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Grifols receives expanded XEMBIFY® (immune globulin subcutaneous human-klhw) label in U.S., strengthening its Ig portfolio for patients

- ***XEMBIFY is the first and only 20% subcutaneous immunoglobulin (SCIg) with FDA-approved dosing for treatment-naïve patients, enabling them to go straight to SCIg without initial intravenous therapy***
- ***Approval, which also includes biweekly dosing, follows phase 4 study data demonstrating comparable total Ig levels when administering XEMBIFY every two weeks versus weekly***
- ***The expanded label for XEMBIFY provides added flexibility and convenience for patients with primary humoral immunodeficiencies***
- ***Increasing adoption of XEMBIFY is part of Grifols' broader Ig business strategy focused on treating immunodeficiencies, which represent more than half of the total Ig market and whose growth is expected to outpace other indications***

Barcelona, Spain, July 29, 2024 – Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), one of the world's leading producers of plasma-derived medicines, today announced that the United States Food and Drug Administration (FDA) has approved an expanded label for XEMBIFY®, the company's 20% subcutaneous immunoglobulin (SCIg), to include treatment-naïve patients with primary humoral immunodeficiencies (PI).

XEMBIFY becomes the first 20% SCIg with this extended label, allowing patients to begin SCIg therapy without first having intravenous administration.

FDA approval of the Supplemental Biologics Application (sBLA) also includes biweekly dosing and is supported by phase 4 clinical trial (NCT04566692) data shared last year. XEMBIFY met its primary endpoint, demonstrating that patients with PI treated with XEMBIFY every two weeks achieved non-inferiority in total Ig levels compared with those who received the medication every seven days.

There were no unique safety issues identified in the trial and the tolerability profiles were consistent between biweekly and weekly administration. The phase 4 trial was a multicenter, single-sequence, open-label study that included 27 subjects across 18 U.S. sites.

Greater adoption of XEMBIFY forms part of Grifols' wider Ig business strategy. The global market for Ig is expected to grow in the high single digits in the coming years as a result of the increase in PI and secondary immunodeficiencies (SID), which together account for up to 55%

of the total Ig market.[1] Ig treatment for immunodeficiencies is expected to outpace all other indications.

“The XEMBIFY label expansion eliminates the need for patients to have initial intravenous treatment, which differentiates XEMBIFY from other SCIg therapies, plus offers patients greater convenience and flexibility with biweekly dosing,” said Joerg Schuettrumpf, Grifols Chief Scientific Innovation Officer. “Grifols plans to launch the new label in the U.S. in the third quarter of 2024 as part of the company’s commitment to increasing options for patients and adapting to their needs and lifestyles.”

The biweekly dosing option is already available in the European markets where XEMBIFY is commercialized, including Czech Republic, France, Iceland, Norway, Slovakia, Spain and Sweden. The company is also working on launching XEMBIFY in other European countries.

XEMBIFY is indicated for PI in the U.S. and both PI and select SID in Europe, Canada and Australia.

About XEMBIFY®

Grifols XEMBIFY is a 20% solution of purified human immunoglobulin (primarily immune globulin G [IgG]) made from large pools of human plasma via modifications of the Immune Globulin (Human), 10% Caprylate/Chromatography Purified (IGIV-C 10%) manufacturing process.

INDICATION

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. XEMBIFY is for subcutaneous administration only.

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- **Thrombosis may occur with immune globulin products, including XEMBIFY®. Risk factors may include: advanced age, prolonged immobilization, 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 of hyperviscosity**

Contraindications

XEMBIFY® is contraindicated in patients who have had an anaphylactic or severe systemic reaction to the administration of human immune globulin. It is contraindicated in IgA-deficient patients with antibodies against IgA and a history of hypersensitivity.

[1] Marketing Research Bureau. Global Usage and Forecast of the Immunoglobulin Market by Region

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Warnings and Precautions

Aseptic meningitis syndrome (AMS). AMS may occur with human immune globulin treatment, including XEMBIFY®. Conduct a thorough neurological exam on patients exhibiting signs and symptoms to rule out other causes of meningitis. Discontinuation of treatment has resulted in remission within several days without sequelae.

Thrombosis. Thrombosis may occur following treatment with immune globulin products, including XEMBIFY®. Thrombosis may occur in the absence of known risk factors. In patients at risk, administer at the minimum dose and infusion rate practicable. Ensure adequate hydration before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk of hyperviscosity.

Hypersensitivity. Severe hypersensitivity reactions may occur with immune globulin products, including XEMBIFY®. In case of hypersensitivity, discontinue infusion immediately and institute appropriate treatment. XEMBIFY contains IgA. Patients with known antibodies to IgA may have a greater risk of developing potentially severe hypersensitivity and anaphylactic reactions.

Renal dysfunction/failure. Acute renal dysfunction/failure, acute tubular necrosis, proximal tubular nephropathy, osmotic nephrosis, and death may occur with use of human immune globulin products, especially those containing sucrose. XEMBIFY® does not contain sucrose. Ensure patients are not volume-depleted prior to starting infusion. In patients at risk due to preexisting renal insufficiency or predisposition to acute renal failure, assess renal function prior to the initial infusion of XEMBIFY® and again at appropriate intervals thereafter. If renal function deteriorates, consider discontinuation.

Hemolysis. XEMBIFY® may contain blood group antibodies that may cause a positive direct antiglobulin reaction and hemolysis. Monitor patients for clinical signs and symptoms of hemolysis. If signs and symptoms are present after infusion, perform confirmatory lab testing.

Transfusion-related acute lung injury (TRALI). Noncardiogenic pulmonary edema may occur in patients following treatment with immune globulin products, including XEMBIFY®. Monitor patients for pulmonary adverse reactions. If TRALI is suspected, perform appropriate tests for the presence of antineutrophil and anti-HLA antibodies in both the product and patient serum. TRALI may be managed using oxygen therapy with adequate ventilatory support.

Transmissible infectious agents. Because XEMBIFY® is made from human blood, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. No cases of transmission of viral diseases, vCJD, or CJD have ever been associated with the use of XEMBIFY®.

Interference with lab tests. After infusion of XEMBIFY®, passively transferred antibodies in the patient's blood may yield positive serological testing results, with the potential for misleading interpretation.

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.

Drug Interactions

Passive transfer of antibodies may transiently interfere with the immune responses to live attenuated virus vaccines (eg, measles, mumps, rubella, and varicella).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information for XEMBIFY® or visit www.xembify.com

Globally, prescribing information varies; refer to the individual country product label for complete information.

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. The company 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 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 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.

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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