Grifols announces FDA approval of Xembify®, 20% subcutaneous immunoglobulin for primary immunodeficiencies

- ***Xembify® is Grifols' first 20% subcutaneous immunoglobulin for the treatment of primary immunodeficiencies***
- ***Grifols is a frontrunner in disease treatment with immunoglobulins, and this approval will enable the company to further expand its portfolio of plasma-derived medicines to benefit of patients and healthcare professionals***
- ***Xembify® represents a significant R+D+i milestone for Grifols and an important step forward in its long-term sustainable growth strategy***
- ***The company plans to launch Xembify® in the United States in the last quarter of the year and is working to obtain additional approvals in Canada, Europe and other global markets***

Barcelona, July 4, 2019.- Grifols (MCE:GRF, MCE:GRF.P NASDAQ:GRFS), a leading global producer of plasma-derived medicines, announced today that Xembify®, its new 20% subcutaneous immunoglobulin, has been approved by the U.S. Food and Drug Administration (FDA). Xembify® is used to treat primary immunodeficiencies.

The FDA approval marks the culmination of an important R+D+i initiative for Grifols, as well as an opportunity to enhance the Bioscience Division's product portfolio. Grifols is currently a market leader in the production and marketing of immunoglobulins, with 30.3%[1] market share (grams) in the United States. Thus, this approval reinforces Grifols' commitment to patients in the United States, allocating an increasing part of its production to supply the needs of this market.

According to Joel Abelson, President of Commercial Bioscience Division, *"This approval reinforces Grifols' longstanding commitment to patients and healthcare professionals by expanding our product portfolio to better serve individuals with primary immunodeficiencies. We are pleased to offer patients living with this challenging chronic disease another important treatment option."*

The company plans to launch Xembify® in the United States in the last quarter of 2019 and is working with healthcare authorities to obtain approval in Canada, Europe and other markets.

[1] *Source: Grifols Global Plasma Database, Provisional Data 2018.*

Immunoglobulins are mainly used to treat primary and secondary immunodeficiencies, as well as rare neurological conditions, such as chronic inflammatory demyelinating polyneuropathy (CIDP). Immunoglobulin use continues to grow in major markets. From 2015-2017, immunoglobulin volumes have experience annual growth rates of about 10% for primary and secondary immunodeficiencies and CIDP[2].

Committed to long-term growth: R+D+i and capital investments

FDA approval of Xembify® reflects Grifols' steadfast commitment to R+D+i and innovation, which have enabled the company to continue developing new formulations and indications that enhance its portfolio of products.

Recent highlights include the 2018 FDA approval of a new intramuscular immunoglobulin (GamaSTAN®) that provides immediate protection against hepatitis A and measles, and a new anti-rabies immunoglobulin (HyperRAB®) to treat patients exposed to the rabies virus.

Grifols intends to allocate EUR 1,400 million toward capital investments over the 2018-2022 period in order to meet the growing demand for plasma-derived medicines and reinforce its long-term growth plan.

Especially noteworthy is the current construction of the world's first purification and sterile filling plant of immunoglobulins in flexible packaging, located on Grifols' industrial complex in Clayton (North Carolina, USA). The plant will require a EUR 140 million investment and is expected to be operational by 2022.

About Xembify®

Indications and usage

XEMBIFY® (immune globulin subcutaneous, human- klhw) is a 20% immune globulin solution for subcutaneous injection indicated for treatment of Primary Humoral Immunodeficiency (PI) in patients 2 years of age and older. This includes, but is not limited to, congenital agammaglobulinemia, common variable immunodeficiency, X-linked agammaglobulinemia, Wiskott-Aldrich syndrome, and severe combined immunodeficiencies.

Important Safety Information

- Thrombosis may occur with immune globulin products, including XEMBIFY®. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors. Thrombosis may occur in the absence of known risk factors.

- For patients at risk of thrombosis, administer XEMBIFY® 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] *Source: Data on File; US, Canada, Spain, Germany, France, Italy*

Warnings and precautions

- Hypersensitivity and anaphylactic reactions may occur. IgA deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity or anaphylactic reactions.
- Aseptic Meningitis Syndrome (AMS) may occur within two days of treatment.
- Monitor for renal function in patients at risk for renal failure.
- Hemolysis can develop. Risk factors include high doses and non-O blood group. Closely monitor for hemolysis and hemolytic anemia.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).
- XEMBIFY® is made from human plasma and may carry a risk of transmitting infectious agents, e.g., viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
- Passive transfer of antibodies may confound serologic testing.

Contraindications

- Anaphylactic or severe systemic reactions to human immunoglobulin or inactive ingredients of XEMBIFY® such as polysorbate 80.
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity

Adverse reactions

The most common adverse reactions in ≥ 5% of subjects in the clinical trial were local adverse reactions including infusion site erythema (redness), infusion site pain, infusion site swelling (puffiness), infusion site bruising, infusion site nodule, infusion site pruritus (itching), infusion site induration (firmness), infusion site scab, infusion site edema, and systemic reactions including cough and diarrhea.

To report suspected adverse reactions, contact Grifols Therapeutics at 1-800-520-2807 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Investor contact:

Investor Relations
inversores@grifols.com - investors@grifols.com
Phone number: +34 93 571 02 21

Media contact:

Raquel Lumbreras raquel_lumbreras@duomocomunicacion.com Borja Gómez borja_gomez@duomocomunicacion.com Duomo Comunicación - **Grifols Press Office** Phone number: +34 91 311 92 89 - +34 91 311 92 90	Brad Pick **Grifols Corporate Communications** Brad.pick@grifols.com

---

GRIFOLS

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. Its four divisions – Bioscience, Diagnostic, Hospital and Bio Supplies – develop, produce and market innovative solutions and services that are sold in more than 100 countries.

Pioneers in the field of the plasma science, Grifols operates a growing network of donation centers worldwide. It transforms collected plasma into essential medicines to treat rare, chronic and, at times, life-threatening conditions. As a recognized leader in transfusion medicine, Grifols also offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion. 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 22,000 employees in 30 countries, 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, please visit www.grifols.com
