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Grifols receives FDA approval to treat surgical bleeding in pediatric patients with its fibrin sealant solution

- ***Younger patients in the U.S. can now benefit from Grifols Fibrin Sealant (FS) and its positive effect on surgical outcomes, including a fast time to hemostasis***

- ***Grifols surgical bleeding management treatments form part of an increasingly robust portfolio of innovative therapeutics enhancing the health and well-being of patients***

Barcelona, Spain, Oct. 29, 2024 - Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global healthcare company and leading manufacturer of plasma-derived medicines, today announced that its plasma-protein based fibrin sealant (FS) for controlling surgical bleeding has received approval from the United States Food and Drug Administration (FDA) for pediatric patients.

The U.S. indication for children and adolescents extends the availability of FS, which is already approved for this patient segment in Europe, in addition to adults. During surgery Grifols FS promotes hemostasis and tissue sealing, resulting in reduced blood loss and potentially fewer complications.

Grifols FS biosurgery treatment is commercialized as VISTASEAL™ in the U.S. and Canada, and VERASEAL™ in Europe and elsewhere. Both brands are marketed and distributed by Johnson & Johnson MedTech, as part of a strategic collaboration between the two companies announced in 2019.

Grifols FS combines two plasma proteins, fibrinogen and thrombin, and is applied with Johnson & Johnson MedTech's airless spray technology to rapidly form clots. The FS solution is now available in 18 countries.

In early 2023, Grifols announced that it had met all primary and secondary endpoints of its phase 3b study evaluating the administration of Grifols FS to pediatric patients, defined as those not having reached 18 years of age. Researchers conducted a global prospective, randomized, active-controlled, single-blind, parallel group clinical trial designed to evaluate the safety and efficacy of the FS as an adjunct to hemostasis during surgery in pediatric patients (compared with an active control). The study included a total of 178 patients enrolled and treated across 18 recruitment centers.

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A greater than 95% efficacy rate was achieved in both treatment arms, with hemostasis within four minutes of application. In addition, Grifols FS demonstrated a good safety and tolerability profile, as the distribution of adverse events was comparable between arms.

“Developing innovative biosurgery solutions reflects Grifols’ ability to provide patients with more medicines across many therapeutic areas to enhance their well-being,” said Joerg Schuettrumpf, Grifols Chief Scientific Innovation Officer.

It’s estimated that between roughly one-third and two-thirds of open surgeries experience disruptive bleeding,[1] while challenging and uncontrollable bleeding during surgery is associated with high mortality rates.[1,2]

About VISTASEAL
VISTASEAL is a single-use product that uses a combination of human fibrinogen and human thrombin to assist with mild to moderate bleeding control when standard surgical techniques such as suture or cautery are ineffective. The sealant is applied in a thin layer over the bleeding tissue in order to generate a cross-linked fibrin clot to achieve hemostasis. VISTASEAL can be utilized in high-risk patients when there are concerns regarding coagulopathy, antiplatelets, anticoagulants, and friable tissue.

VISTASEAL™ Fibrin Sealant (Human)
IMPORTANT SAFETY INFORMATION

INDICATION
VISTASEAL™, a fibrin sealant, is indicated as an adjunct to hemostasis for mild to moderate bleeding in patients undergoing surgery when control of bleeding by standard surgical techniques (such as suture, ligature, and cautery) is ineffective or impractical. VISTASEAL™ is effective in heparinized patients.

CONTRAINDICATIONS
Do not inject directly into the circulatory system.
Do not use for the treatment of severe or brisk arterial bleeding.
Do not use in patients with history of anaphylaxis or severe systemic reactions to human blood products.
Do not use VISTASEAL™ for spraying unless the minimum recommended distance from the applicator tip to the bleeding site can be achieved.

WARNINGS AND PRECAUTIONS
Thromboembolic events may occur if VISTASEAL™ is administered intravascularly.
Hypersensitivity reactions can occur.
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.

ADVERSE REACTIONS
The most common adverse reactions (reported in >1% of patients) were procedural pain, and nausea.

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[1] Corral M, Ferko N, Hollmann S, Broder MS, Chang E. Health and economic outcomes associated with uncontrolled surgical bleeding: a retrospective analysis of the Premier Perspectives Database. *Clinicoecon Outcomes Res*. 2015;7:409-421. doi:10.2147/CEOR.S86369

[2] Marietta M, Facchini L, Pedrazzi P, Busani S, Torelli G. Pathophysiology of bleeding in surgery. *Transplant Proc*. 2006;38(3):812-814. doi:10.1016/j.transproceed.2006.01.047

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

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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 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. 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. 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 23,000 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 about Grifols, please visit grifols.com

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The facts and figures contained in this report that do not refer to historical data are “future projections and assumptions”. Words and expressions such as “believe”, “hope”, “anticipate”, “predict”, “expect”, “intend”, “should”, “will seek to achieve”, “it is estimated”, “future” and similar expressions, in so far as they relate to the Grifols group, are used to identify future projections and assumptions. These expressions reflect the assumptions, hypotheses, expectations and predictions of the management team at the time of writing this report, and these are subject to a number of factors that mean that the actual results may be materially different. The future results of the Grifols group could be affected by events relating to its own activities, such as a shortage of supplies of raw materials for the manufacture of its products, the appearance of competitor products on the market, or changes to the regulatory framework of the markets in which it operates, among others. At the date of compiling this report, the Grifols group has adopted the necessary measures to mitigate the potential impact of these events. Grifols, S.A. does not accept any obligation to publicly report, revise or update future projections or assumptions to adapt them to events or circumstances subsequent to the date of writing this report, except where expressly required by the applicable legislation. This document does not constitute an offer or invitation to buy or subscribe shares in accordance with the provisions of the following Spanish legislation: Royal Legislative Decree 4/2015, of 23 October, approving recast text of Securities Market Law; Royal Decree Law 5/2005, of 11 March and/or Royal Decree 1310/2005, of 4 November, and any regulations developing this legislation. In addition, this document does not constitute an offer of purchase, sale or exchange, or a request for an offer of purchase, sale or exchange of securities, or a request for any vote or approval in any other jurisdiction. The information included in this document has not been verified nor reviewed by the external auditors of the Grifols group.