

Grifols' TAVLESSE[®] (fostamatinib) receives NICE recommendation for treating refractory chronic immune thrombocytopenia

- TAVLESSE[®] is now available across the United Kingdom for adult patients with chronic ITP
- Fostamatinib is the first and only SYK inhibitor indicated for adult patients with chronic ITP who have not responded to previous treatments
- Grifols continues its phased European roll-out of the treatment, also available in Czech Republic, France, Germany, Italy, Norway and Spain

Barcelona, Spain, Oct. 19, 2022 - Grifols (MCE: GRF, MCE: GRF.P, NASDAQ: GRFS), a global leader in plasma medicines with more than 110 years contributing to the health and well-being of people, today announced that its drug TAVLESSE[®] (fostamatinib), used to treat chronic immune thrombocytopenia (ITP) in adult patients refractory to other treatments,¹ is now recommended by the National Institute for Health and Care Excellence (NICE).

With NICE's recommendation, specifically for those patients who have previously had a thrombopoietin receptor agonist (TPO-RA), or for whom a TPO-RA is unsuitable,² TAVLESSE[®] can now be accessed and reimbursed by National Health Service across all the United Kingdom. Last year the Scottish Medicines Consortium advised acceptance of the treatment.³

Fostamatinib is the first and only SYK (spleen tyrosine kinase) inhibitor indicated for adult patients with chronic ITP who have had an insufficient response to previous treatments. It is the only targeted agent that works by protecting platelets from destruction.⁴

Grifols has worked in close collaboration with UK healthcare professionals and UK patient associations to ensure recognition of the unmet needs of patients with refractory ITP and the value of TAVLESSE.[®]

"We are delighted that fostamatinib is now available for our patients. It works in a very different way than other treatments for ITP and we are looking forward to using it," said Dr. Nichola Cooper, a consultant at Imperial College Healthcare Trust in London.

Mervyn Morgan, CEO of the UK and Ireland Support Association (ITPSA), said: "This is wonderful news and will be welcomed by ITP patients across the country. Fostamatinib will be another tool for hematologists to use in supporting patients with chronic ITP."

Despite the availability of several different therapeutic approaches with drugs having varying mechanisms of action, ITP is able to persist for a number of years.⁴ Fostamatinib represents a novel treatment approach that can be orally administered and requires minimal titration;

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reducing both clinical time and the need for professional healthcare support. It was shown to produce a rapid, durable response among patients with longstanding ITP who were considered difficult to treat having previously received other treatments.⁴

“TAVLESSE® is the first new drug for treating chronic ITP in over a decade, addressing the unmet needs of patients who live with this disease,” said Paula Blackmore, Managing Director Grifols UK. “Grifols is committed to providing medicines and solutions that enhance people’s quality of life and well-being.”

TAVLESSE® is also available in Czech Republic, France, Germany, Italy, Norway and Spain. Grifols continues a phased rollout across the rest of Europe of the treatment, the first oral non-plasma therapy that the company’s flagship Biopharma Business Unit has launched in Europe.

Over time Grifols expects to further strengthen its industry-leading portfolio through additional innovative in-licensing agreements to treat existing and emerging diseases, benefiting patients and offering additional therapeutic alternatives to healthcare providers.

TAVLESSE® is also commercially available in the U.S. under the brand name TAVALISSE®. Grifols has exclusive rights to fostamatinib in chronic ITP in Europe, Turkey, Middle East, North Africa and CIS countries thanks to a Collaboration and License Agreement reached with U.S.-based Rigel Pharmaceuticals.

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 (TPO-RAs) and splenectomy. However, not all patients respond to existing therapies. As a result, there remains a significant medical need for additional treatment options.

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About Grifols

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. A leader in essential plasma-derived medicines and transfusion medicine, the company develops, produces and provides innovative healthcare services and solutions in more than 110 countries.

Patient needs and our ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive our innovation in plasma-based therapies and other biopharmaceuticals to enhance quality of life. Grifols is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology and infectious diseases.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 400 across North America, Europe, Africa and the Middle East and China.

As a recognized leader in transfusion medicine, Grifols offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion, in addition to clinical diagnostic technologies. We provide high-quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. In addition, the company supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 27,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety, and ethical leadership.

In 2021, Grifols' economic impact in its core countries of operation was EUR 7.7 billion. The company also generated 141,500 jobs, including indirect and induced.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Grifols non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

For more information, please visit www.grifols.com

About Rigel

Rigel Pharmaceuticals, Inc. (Nasdaq: RIGL) is a biotechnology company dedicated to discovering, developing and providing novel small molecule drugs that significantly improve the lives of patients with hematologic disorders, cancer, and rare immune diseases. Founded in 1996, Rigel is based in South San Francisco, California. For more information on Rigel, the Company's marketed product and pipeline of potential products, visit www.rigel.com.

References

- [1.](https://www.ema.europa.eu/en/documents/product-information/tavlesse-epar-product-information_en.pdf) Instituto Grifols S.A. Tavlesse® (fostamatinib): Summary of Product Characteristics. Available from: https://www.ema.europa.eu/en/documents/product-information/tavlesse-epar-product-information_en.pdf [Last accessed: September 2022].
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- [3.](#) SMC advice fostamatinib 100mg and 150mg film-coated tablets (Tavlesse®). January 2021
- [4.](#) Newland A, McDonald V. Fostamatinib: a review of its clinical efficacy and safety in the management of chronic adult immune thrombocytopenia. *Immunotherapy*. 2020 Dec;12(18):1325-1340. doi: 10.2217/imt-2020-0215. Epub 2020 Oct 6. PMID: 33023353.

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The facts and figures contained in this report that do not refer to historical data are “future projections and assumptions”. Words and expressions such as “believe”, “hope”, “anticipate”, “predict”, “expect”, “intend”, “should”, “will seek to achieve”, “it is estimated”, “future” and similar expressions, in so far as they relate to the Grifols group, are used to identify future projections and assumptions. These expressions reflect the assumptions, hypotheses, expectations and predictions of the management team at the time of writing this report, and these are subject to a number of factors that mean that the actual results may be materially different. The future results of the Grifols group could be affected by events relating to its own activities, such as a shortage of supplies of raw materials for the manufacture of its products, the appearance of competitor products on the market, or changes to the regulatory framework of the markets in which it operates, among others. At the date of compiling this report, the Grifols group has adopted the necessary measures to mitigate the potential impact of these events. Grifols, S.A. does not accept any obligation to publicly report, revise or update future projections or assumptions to adapt them to events or circumstances subsequent to the date of writing this report, except where expressly required by the applicable legislation. This document does not constitute an offer or invitation to buy or subscribe shares in accordance with the provisions of the following Spanish legislation: Royal Legislative Decree 4/2015, of 23 October, approving recast text of Securities Market Law; Royal Decree Law 5/2005, of 11 March and/or Royal Decree 1310/2005, of 4 November, and any regulations developing this legislation. In addition, this document does not constitute an offer of purchase, sale or exchange, or a request for an offer of purchase, sale or exchange of securities, or a request for any vote or approval in any other jurisdiction. The information included in this document has not been verified nor reviewed by the external auditors of the Grifols group.