GRIFOLS

Grifols' Biotest launches Yimmugo® in the United States

- ***Grifols and Biotest expand access to treatment for people living with immunedeficiencies***
- ***Biotest-developed Yimmugo received FDA approval for U.S. in mid-2024***
- ***The launch strengthens Grifols' robust portfolio of immunoglobulins available to U.S. patients***

Barcelona, Spain, October 9, 2025 - Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), a global healthcare company and leading producer of plasma-derived medicines and innovative diagnostic solutions, today announced that Yimmugo®, an innovative intravenous immunoglobulin (IVIg) therapeutic, produced by Biotest – a Grifols Group company – will officially launch in the United States for the treatment of primary immunodeficiencies (PID).

Following FDA approval for U.S. commercialization earlier in 2024, the first for a Biotest medicine, Yimmugo will now be available to help address the growing number of patients living with primary immunodeficiencies and other medical conditions in the country. It is estimated that one in every 1,200 people[1] in the U.S. is affected by PID, a condition where the body's immune system's ability to fight infections and diseases is weakened or does not function properly.

Developed by Biotest, Yimmugo is manufactured using a state-of-the-art process at the company's FDA-certified "Next Level" production facility in Dreieich, Germany. Already approved and successfully launched in Europe in 2022, the U.S. introduction of Yimmugo is expected to significantly contribute to Grifols Group's sales and support the company's future growth strategy.

Grifols has built a strong portfolio of industry-leading immunoglobulin therapies, including both intravenous and subcutaneous formulations. Global demand for immunoglobulin treatments continues to rise, with a projected compound annual growth rate (CAGR) of 6.9%, reaching an estimated market size of $36.7 billion in 2034, up from $20.1 billion in 2025[2].

"The U.S. launch of Yimmugo marks a cornerstone in Biotest's long-term strategy and highlights the company's continuous growth trajectory," said Dr. Jörg Schüttrumpf, Chief Scientific Innovation Officer at Grifols and CEO of Biotest AG. "It also demonstrates Grifols' and Biotest's shared commitment to innovation and to improving the lives of people worldwide by expanding access to care."

Yimmugo will be distributed in the United States by Kedrion Inc., a recognized leader in plasma-derived therapies.

---

[1] U.S. Pharmacist. (n.d.). Primary immunodeficiency: Etiology and incidence. Retrieved from https://www.uspharmacist.com/article/primary-immunodeficiency-etiology-and-incidence

[2] Global Market Insights Inc. (2025, July). *Immunoglobulin Market - By Product Type, By Route of Administration, By Application, By End Use - Global Forecast 2025–2034*. Global Market Insights. Retrieved October 8, 2025, from https://www.gminsights.com

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.

INDICATIONS AND USAGE
YIMMUGO® (immune globulin intravenous, human – dira) is a 10% immune globulin (Ig) liquid indicated for the treatment of primary humoral immunodeficiency in patients 2 years of age and older.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS, RENAL DYSFUNCTION, and ACUTE RENAL FAILURE

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

CONTRAINDICATIONS

YIMMUGO is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human Ig and in patients with immunoglobulin A (IgA) deficiency who have antibodies against IgA and a history of hypersensitivity.

WARNINGS AND PRECAUTIONS
Severe hypersensitivity reactions, including anaphylaxis, have been reported after administration. In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. YIMMUGO contains ≤300 mcg/mL of IgA. Patients with known antibodies to IgA may be at greater risk.

Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to IGIV treatment. Risk factors for hemolysis include high doses and non-O blood group. Monitor patients for hemolysis.

Renal failure: Monitor renal function, including blood urea nitrogen (BUN) and serum creatinine, and urine output in patients at risk of developing acute renal failure.

Hyperproteinemia, increased serum viscosity, and hyponatremia may occur in patients receiving IGIV treatment, including YIMMUGO.

Aseptic meningitis syndrome may occur in patients receiving IGIV treatment, especially with high doses or rapid infusion.

Transfusion-related acute lung injury: Monitor patients for pulmonary adverse reactions.

Transmissible infectious agents: YIMMUGO is made from human plasma and may contain infectious agents, eg, viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

Interference with laboratory tests: After infusion of Ig, transitory rise of various passively transferred antibodies in the blood may yield positive serological results, with potential for misleading interpretation.

ADVERSE REACTIONS

The most common adverse reactions occurring in ≥5% of patients were headache, upper respiratory tract infections, fatigue, nausea, and increased blood pressure.

To report SUSPECTED ADVERSE REACTIONS, contact Kedrion Biopharma Inc. at 1-855-3KDRION (1-855-353-7466) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for complete prescribing details, including Boxed Warning.

References: 1. YIMMUGO [prescribing information]. Kedrion Biopharma Inc.; 2024. **2.** Duellberg C, Hannappel A, Kistner S, Maneg O. Biochemical characterization of a new 10% IVIG preparation [IgG Next Generation (BT595)/Yimmugo®] obtained from a manufacturing process preserving IgA/IgM potential of human plasma. *Drugs R D.* 2023;23(3):245-255.

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 four main therapeutic areas: immunology, infectious diseases, pulmonology and critical care.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with close to 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. It provides high-quality biological supplies for life-science research, clinical trials and for manufacturing pharmaceutical and diagnostic products. The company also supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 23,800 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

MEDIA CONTACTS:

Grifols Press Office
media@grifols.com

Tel. +34 93 571 00 02

Investors

Investors Relations & Sustainability
inversores@grifols.com - investors@grifols.com
sostenibilidad@grifols.com - 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 'projections and future hypotheses'. Words and expressions such as 'believe', 'expect', 'anticipate', 'predict', 'hope', 'intend', 'should', 'will try to achieve', 'is estimated', 'future' and similar expressions, insofar as they refer to the Grifols group, are used to identify future projections and hypotheses. 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 series of factors that mean that the real results may be materially different. The future results of the Grifols group could be affected by events related to its own activities, such as shortages of supplies of raw materials for the manufacture of its products, the appearance on the market of competing products, or changes in the regulatory framework of the markets in which it operates, among others. At the date of preparation of this report, the Grifols group has adopted the necessary measures to mitigate the potential impact of these events. Grifols, S.A. assumes no obligation to publicly report, revise or update the projections or future hypotheses to adapt them to facts or circumstances after the date of writing of this report, except when expressly required by applicable legislation. This document does not constitute an offer or invitation to purchase or subscribe shares in accordance with the provisions of Law 6/2023, of 17 March, on the Securities Markets and Investment Services, and any regulations implementing said legislation. Furthermore, this document does not constitute an offer to purchase, sell or exchange, or a solicitation of an offer to purchase, sell or exchange any securities, or a solicitation of any vote or approval in any other jurisdiction. The information contained in this document has not been verified or revised by the external auditors of the Grifols group.