PRESS RELEASE

Biotest announces US FDA approval of Grifols' Fesilty™ (fibrinogen, human-chmt)

- **Fesilty™ (fibrinogen, human-chmt) approved by the U.S. Food and Drug Administration (FDA)**
- **This new fibrinogen product was developed and is manufactured by Biotest AG and will be commercialized in the U.S. by Grifols**
- **U.S. market entry planned in first half of 2026**

Dreieich, 19 December 2025. Biotest AG, part of the Grifols group, today announced that Grifols has received approval from the U.S. Food and Drug Administration (FDA) for Fesilty™ (fibrinogen, human-chmt), which is manufactured by Biotest and will be commercialized in the U.S. by Grifols.

Within the U.S., Fesilty™ is indicated for the treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency (CFD), including hypo- or afibrinogenemia. This approval will allow Grifols to launch this product in the first half of 2026.

Human fibrinogen is one of the Biotest pipeline products that contributes a significant benefit to the whole Grifols group – now and in the future. Biotest received approval for human fibrinogen under the brand name Prufibry® in Germany in November. Additional approvals in Europe are expected in 2026.

"This FDA approval marks a major achievement for both Biotest and Grifols," said Dr. Jörg Schüttrumpf, Chief Executive Officer of Biotest AG. "We are proud that our plasma expertise contributes directly to expanding patient access to life-saving fibrinogen therapies in the treatment of critical conditions worldwide."

Manufactured at Biotest Next Level

Human fibrinogen is produced at the Biotest Next Level (BNL) facility in Dreieich, Germany — one of the most advanced plasma protein production plants in Europe. The plant combines high efficiency, robust viral safety, and sustainability in the use of plasma as a raw material.

A shared success within the Grifols Group

As part of the Grifols group, Biotest plays a key role in advancing plasma-derived therapies from research to large-scale manufacturing. With Prufibry® already approved in Germany, and now Fesilty™ approved in the United States, the companies together expand access to fibrinogen replacement therapy for patients around the world.

About Fesilty™

Fesilty is a human fibrinogen product commercialized in the U.S. by Grifols and indicated for treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency, including hypo- or afibrinogenemia. It was developed and is manufactured by Biotest AG in Dreieich, Germany. The newly developed manufacturing process of the product leads to high-purity fibrinogen with a defined concentration, high level of viral safety and good solubility.

About fibrinogen and fibrinogen deficiency

Fibrinogen is a blood clotting factor that is produced in the liver. It plays a key role in primary haemostasis (stopping blood loss from bleeding wounds) and wound healing. In case of a lack or shortage of fibrinogen blood's ability to clot is impaired which leads to a much greater risk of bleeding and delayed haemostasis. The fibrinogen concentrate alternatives fresh frozen plasma (FFP) and cryoprecipitate contain variable amounts of fibrinogen and must be thawed prior to treatment. The defined amount of fibrinogen in the fibrinogen concentrate will allow a tailor-made, patient specific and highly effective therapy.

About Biotest

Biotest is a provider of biological therapeutics derived from human plasma. With a value-added chain that extends from pre-clinical and clinical development to worldwide sales, Biotest has specialised primarily in the areas of clinical immunology, haematology and intensive care medicine. Biotest develops and markets immunoglobulins, coagulation factors and albumin based on human blood plasma. These are used for diseases of the immune and haematopoietic systems. Biotest has more than 2,600 employees worldwide. Since May 2022, Biotest has been a part of the Grifols Group, based in Barcelona, Spain (www.grifols.com).

IR contact

Dr Monika Baumann (Buttkereit)
Phone: +49-6103-801-4406
Mail: ir@biotest.com

PR contact

Miriam Oehme
Phone: +49 -152 07016 992
Mail: pr@biotest.com

Biotest AG, Landsteinerstr. 5, 63303 Dreieich, Germany, www.biotest.com

Ordinary shares: securities' ID No. 522720; ISIN DE0005227201
Preference shares: securities' ID No. 522723; ISIN DE0005227235
Listing: Open Market: Berlin, Düsseldorf, Hamburg/ Hanover, Munich, Stuttgart, Tradegate