Grifols introduces HyperHEP B® (hepatitis B immune globulin [human]), a new formulation to treat patients exposed to hepatitis B

- *The new formulation delivers anti-hepatitis B virus antibodies using a unique and sophisticated caprylate chromatography process*

- *Grifols has been a trusted global provider of hepatitis B immune globulin (HBIG) for over 45 years and continues to expand its leadership in disease treatment with immunoglobulin (IgG), building out its preeminent hyperimmune portfolio*

- *The manufacturing process provides for a significant reduction in procoagulant activity and IgG aggregates, and is the only HBIG to offer a neonatal syringe format specifically to protect infants born to hepatitis B surface antigen (HBsAg)-positive mothers*

Barcelona, Spain, June 1, 2021 – Grifols (MCE: GRF, MCE: GRF.P, and NASDAQ: GRFS), a leading global producer of plasma-derived medicines and provider of a variety of postexposure prophylaxis and IgG products for patients, today began commercializing HyperHEP B, a new formulation of its hepatitis B immune globulin [human] for hepatitis B postexposure prophylaxis.

The new formulation, which was approved by the U.S. Food and Drug Administration (FDA) in December 2020, uses a unique caprylate chromatography process, which significantly reduces procoagulant activity and IgG aggregates. It also includes FDA labeling for capacity to remove pathogenic prions. HyperHEP B is the newest version of Grifols' current HBIG, HyperHEP B S/D, which is presently prescribed globally in over 20 countries. Earlier this year Grifols, in partnership with Direct Relief, donated six million international units (IU) of HyperHEP B S/D to various underserved countries around the world.

"Since the launch of the first version of HyperHEP B 45 years ago, millions of patients worldwide have relied on this critical product to decrease risks associated with hepatitis B exposure," said Bill Zabel, President, Grifols North America Sales and Commercial Operations. "With a continued commitment to improving the lives of patients, we're establishing new purification standards around this critical treatment. This new formulation increases the long-standing confidence physicians have in Grifols' market leading hyperimmune portfolio."

It is estimated that between 800,000 and 1.4 million people in the U.S. are currently infected with hepatitis B. For patients who have not been previously vaccinated, the Advisory Committee on Immunization Practices (ACIP) and Centers for Disease Control and Prevention (CDC)

recommend immediate prophylaxis following exposure to hepatitis B, including both HBIG and hepatitis B (HepB) vaccine as soon as possible after exposure (preferably within 24 hours).

“HBIG for use in prophylaxis is an important treatment choice for our patients who are exposed to the hepatitis B virus. HyperHEP B gives us the flexibility we need with three different presentations, including a pre-filled neonatal syringe,” said Mike Cushner, Director of Inventory, SUNY Upstate Medical Center in Syracuse, NY. “The unique manufacturing process yields a product that aligns well with our own focus on patient well-being in procuring therapies that meet high safety and quality standards.”

Additionally, an estimated 25,000 infants are born to HBsAg-positive mothers each year in the U.S. and about 90% of infants with hepatitis B go on to develop chronic infection. For infants born to hepatitis B-infected mothers, the ACIP and CDC recommends that they receive postexposure prophylaxis to reduce their risk for perinatal hepatitis B virus (HBV) infection. Postexposure prophylaxis consists of HepB vaccine and HBIG administered within 12 hours of birth. Grifols is the only manufacturer that presently produces HBIG in a neonatal syringe format specifically to protect infants born to HBsAg-positive mothers.

HyperHEP B will now be available to U.S. healthcare providers and patients in three sizes (0.5 mL neonatal syringe, 1 mL vial, and 5 mL vial) through all major distributors. This new formulation is manufactured at Grifols’ state-of-the-art manufacturing plant in Clayton, N.C., according to the highest quality and safety standards. Each vial or syringe contains anti-HBs antibody equivalent to or exceeding the potency of anti-HBs in a U.S. reference HBIG (Center for Biologics Evaluation and Research, FDA).

Please see Important Safety Information for HyperHEP B below and refer to the full Prescribing Information or visit www.HyperHEPB.com.

Important Safety Information for HyperHEP B® (hepatitis B immune globulin [human])

HyperHEP B® (hepatitis B immune globulin [human]) is indicated for postexposure prophylaxis in the following situations: acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to an HBsAg-positive person and household exposure to persons with acute HBV infection.

HyperHEP B should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human IgG preparations. Epinephrine should be available.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, hepatitis B immune globulin (human) should be given only if the expected benefits outweigh the risks.

Local pain and tenderness at the injection site, urticaria, and angioedema may occur; anaphylactic reactions, although rare, have been reported following the injection of human

immunoglobulin preparations. Administration of live virus vaccines (eg, MMR) should be deferred for approximately 3 months after hepatitis B immune globulin (human) administration.

HyperHEP B is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent that can cause disease. There is also the possibility that unknown infectious agents may be present in such products.

Please see full Prescribing Information for HyperHEP B.

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.

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 plasma industry, Grifols operates a growing network of donation centers worldwide. It transforms collected plasma into essential medicines to treat chronic, rare 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 24,000 employees in 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2020, Grifols' economic impact in its core countries of operation was EUR 7.5 billion. The company also generated 140,000 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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