

Grifols begins European launch of XEMBIFY® in Spain to treat immunodeficiencies

- *Primary immunodeficiencies (PID) affect one in every 2,000 births. For secondary immunodeficiencies (SID), it is estimated that antibody deficiency may be 30 times more common than primary deficiencies¹*
- *Spain is the first country of the European Union where the product is available. Grifols expects to expand the number of countries with access to XEMBIFY® over the next year*
- *Grifols' strategy is focused on helping treat the expected significant growth in immunodeficiencies and the development of new indications*

Barcelona, Spain, June 26, 2023 – Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global leader in plasma medicines, has started marketing XEMBIFY®, its 20% subcutaneous immunoglobulin, in Spain. This plasma medicine is indicated for treating primary immunodeficiencies (PID) and certain secondary immunodeficiencies (SID), which are expected to grow significantly in the coming years.

Spain is the first country in the European Union where the product is available, although it has already been approved by the health authorities of several European countries and the United Kingdom. Grifols plans to expand the number of countries with access to XEMBIFY® over the next year.

PID affects one in every 2,000 births¹. For SID, it is estimated that antibody deficiency can be 30 times more common than primary deficiencies. These include those produced in patients with multiple myeloma, a type of cancer of which between 2,500 and 3,000 new cases² are diagnosed in Spain each year, and those produced in patients with chronic lymphocytic leukemia (CLL), the most frequent type of leukemia in the western world,³ with an estimated average annual prevalence of some 16,000 cases in Spain from 2011 to 2025.⁴

In addition, Grifols plans to launch XEMBIFY® in Australia in the second half of the year and continues to drive growth in the United States. Available in the U.S. since 2019, XEMBIFY® is an effective, safe and well-tolerated treatment for patients and continues to gain traction. In the first quarter of 2023, XEMBIFY® revenues increased by +34% at constant exchange rates.

¹ Patel SY, Carbone J, Jolles S. The Expanding Field of Secondary Antibody Deficiency: Causes, Diagnosis, and Management. *Front Immunol.* 2019;10:33

² Current situation and challenges of multiple myeloma in Spain (2018). Spain: Ernst & Young S.L.; 2018. [https://www.ey.com/Publication/vwLUAssets/ey-situacion-actual-y-retos-del-mieloma-multiple-en-espana-2018/\\$FILE/ey-situacion-actual-y-retos-del-mieloma-multiple-en-espana-2018.pdf](https://www.ey.com/Publication/vwLUAssets/ey-situacion-actual-y-retos-del-mieloma-multiple-en-espana-2018/$FILE/ey-situacion-actual-y-retos-del-mieloma-multiple-en-espana-2018.pdf)

³ Eichhorst B, Robak T, Montserrat E, et al. Chronic lymphocytic leukemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol.* 2021;32(1):23-33. doi:10.1016/j.annonc.2020.09.019

⁴ Montañés B, Casado G, Medina Á, Nieto P, Ramírez-Payer Á. Cost minimization analysis of chronic lymphocytic leukemia in Spain in the era of oral targeted therapies. *Farm Hosp.* 2022;46(2):72-79. Published 2022 Jan 11.

"Grifols is proud that XEMBIFY® is now available in the Spanish market, the first in a series of upcoming launches planned in different countries throughout the European Union. Thousands of patients and healthcare professionals in Spain can benefit from this new treatment, which will contribute to improving the quality of life of patients," said Joana Sabat, Grifols Senior Vice-President, Biopharma Launch Unit.

In addition, Grifols is working to obtain an indication for XEMBIFY® in the U.S. for the treatment of patients with hypogammaglobulinemia and recurrent or severe infections associated with B-cell CLL. This is one of the indications with the highest growth potential in the field of SID, as CLL is expected to increase 9.5% in the U.S. between 2018-2025,⁵ with a potential market exceeding USD 1 billion.

A market with significant potential

PID and SID, as well as minority diseases such as chronic inflammatory demyelinating polyneuropathy, Guillain Barré syndrome, Kawasaki disease, multifocal motor neuropathy, chronic immune thrombocytopenia and myasthenia gravis, are treated with immunoglobulins. The use of immunoglobulins continues to grow in major markets. Between 2016-2020, it is estimated that the consumption of immunoglobulins had an average annual growth rate of over 8%.⁶

The global immunoglobulin market is expected to continue to grow in the coming years, driven primarily by PID and SID, which account for approximately 40% to 55% of the total immunoglobulin market.

This growth is due to the improvement in the diagnosis of PID, which has resulted in more patients being treated with immunoglobulins.⁷ SID have increased notably due to the aging of the population and the use of immunosuppressive therapies, such as immuno-oncological treatments, for which immunoglobulins are the only option to avoid the development of complications.⁸

About XEMBIFY®

XEMBIFY®, with proven safety, efficacy and tolerability, presents a balanced formulation to confidently treat a wide range of immunodeficiency patients.

XEMBIFY® features a unique caprylate chromatography manufacturing process that yields highly purified immunoglobulin G (IgG). XEMBIFY® provides a flexible immunoglobulin treatment option (daily, weekly or biweekly), offering patients reliable protection against infections.

⁵ Marketing Research Bureau. Report Analysis of the 2018 IVIG/SCIG Market in the United States and 2025 Forecast.

⁶ Marketing Research Bureau. Global Usage and Forecast of the Immunoglobulin Market by Region

⁷ J. Kerr, I. Quinti, M. Eibl, H. Chapel, P. J. Späth, W. A. Carrock Sewell, A. Salama, I. N. van Schaik, T. W. Kuijpers and H.-H. Peter, "Is dosing of therapeutic immunoglobulins optimal? A review of a three-decade long debate in Europe," Front Immunol, vol. 5, no. 629, 2014.

⁸ Sánchez-Ramón S, Bermúdez A, González-Granado LI, Rodríguez-Gallego C, Sastre A, Soler-Palacín P; ID-Signal Onco-Hematology Group. Primary and Secondary Immunodeficiency Diseases in Oncohematology: Warning Signs, Diagnosis, and Management. Front Immunol. 2019 Mar 26;10:586.

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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 24,000 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 2022, Grifols' economic impact in its core countries of operation was EUR 9.6 billion. The company also generated 193,000 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

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