# **GRIFOLS**

# Grifols' Biotest launches Yimmugo<sup>®</sup> 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<sup>®</sup>, 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<sup>1</sup> 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 protected 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<sup>2</sup>.

"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 plasmaderived therapies.

<sup>2</sup> 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 <a href="https://www.gminsights.com">https://www.gminsights.com</a>

<sup>&</sup>lt;sup>1</sup> U.S. Pharmacist. (n.d.). Primary immunodeficiency: Etiology and incidence. Retrieved from <a href="https://www.uspharmacist.com/article/primary-immunodeficiency-etiology-and-incidence">https://www.uspharmacist.com/article/primary-immunodeficiency-etiology-and-incidence</a>

# 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 <u>YIMMUGO</u>.

- 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 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

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