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Grifols begins commercializing TAVLESSE® in France, Italy and Spain to treat chronic immune thrombocytopenia

- TAVLESSE® (fostamatinib) is indicated for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments
- First oral therapy from Grifols Bioscience Division expands and diversifies portfolio to benefit patients and offer more therapeutic options for healthcare professionals
- Drug is already available in Germany and the UK as part of European rollout that will soon include the Czech Republic and Nordic countries

Barcelona, Spain, September 28, 2021 - Grifols (MCE: GRF, MCE: GRF.P, NASDAQ: GRFS), one of the world's top three producers of plasma-derived medicines and a forerunner in the research and development of therapeutic alternatives that drive scientific and social advancements, today announced that TAVLESSE® (fostamatinib), used to treat chronic immune thrombocytopenia (ITP) in adult patients refractory to other treatments, is now available in France, Italy and Spain and reimbursable from their respective health systems.

Fostamatinib is the first and only SYK (spleen tyrosine kinase) inhibitor indicated in adult patients with ITP who have had an insufficient response to a previous treatment. It is the only targeted agent that reduces the immune system's destruction of platelets, which are critical for blood clotting and healing.

Medical associations such as the Spanish Society of Hematology and Hemotherapy (SEHH in Spanish) and the Spanish Group for Immune Thrombocytopenia (GEPTI) include fostamatinib in their recommendations to treat ITP.

TAVLESSE® is the first new class of drug for treating chronic ITP in over a decade, addressing the unmet needs of patients who live with this disease. Worldwide, it is estimated that there are well over 200,000 people affected by ITP[1].

The treatment is already available in Germany and the UK as part of a phased rollout across the rest of Europe planned over the following months that will soon include the Czech Republic, Denmark, Finland, Norway and Sweden.

“This is the first oral therapy from Grifols’ flagship Bioscience Division that the company has launched in Europe,” said Thierry Heinrich, Vice President of Sales & Commercial, Bioscience Division, Europe. “Over time we expect to further strengthen our industry-leading portfolio through additional innovative in-licensing agreements to treat existing and emerging diseases. This will benefit patients and offer additional therapeutic alternatives to healthcare providers.”

Early in 2020, the European Commission approved TAVLESSE® to treat ITP in adult patients refractory to other treatments. It is also commercially available in the U.S. under the brand name TAVALISSE®.

Grifols has exclusive rights to fostamatinib in chronic ITP, as well as any potential future indications like autoimmune hemolytic anemia (AIHA), and IgA nephropathy (IgAN), in Europe and Turkey thanks to a Collaboration and License Agreement reached with U.S.-based Rigel Pharmaceuticals in January 2019.

About chronic immune thrombocytopenia (ITP)

In patients with ITP, the immune system attacks and destroys the body's own blood platelets, which play an active role in blood clotting and healing. Common symptoms of ITP are excessive bruising and bleeding. People suffering with chronic ITP may live with an increased risk of severe bleeding events that can result in serious medical complications or even death. Current therapies for ITP include steroids, blood platelet production boosters (TPOs) and splenectomy. However, not all patients respond to existing therapies. As a result, there remains a significant medical need for additional treatment options for patients with ITP.

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[1]*National Organization for Rare Disorders: https://www.org/rare-diseases/immune-thrombocytopenia/*

https://www.grifols.com/en/view-news/-/news/grifols-begins-commercializing-tavlesse-in-france-italy-and-spain-to-treat-chronic-immune-thrombocytopenia