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Grifols' Biotest to achieve USD 1 billion in US sales of Yimmugo® over next seven years

- ***Biotest, a Grifols Group company, is expected to launch its recently FDA-approved intravenous immunoglobulin in the U.S. in first quarter 2025***
- ***Yimmugo will be distributed by Kedrion in the U.S. as part of a broader Group channel strategy, with Grifols focusing on continued growth of its current portfolio for this market***
- ***It adds to Grifols' strong franchise of intravenous and subcutaneous immunoglobulins to meet growing patient demand for these therapeutics***
- ***Yimmugo will be followed by other proteins in the pipeline, including fibrinogen and trimodulin, both in late-stage development***

Barcelona, Spain, July 1, 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, forecasts approximately USD 1 billion in revenue from sales in the United States of its intravenous immunoglobulin (Ig) Yimmugo® during the next seven years, following recent Food and Drug Administration (FDA) approval to treat primary immunodeficiencies (PID).

Yimmugo is the first Biotest medicine to be commercialized in the U.S. from its new FDA-certified "Next Level" production facility in Dreieich, Germany, which is already approved for production and marketing in Europe, where Yimmugo has been commercialized since late 2022. It will launch in the U.S. in the first quarter of 2025 and be distributed by Kedrion under a seven-year agreement with Biotest, part of an overarching Grifols Group channel strategy to ensure extensive reach and availability of its Ig therapeutics. Grifols Group and Kedrion have a longstanding collaborative relationship.

Grifols itself will focus on continuing the growth of its leading and well-established intravenous and subcutaneous Ig treatments. Now with Yimmugo, the Group's U.S. portfolio will have an additional option to address the growing demand for Ig to treat immunodeficiencies, in which part of the body's immune system is missing or does not function properly, and other medical conditions.

"Ensuring that patients receive the best possible care is at the core of our mission," said Roland Wandeler, President Grifols Biopharma Business Unit. "Our distribution strategy will enable us to maximize the availability of Grifols' top-tier intravenous and subcutaneous immunoglobulins across the U.S., offering patients a comprehensive range of effective treatment options."

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Yimmugo, a key driver of Grifols Group's U.S. growth strategy, will be followed by other Group proteins in this market, including fibrinogen and trimodulin, both in late-stage development. Its fibrinogen concentrate would be the first to receive a U.S. indication to treat acquired fibrinogen deficiency, while trimodulin is a polyvalent antibody composition for community-acquired pneumonia (CAP) or severe community-acquired pneumonia (sCAP).

"With Yimmugo we are very excited to enter this important market for our industry and are committed to developing and delivering more therapies to patients in the U.S. in the coming years," said Peter Janssen, CEO of Biotest AG. "I am confident that Yimmugo will be a commercial success in the U.S. and provide an additional meaningful treatment option to patients."

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.

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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, 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

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