GRIFOLS

Grifols' Biotest receives first regulatory approval for its fibrinogen concentrate

- ***Germany is the first country to grant marketing authorization and will be followed by other European countries such as Austria and Spain***

- ***The new therapy, commercialized as Prufibry® in Germany, is approved for both congenital and acquired fibrinogen deficiency and is expected to be available to patients in Germany by the end of 2025***

- ***The fibrinogen concentrate complements Grifols' and Biotest's bleeding management portfolio, expanding therapeutic options for patients***

Barcelona, Spain, November 13, 2025 - Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), a global healthcare company and leading producer of plasma-derived medicines, today announced that its fibrinogen concentrate has been approved by the German competent authority, the Paul-Ehrlich-Institut, for the treatment of congenital (CFD) and acquired fibrinogen deficiency (AFD).

Germany is the first European country to grant marketing authorization for the company's fibrinogen concentrate, following a decentralized regulatory procedure with Austria and Spain expected to follow in 2026.

The new fibrinogen concentrate, developed and produced by Biotest (a Grifols Group company), has been approved to treat CFD and AFD caused by bleeding due to surgery or trauma for adults, children and adolescents (0-18 years). CFD is a rare inherited condition present from birth and caused by genetic mutations affecting the production or function of fibrinogen, while AFD typically results from severe bleeding during complex surgical procedures or trauma.

Fibrinogen, a plasma protein produced in the liver, plays a key role in stopping blood loss and in wound healing. When fibrinogen levels are too low, the body cannot effectively stop bleeding.

Treatment options for low fibrinogen levels include fresh frozen plasma, cryoprecipitate or fibrinogen concentrate. Cryoprecipitate and fresh frozen plasma contain other proteins and components that are not essential for fibrinogen replacement and often require infusions of large volumes to achieve adequate fibrinogen levels.

Grifols' fibrinogen concentrate is a highly purified product with a precisely defined amount of fibrinogen, allowing for a predictable response and a rapid replenishment of fibrinogen, which is important in these critical moments.

"With this approval, patients in Germany will have access to a safe, effective and reliable treatment to help prevent and control major bleeding, including in life-threatening cases, particularly in surgical and trauma scenarios," said Dr. Jörg Schüttrumpf, Chief Scientific Innovation Officer at Grifols and CEO of Biotest AG. "It's a meaningful step forward in our mission to transform care for patients facing critical

bleeding risks. We believe this product will give physicians the confidence to act decisively and swiftly when faced with a bleeding patient – especially in situations where every second counts."

The product, which will be commercialized under the brand Prufibry® in Germany, is produced in the "Biotest Next Level" production facility in Dreieich, Germany. The state-of-the-art manufacturing process yields a highly purified product with robust viral safety, contributing to a sustainable use of the valuable plasma.

Beyond Europe, Grifols has also submitted a biologic license application for the fibrinogen concentrate in the U.S., with regulatory determination expected by the end of the year.

Strong clinical development program

The results of the clinical trials supporting regulatory approval have been published in leading scientific journals. In June 2025, *eClinicalMedicine* (*The Lancet*) published the positive results of AdFIrst, a Phase 3 study[1] evaluating Grifols' fibrinogen concentrate in patients with AFD. The article highlights that the trial met its primary endpoint, demonstrating non-inferiority to standard of care in reducing intraoperative blood loss, while maintaining an excellent safety profile.

In October 2025, *Thrombosis and Haemostasis* published the results of a study[2] evaluating our fibrinogen concentrate in patients with CFD. This research confirmed the therapy's favorable pharmacokinetic profile, strong hemostatic efficacy and safety in both adult and pediatric patients.

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 four main therapeutic areas: immunology, infectious diseases, pulmonology and critical care.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with close to 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.

Grifols, with more than 23,800 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.

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[1] Rahe-Meyer N, et al. Efficacy and safety of human fibrinogen concentrate (BT524) in patients with major haemorrhage undergoing major orthopaedic or abdominal surgery (AdFIrst): a randomised, active-controlled, multicentre, partially blinded, phase 3 non-inferiority trial. *eClinicalMedicine*. 2025; 103264, https://doi.org/10.1016/j.eclinm.2025.103264.

[2] Djambas Khayat C, El-Beshlawy A, Meddeb B, et al. Pharmacokinetics, hemostatic efficacy, and safety of a new human fibrinogen concentrate in adult and pediatric patients with congenital fibrinogen deficiency. *Thromb Haemost*. 2025. https://doi.org/10.1055/a-2715-2994.

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 www.grifols.com

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