GRIFOLS

Grifols launches FESILTY™ (fibrinogen, human-chmt) in the U.S.

- ***The new fibrinogen concentrate, approved in the U.S. for acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, is now available in the U.S.***

- ***FESILTY complements Grifols' bleeding management portfolio, expanding therapeutic options for patients.***

Barcelona, Spain, June 15, 2026 – Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global healthcare company and leading producer of plasma-derived medicines, today announced the U.S. launch of its new fibrinogen concentrate. Approved by the U.S. Food and Drug Administration in December for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency (CFD), including hypo- or afibrinogenemia, FESILTY™ (fibrinogen, human-chmt) is now available in the U.S. FESILTY is not indicated for dysfibrinogenemia.

FESILTY provides health care professionals a new treatment option for acute bleeding in patients with CFD, a rare inherited condition caused by genetic mutations that impair the production or function of fibrinogen. Produced in the liver, fibrinogen is a plasma protein essential for blood clotting and wound healing. When fibrinogen levels are insufficient, the body's ability to effectively control bleeding is compromised, particularly during acute bleeding episodes.

A highly purified product with a precisely defined amount of fibrinogen, FESILTY enables rapid and predictable restoration of fibrinogen levels – which is critical during bleeding events in patients with CFD. In contrast, alternate treatment options such as cryoprecipitate and fresh frozen plasma include additional proteins, often require infusions of large volumes to achieve adequate fibrinogen levels, and take longer to prepare and administer. FESILTY can be stored at room temperature at the point of care and is supplied as a complete kit, allowing for rapid reconstitution in approximately three minutes.

"The availability of an additional fibrinogen concentrate in the U.S. is a meaningful development for clinicians caring for patients with congenital fibrinogen deficiency during acute bleeding events," said Guy Young, MD, Director, Hemostasis and Thrombosis Center at University of Southern California's Keck School of Medicine. "Targeted fibrinogen replacement is becoming increasingly well supported, and purified concentrates can be especially useful because they allow for predictable dosing, can be administered quickly and do not require crossmatching."

The launch of FESILTY enhances Grifols' bleeding management offering and further expands its portfolio of plasma-derived medicines to benefit patients and healthcare professionals.

"With FESILTY now available in the U.S., health care providers have a safe, effective and reliable treatment for acute bleeding episodes in patients with CFD – when every minute counts," said Roland Wandeler, President of Grifols Biopharma. "This milestone reflects our continued commitment to bringing more medicines to more patients around the world."

Clinical evidence supporting approval

FDA approval of FESILTY was based on evidence from the clinical study "A Prospective, Open-label, Phase I/III Study Investigating Pharmacokinetic Properties of BT524 and Efficacy and Safety of BT524 in the Treatment and Prophylaxis of Bleeding in Patients With Congenital Fibrinogen Deficiency" (NCT02065882).

Two medical journals recently published results from this study. The findings, published in Thrombosis and Haemostasis (October 2025)[1] and Thrombosis Research (March 2026)[2] confirmed the therapy's pharmacokinetics, hemostatic efficacy, and safety for treatment of acute bleeding episodes in both adults and children with CFD.

Important Safety Information

Indications and Usage
FESILTY (fibrinogen, human-chmt) is a human blood coagulation factor indicated for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including hypo- or afibrinogenemia.

Limitations of Use:
FESILTY is not indicated for dysfibrinogenemia.

Contraindications
FESILTY is contraindicated in patients who have severe hypersensitivity reactions, including anaphylaxis, to FESILTY or its components (arginine hydrochloride, polysorbate 80, sodium citrate dihydrate, trehalose dihydrate).

Warnings and Precautions
Hypersensitivity reactions have occurred in patients receiving FESILTY. Should symptoms occur, discontinue FESILTY and administer appropriate treatment.

Thrombotic events have occurred in patients receiving FESILTY. Weigh the benefits of administration versus the risks of thrombosis.

FESILTY is made from pooled human plasma and may carry the 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 serious adverse reactions observed with FESILTY were thrombotic events, including portal vein thrombosis, deep vein thrombosis, and pain in extremity with clinically suspected thrombosis. One patient had an episode of epilepsy and died due to extradural hematoma 4 weeks after administration of FESILTY.

In a clinical study, the most common adverse reactions that occurred in >2% of patients receiving FESILTY were pain in extremity, back pain, hypersensitivity reactions, pyrexia, thrombosis, fibrin D dimer increased, headache, and vomiting.

Please see full Prescribing Information for FESILTY.

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[1] 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.

[2] Khayat, Claudia Djambas, et al. Efficacy and safety of prophylaxis and treatment of bleeding events with a novel fibrinogen concentrate from human plasma in patients with congenital fibrinogen deficiency. *Thrombosis Research*. 2026. https://www.thrombosisresearch.com/article/S0049-3848(26)00035-6/fulltext

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 focuses on treating conditions centered on six core therapeutic areas: immunology, neurology, pulmonology, hematology, hepatology and intensive care.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's most diversified with more than 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 25,000 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 www.grifols.com

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