PRESS RELEASE

Biotest obtains approval for new human fibrinogen Prufibry® in Germany

- **New life-saving therapy for patients with congenital and acquired fibrinogen deficiency**
- **Clinical studies demonstrate efficacy and safety in bleeding control and surgical settings**
- **Important expansion to Biotest's intensive care and coagulation factor portfolio**
- **Produced at the highly efficient Biotest Next Level facility in Dreieich**

Dreieich, 13 November 2025. Biotest AG, part of the Grifols Group, announced today that the German competent authority, the Paul-Ehrlich-Institut, has approved Prufibry® (human fibrinogen; development name BT524) for the German market. Biotest's human fibrinogen 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.

"Prufibry® expands Biotest's product portfolio in the field of intensive care and coagulation disorders with a new, highly purified plasma protein," emphasises Dr Jörg Schüttrumpf, Chief Executive Officer of Biotest AG. "With this approval, patients suffering from congenital and acquired fibrinogen deficiency will gain access to an effective, reliable and safe therapy to prevent and control life-threatening bleeding events especially in surgical and trauma settings."

Clinical development and indications

This approval is based on a comprehensive clinical development program including pivotal Phase III trials. The studies demonstrated that BT524 effectively restored fibrinogen levels and controlled bleeding episodes in patients with congenital afibrinogenemia and hypofibrinogenemia. In addition, perioperative use of BT524 in major surgeries confirmed its efficacy in preventing excessive bleeding when standard coagulation support was insufficient.

The approval covers the following indications in adults, children and adolescents (0-18 years):

Biotest's human fibrinogen is indicated:

- for the treatment and peri-operative prophylaxis of bleeding in patients with congenital hypo- or afibrinogenaemia with bleeding tendency.
- as complementary therapy to management of uncontrolled severe haemorrhage in acquired hypofibrinogenaemia caused by surgery or trauma.

Manufactured at Biotest Next Level

Biotest's human fibrinogen is produced in the new "Biotest Next Level" production facility at the Dreieich site. This state-of-the-art manufacturing platform enables high yields, robust viral safety, and sustainable use of the valuable raw material plasma.

The approval represents another important milestone in Biotest's strategy to broaden its specialty plasma protein portfolio and to strengthen supply security for patients worldwide.

Outlook

With the approval in Germany, the launch of Biotest's human fibrinogen is expected by the end of 2025. Further approvals in European and international markets are planned.

Prufibry® joins Biotest's established coagulation factor products and complements the company's growing specialty portfolio.

About Prufibry®
The newly developed manufacturing process of human fibrinogen leads to high-purity fibrinogen with a defined concentration, high level of viral safety and good solubility.

About AdFIrst trial no. 995
The AdFIrst trial was a prospective, active-controlled, multicentre phase III trial investigating the efficacy and safety of the Fibrinogen concentrate (BT524) in patients with acquired fibrinogen deficiency. Patients who had high blood loss during planned spinal or abdominal surgery were randomized 1:1 to treatment with Fibrinogen concentrate (BT524) or fresh frozen plasma (FFP)/Cryoprecipitate. To evaluate the efficacy of BT524, further blood loss was compared between treatment options. Further information about the trial design can be found at www.clinicaltrialsregister.eu (EudraCT number: 2017-001163-20).

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 totreatment. 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