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Grifols achieves positive topline results from phase 3b study of its fibrin sealant to treat surgical bleeding in pediatric patients

- ***All primary and secondary endpoints met, with Grifols Fibrin Sealant (FS) showing a positive safety and tolerability profile***

- ***An indication for younger patients would enable Grifols to broaden the reach of its FS-based biosurgery solutions, VISTASEAL™ and VERASEAL™, which are marketed and distributed by Ethicon***

- ***Grifols continues to innovate across its businesses, applying its ever-expanding knowledge of plasma-protein science and other biotherapies to treat patients***

Barcelona, Spain, January 11, 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 that its plasma-protein based fibrin sealant (FS) for controlling surgical bleeding obtained positive topline results from a phase 3b clinical trial in pediatric patients.

Having met all primary and secondary endpoints, the study is expected to facilitate regulatory approval to expand the use of the FS-based biosurgery treatment, currently indicated for adults, to children and adolescents as well.

Known commercially as VISTASEAL™ in the United States and VERASEAL™ in Europe, Grifols FS is marketed and distributed by Ethicon*, a Johnson & Johnson MedTech company, 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 Ethicon's airless spray technology to rapidly form clots. Since being introduced a few years ago, the FS product has launched in 20 countries.

Researchers investigating the application of Grifols FS to pediatric patients, defined as not having reached 18 years of age, conducted a 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 subjects, the international study included a total of 178 patients enrolled and treated across 18 recruitment centers.

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In both treatment arms, Grifols FS had a 95% efficacy rate, achieving hemostasis within four minutes of application. In addition, the solution demonstrated a good safety and tolerability profile, as the distribution of adverse events was comparable between arms.

The trial fulfills legal and regulatory obligations as well as supports regulatory licenses from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

“Our innovative work in developing biosurgery solutions is a reflection of Grifols’ ability to apply its ever-deeper knowledge of plasma science and other biopharmaceuticals to treat patient needs across multiple therapeutic areas,” said Cesar Cerezo, Grifols senior vice president of Drug Development.

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 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 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 400 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.

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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

Grifols, with more than 27,000 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 2021, Grifols' economic impact in its core countries of operation was EUR 7.7 billion. The company also generated 141,500 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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