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Grifols receives FDA approval for expanded immunoglobulin purification and filling capacity at its North Carolina site

- ***New building increases Grifols' global capacity to produce its leading Gamunex®-C immunoglobulin (Ig) brand to 60 million grams annually; next up for FDA review is the plant's output of XEMBIFY®, the company's subcutaneous Ig***

- ***Grifols is ramping up its state-of-the-art Ig capabilities as demand for this class of plasma-protein medicines continues to grow, particularly to treat immunodeficiencies***

- ***It's the latest accomplishment for the Clayton, N.C., campus, nearing its 50-year anniversary and currently one of the largest sites worldwide for the manufacturing of plasma-derived therapeutics***

Barcelona, Spain, Nov. 13, 2023 – Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global leader in plasma medicines with more than 110 years contributing to improve the health and well-being of people, today announced it has received approval from the U.S. Food and Drug Administration (FDA) for its new immunoglobulin (Ig) purification and filling facility at its Clayton, North Carolina, manufacturing campus, one of the world's largest sites for producing plasma-derived medicines.

The FDA approval is specifically for Gamunex®-C, a leading Grifols Ig brand. This enables the company to manufacture an additional 16 million grams of the therapy annually, bringing total global capacity to 60 million grams. Soon Grifols will seek FDA authorization for the new plant to also produce XEMBIFY®, its quickly growing subcutaneous Ig.

Patient need for Ig therapeutics is expected to rise, especially to treat the growing prevalence of immunodeficiencies, which account for approximately 40% to 55% of the total Ig market.[1]

Purification and filling follows the fractionation of plasma into separate proteins, including Ig, alpha-1 proteinase inhibitor, albumin and antithrombin-III, each indicated for different conditions. It is the last step before finished medicine vials are packaged and shipped.

Grifols Engineering engineered and built the new 150,000-square-foot, Green Globes®-certified purification and filling facility. It is the most recent expansion of Grifols' flagship Clayton plasma-medicine manufacturing campus. As it approaches its 50-year anniversary in 2024, the site has evolved into a global showcase for the advanced manufacturing of hemoderivatives. Over the last decade, Grifols has invested approximately USD 1 billion in the site, including a new plasma

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

fractionation building that began production in early 2022 and increases the site's overall fractionation capacity to 12 million liters/year, more than half of the company's global total.

"Having achieved FDA approval earlier than expected for our new purification and filling plant, Grifols continues investing in new technology and expanding our plasma-medicine manufacturing capabilities to address the growing need for immunoglobulins and other plasma-protein therapeutics," said Victor Grifols Deu, Grifols Chief Operating Officer.

About XEMBIFY® and GAMUNEX®-C

XEMBIFY® (immune globulin subcutaneous human–klhw) and GAMUNEX®-C (immune globulin injection [human], 10% caprylate/chromatography purified) are approved for treatment of primary humoral immunodeficiency disease (PIDD) in patients 2 years of age and older. If you have PIDD, you may only take XEMBIFY under the skin (subcutaneously), while GAMUNEX-C may be taken subcutaneously or in a vein (intravenously).

IMPORTANT SAFETY INFORMATION

WARNING: THROMBOSIS

- Thrombosis (formation of blood clots within blood vessels) may occur with immune globulin (IG) products, including XEMBIFY and GAMUNEX-C. Before you take XEMBIFY or GAMUNEX-C, talk to your doctor if you:
  - Are older
  - Are sedentary (need to lie down or sit down) for long periods of time
  - Are taking estrogen-containing medicines (birth control pills, hormone replacement therapy)
  - Have a permanent intravenous (IV) catheter
  - Have hyperviscosity of the blood (diseases such as multiple myeloma or other causes of elevated proteins in the blood)
  - Have a history of blood clots in veins or arteries
  - Have cardiovascular (heart) problems or previous history of stroke
- Thrombosis may occur even if you don't have any risk factors
- If you are at risk of thrombosis, your doctor may prescribe XEMBIFY or GAMUNEX-C at the minimum dose and infusion rate. Make sure you drink plenty of fluid before taking XEMBIFY or GAMUNEX-C. Your doctor will check you regularly for signs and symptoms of thrombosis and will check your blood viscosity if you are at risk of hyperviscosity

GAMUNEX-C ADDITIONAL WARNING: RENAL DYSFUNCTION OR FAILURE

- Serious kidney (renal) disease and death may occur with intravenous immune globulin (IVIG) products, including GAMUNEX-C. Before you take GAMUNEX-C, talk to your doctor if you:
  - Have a kidney problem
  - Have Type II diabetes
  - Are older than 65
- You are more likely to develop serious kidney disease if you
  - are dehydrated
  - have a blood infection (sepsis)
  - have high protein content in your blood
  - are receiving other medicines that may be harmful to the kidneys
- Renal dysfunction or failure are more common in patients receiving IVIG products that contain sucrose. GAMUNEX-C does not contain sucrose
- If you are at risk of renal dysfunction or failure, your doctor may prescribe GAMUNEX-C at the minimum dose and infusion rate. Drink plenty of fluid before taking GAMUNEX-C. Your doctor will check your kidney function and urine output periodically
- Tell your doctor if you experience decreased urination, sudden weight gain, swelling in your legs (edema), or shortness of breath

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Who should not use XEMBIFY or GAMUNEX-C?

- Do not use XEMBIFY or GAMUNEX-C if:
    - you have had a severe allergic reaction to human immune globulin
    - you have been told by a doctor that you are immunoglobulin A (IgA) deficient and have developed antibodies to IgA and hypersensitivity after exposure to a previous plasma product

What are possible serious side effects of XEMBIFY or GAMUNEX-C?

- **Hypersensitivity.** Severe allergic reactions may occur with immune globulin products, including XEMBIFY and GAMUNEX-C. If you have a severe allergic reaction, stop the infusion immediately and get medical attention. XEMBIFY and GAMUNEX-C contain IgA. If you have known antibodies to IgA, you may have a greater risk of developing potentially severe allergic reactions
- **Aseptic meningitis syndrome (AMS).** Aseptic meningitis is a non-infectious inflammation of the membranes that cover the brain. It causes a severe headache syndrome, which may occur with human immune globulin treatment, including XEMBIFY and GAMUNEX-C. If you are showing signs and symptoms of AMS, your doctor may conduct a thorough neurological evaluation including spinal tap (sampling fluid which surrounds the spinal cord) to rule out other causes of meningitis. Stopping human immune globulin treatment has resulted in the end of signs and symptoms within several days. Treatment may include analgesics (pain medicines) and/or a special procedure known as a "blood patch" to stop headache
- **Kidney problems or failure.** Kidney problems or failure may occur with use of human immune globulin products, especially those containing sucrose (sugar). XEMBIFY and GAMUNEX-C do not contain sucrose. If you have kidney disease or diabetes with kidney involvement, your doctor should perform a blood test to assess your hydration level and kidney function before beginning immune globulin treatment and at appropriate intervals thereafter. If your doctor determines that kidney function is worsening, they may discontinue treatment
- **Hemolysis.** Your doctor should monitor you for symptoms of hemolysis (destruction of red blood cells causing anemia, or low red blood cell count). If your doctor suspects hemolysis, they should perform additional tests to confirm
- **Transfusion-related acute lung injury (TRALI).** TRALI is a rare but serious syndrome characterized by sudden acute respiratory distress following transfusion. If your doctor suspects TRALI, they will monitor you for any other lung issues. TRALI may be managed with oxygen therapy
- **Transmissible infectious agents.** Because XEMBIFY and GAMUNEX-C are made from human blood, they may carry a risk of transmitting infectious agents such as viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. No cases of transmission of viral diseases or CJD have been associated with the use of XEMBIFY or GAMUNEX-C
- **Interference with lab tests.** Because XEMBIFY and GAMUNEX-C contain a variety of antibodies, blood tests to determine antibody levels may be falsely elevated. Be sure to tell your doctor or lab technician if you are using XEMBIFY or GAMUNEX-C

What are other possible side effects of XEMBIFY?

- In clinical studies of XEMBIFY, some patients experienced local side effects (at the injection site) including pain, redness, puffiness, bruising, nodules, itching, firmness, scabbing and swelling at the site on the skin where the injection occurred. Some patients experienced non-injection-site side effects including cough and diarrhea
- Use of XEMBIFY may interfere with the immune response to virus vaccines, such as vaccines for measles, mumps, rubella, and varicella. Tell your doctor you are taking XEMBIFY before getting vaccinations

What are other possible side effects of GAMUNEX-C?

- **Intravenous:** In clinical studies in patients with PIDD who received GAMUNEX-C intravenously, the most common side effects were cough; irritation and inflammation of the mucous membrane inside the nose; sore throat caused by inflammation of the back of the throat; pain in the region of the head or neck; a condition in which the airways narrow and swell and produce extra mucus; a sensation of

unease and discomfort in the upper stomach; raised body temperature or fever; loose stools; and swelling of the tissue lining the sinuses.

- **Subcutaneous:** In clinical studies in patients with PIDD who received GAMUNEX-C subcutaneously, the most common side effects were infusion-site reactions such as redness, swelling, and itching; extreme tiredness; pain in the region of the head or neck; a runny nose, nasal congestion, sneezing, cough, and sputum production; joint pain; loose stools; a sensation of unease and discomfort in the upper stomach; swelling of the tissue lining the sinuses; inflammation of the airways that carry air to the lungs; a feeling of unhappiness, sadness, melancholy, gloom, hopelessness, or low spirits; red rash or bumps, itchy, swollen, and tender skin with or without blisters or a burning feeling; a severe throbbing pain or a pulsing sensation, usually on just one side of the head; muscle pain; familiar infectious diseases such as the common cold or flu; and raised body temperature or fever.

Please see full Prescribing Information for XEMBIFY and GAMUNEX-C.
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.

MEDIA CONTACTS:

Grifols Press Office
media@grifols.com
Tel. +34 93 571 00 02

Investor contact:

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

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 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. 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 grifols.com