Merck KGaA
Darmstadt, Germany

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COMPANY STATEMENT

Merck KGaA, Darmstadt, Germany statement on Rebif® (interferon beta-1a) contribution to the US National Institute of Allergy and Infectious Diseases for the ACTT 3 trial

As part of the global effort to investigate potential COVID-19 therapeutics and our support of independent research, Merck KGaA, Darmstadt, Germany is collaborating with the US National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH) by contributing 3,000 units of Rebif® (subcutaneous interferon beta-1a) for the Adaptive COVID-19 Treatment Trial 3 (ACTT 3), which is enrolling hospitalized adults with COVID-19 in the United States and in other countries. The NIAID-led study is evaluating treatment with Rebif® in combination with remdesivir compared with remdesivir alone, in over 1,000 hospitalized adults diagnosed with COVID-19 and will evaluate time to recovery in the combination therapy group relative to the remdesivir-only group.

This contribution complements our previously announced donation of up to 300,000 units of Rebif® to the international trials sponsored by the French INSERM institute (Institut National de la Santé et de la Recherche Médicale) and the World Health Organization (DisCoVery and SOLIDARITY).

Rebif® is indicated for the treatment of relapsing forms of multiple sclerosis (MS). To date, Rebif® is not approved by any regulatory authority for the treatment of COVID-19 or for use as an antiviral agent.

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

For additional information on this trial please visit https://www.niaid.nih.gov/news-events/nih-clinical-trial-testing-remdesivir-plus-interferon-beta-1a-covid-19-treatment-begins

About Rebif® (interferon beta-1a)
Rebif® (subcutaneous 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.

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.

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.

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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.

Epidemiological data do not suggest a clear relationship between interferon beta use and major congenital malformations, but interferon beta may cause fetal harm based on animal studies. Data from a large human population-based cohort study, as well as other published studies over several decades, have not identified a drug-associated risk of major birth defects with interferon beta products during early pregnancy. Findings regarding a potential risk for low birth weight or miscarriage with the use of interferon beta products in pregnancy have been inconsistent.

Please see the full Prescribing Information for additional information: https://www.emdserono.com/us-en/pi/rebif-pi.pdf.

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