

## Grifols' Biotest receives FDA approval for innovative Yimmugo<sup>®</sup> immunoglobulin to treat primary immunodeficiencies

- *With Biotest-developed Yimmugo, Grifols adds to its remarkable franchise of intravenous and subcutaneous immunoglobulins to meet strong demand*
- *Yimmugo, already approved for production and marketing in Europe, is the first U.S.-approved medicine in Biotest's portfolio and is manufactured with an innovative process at Biotest's new FDA-certified 'Next Level' facility*
- *U.S. approval of Yimmugo paves the way for other Biotest proteins in late-stage development, including fibrinogen and trimodulin*
- *Launching Yimmugo in the U.S. will over time significantly add to Grifols Group sales and underpins its future growth strategy*

**Barcelona, Spain, June 17, 2024** – Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), one of the world's leading producers of plasma-derived medicines, today announced that Biotest, a Grifols Group company, has received approval from the United States Food and Drug Administration (FDA) for Yimmugo<sup>®</sup>, an innovative intravenous immunoglobulin (Ig) therapeutic, to treat primary immunodeficiencies (PID).

Yimmugo, developed by Biotest, adds to Grifols' strong franchise of industry-leading intravenous and subcutaneous Ig treatments at a time of growing demand for plasma-derived medicines to treat immunodeficiencies, in which a part of the body's immune system is missing or does not function properly, and other medical conditions.

The first U.S.-approved medicine in Biotest's portfolio, Yimmugo is produced using a state-of-the-art process at Biotest's new FDA-certified "Next Level" production facility in Dreieich, Germany, which is already approved for production and marketing in Europe.

The launch of Yimmugo in the U.S. in the second part of 2024 follows its successful introduction in Europe at the end of 2022 and is poised to add to Grifols' future revenue growth and profitability.

Yimmugo is the first of a threesome of Biotest plasma proteins on the horizon destined for markets including the U.S. The other two, both in late-stage development, are a fibrinogen concentrate (FC) to treat acquired fibrinogen deficiency – it would be the first FC approved for this indication in the U.S. – and trimodulin, a polyvalent Ig to treat community-acquired pneumonia (CAP) or severe community-acquired pneumonia (sCAP).

"The addition of Biotest's Yimmugo to our strong portfolio of intravenous and subcutaneous immunoglobulins provides another innovative treatment option for patients with primary

# GRIFOLS

immunodeficiencies who rely on these essential medicines in their daily lives,” said Roland Wandeler, President Grifols Biopharma Business Unit.

The strategic acquisition of Biotest and the integration of its specialized resources has significantly accelerated Grifols innovation, deepened its product pipeline and furthered its industry leadership.

## About Yimmugo® (IgG Next Generation)

Yimmugo is a newly developed polyvalent immunoglobulin G preparation from human blood plasma for intravenous administration (IVIg). The sugar-free ready-to-use solution is approved in the US for substitution therapy in primary antibody deficiency syndromes. Yimmugo is the first approved product from the new Biotest Next Level production facility. The modern production process stands for the highest product quality and an extremely responsible use of resources.

### IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION and ACUTE RENAL FAILURE

See full Prescribing Information for [YIMMUGO](#).

- Thrombosis may occur with immune globulin intravenous (IGIV) products, including YIMMUGO. (5.3)
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with the administration of IGIV products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. YIMMUGO does not contain sucrose. (5.4)

For patients at risk of thrombosis, renal dysfunction or renal failure, administer YIMMUGO at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity. (2.1, 2.3, 5.3)

## 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 Grifols' ever-growing knowledge of many chronic, rare and prevalent conditions, at times life-threatening, drive the company's innovation in both plasma 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 390 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. It provides high-quality biological supplies for life-science research, clinical trials, and for manufacturing pharmaceutical and diagnostic products. The company also supplies tools,

# GRIFOLS

information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 23,000 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.

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 about Grifols, please visit [www.grifols.com](http://www.grifols.com)

---

## **MEDIA CONTACTS:**

### **Grifols Press Office**

[media@grifols.com](mailto:media@grifols.com)

Tel. +34 93 571 00 02

## **INVESTORS:**

### **Grifols Investors Relations & Sustainability**

[inversores@grifols.com](mailto:inversores@grifols.com) - [investors@grifols.com](mailto:investors@grifols.com)

[sostenibilidad@grifols.com](mailto:sostenibilidad@grifols.com) - [sustainability@grifols.com](mailto:sustainability@grifols.com)

Tel. +34 93 571 02 21

## **LEGAL DISCLAIMER**

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.