in controlled clinical trials beyond 2-years has not been established.

#### **IMPORTANT SAFETY INFORMATION:**

Rebif is contraindicated in patients with a history of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation.

# Merck KGaA

Darmstadt, Germany

Rebif should be used with caution in patients with depression, a condition that is common in people with multiple sclerosis. Depression, suicidal ideation, and suicide attempts have been reported to occur with increased frequency in patients receiving interferon compounds, including Rebif.

Severe liver injury, including some cases of hepatic failure requiring liver transplantation, has been reported rarely in patients taking Rebif. The potential for liver injury should be considered when used in combination with other products associated with liver injury. Monitor liver function tests and patients for signs and symptoms of hepatic injury. Consider discontinuing Rebif if hepatic injury occurs.

Anaphylaxis and other allergic reactions (some severe) have been reported as a rare complication of Rebif. Discontinue Rebif if anaphylaxis occurs.

In controlled clinical trials, injection site reactions occurred more frequently in Rebif-treated patients than in placebo-treated and Avonex-treated patients. Injection site reactions including injection site pain, erythema, edema, cellulitis, abscess, and necrosis have been reported in the postmarketing setting. Do not administer Rebif into affected area until fully healed; if multiple lesions occur, discontinue Rebif until skin lesions are healed.

Decreased peripheral blood counts in all cell lines, including pancytopenia, have been reported in Rebif-treated patients. In controlled clinical trials, leukopenia occurred at a higher frequency in Rebif-treated patients than in placebo and Avonex-treated patients. Thrombocytopenia and anemia occurred more frequently in 44 mcg Rebif-treated patients than in placebo-treated patients. Patients should be monitored for symptoms or signs of decreased blood counts. Monitoring of complete blood and differential white blood cell counts is also recommended.

Cases of thrombotic microangiopathy (TMA), some fatal, have been reported with interferon beta products, including Rebif, up to several weeks or years after starting therapy. Discontinue Rebif if clinical symptoms and laboratory findings consistent with TMA occur, and manage as clinically indicated.

Caution should be exercised when administering Rebif to patients with pre-existing seizure disorders. Seizures have been temporally associated with the use of beta interferons, including Rebif, in clinical trials and in postmarketing reports.

The most common side effects with Rebif are injection-site disorders, headaches, influenza-like symptoms, abdominal pain, depression, elevated liver enzymes, and hematologic abnormalities.

There are no adequate and well-controlled studies in pregnant women. Rebif should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Please see the full Prescribing Information for additional information: [http://www.emdserono.com/ms.country.us/en/images/Rebif\\_PI\\_tcm115\\_140051.pdf?Version=](http://www.emdserono.com/ms.country.us/en/images/Rebif_PI_tcm115_140051.pdf?Version=)

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