PRESS RELEASE

Biotests' positive fibrinogen phase III trial results published in The Lancet's eClinicalMedicine

- **The data will also be presented tomorrow as part of three abstracts at the currently ongoing International Society on Thrombosis and Haemostasis (ISTH) 2025 Congress**
- **The Phase III AdFIrst study met its primary endpoint demonstrating that Grifols fibrinogen concentrate, BT524, was non-inferior to standard of care for the treatment of bleeding in acquired fibrinogen deficiency (AFD)**
- **BT524 on track to launch in Europe later this year and, pending FDA approval, in the U.S. in early 2026**

Dreieich, 23 June 2025. Biotest today announces that the positive Phase III study data on its fibrinogen concentrate, BT524, has been published in eClinicalMedicine, a peer-reviewed journal published by The Lancet Discovery Science Suite.

The article[1] highlights that the trial met its primary endpoint, demonstrating that treatment with BT524 is non-inferior to standard of care (SOC) with cryoprecipitate or fresh frozen plasma (FFP) in reducing clinically relevant intraoperative bleeding in patients with acquired fibrinogen deficiency (AFD) undergoing planned major spinal or abdominal surgery.

Specifically, the adjusted mean of intraoperative blood loss was 1381 mL (95% confidence interval [CI] 1187–1574) in the BT524 group and 1660 mL (95% CI 1461–1860) in the FFP/cryoprecipitate group, resulting in a difference of blood loss of 279 mL between the study groups. BT524 demonstrated a positive safety profile and a statistically significant lower incidence of thromboembolic events (TEEs).

Fibrinogen, a plasma protein produced in the liver, plays a key role in stopping blood loss and in wound healing. AFD is typically associated with major uncontrolled bleeding (such as during surgical procedures, trauma or postpartum hemorrhage). Low fibrinogen levels are insufficient to arrest bleeding and are commonly treated with fibrinogen sources such as cryoprecipitate. BT524 from Biotest was developed in collaboration with the Grifols Group.

"The trial results, now featured in this prestigious clinical medicine journal, support the potential of BT524 to be considered for patients with clinically relevant uncontrolled bleeding," said Dr. Jörg Schüttrumpf, CEO of Biotest AG. "We look forward to finalizing regulatory approval processes in Europe and the United States as soon as possible."

Niels Rahe-Meyer, M.D., Hannover Medical School, Germany, Department of Anesthesiology and Intensive Care Medicine, and main trial coordinator, added, "We look forward to sharing the results of the AdFIrst study more broadly with the medical community as part of the research publication and at ISTH. These data could represent a breakthrough in our understanding of hemorrhage management with fibrinogen."

Data from the study will be presented as part of three abstracts at the currently ongoing upcoming International Society on Thrombosis and Haemostais (ISTH) 2025 Congress in Washington, D.C., on June 21-25.

Abstract details include:

Abstract Number: PB1276

Title: Use of Fibrinogen Concentrate during Major Surgeries: Post-hoc Analysis of the Phase III AdFIrst Trial

Presenter: Silke Aigner

Session Date and Time: June 24, 10:50 – 11:10 a.m. (EDT)

Abstract Number: PB1217

Title: Early Intra-operative Use of a Fibrinogen Concentrate in Patients Undergoing Major Abdominal Surgery

Presenter: Ashok Roy

Session Date and Time: June 24, 10:50 – 11:10 a.m. (EDT)

Abstract Number: PB1219

Title: Efficacy and Safety of Fibrinogen Concentrate During Major Spinal Surgery: Phase III Randomized Trial

Presenter: Maria José Colomina

Session Date and Time: June 24, 13:45 – 14:45 p.m. (EDT)

Previously AdFIrst data have been presented at congresses including the International Symposium on Intensive Care & Emergency Medicine (ISICEM); Network for the Advancement of Patient Blood Management, Haemostasis and Thrombosis (NATA); and the European Society of Anaesthesiology and Intensive Care (ESAIC).

About AdFIrst trial

The completed trial for Grifols' fibrinogen concentrate (BT524), known as AdFIrst (Adjusted Fibrinogen Replacement Strategy), was a prospective, active-controlled, multicenter phase 3 non-inferiority trial investigating the efficacy and safety of 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 BT524 or cryoprecipitate or fresh frozen plasma (FFP). To evaluate the efficacy of BT524, further blood loss was compared between both treatment options. The primary endpoint was intraoperative blood loss from the time of decision to treat until the end of surgery with a non-inferiority margin of 150 mL, assessed in the per-protocol analysis set (PPS). Safety was assessed in all patients who received at least one dose of trial drug. Further information about the trial design can be found at www.clinicaltrialsregister.eu (EudraCT number: 2017-001163-20) or ClinicalTrials.gov: NCT03444324.

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 the 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 effective therapy.

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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.

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 2,500 employees worldwide. Since May 2022, Biotest has been a part of the Grifols Group, based in Barcelona, Spain (www.grifols.com).

Biotest AG will now also be publishing official press releases via **X**. You can find us at: https://twitter.com/BiotestAG

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