Biotest

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PRESS RELEASE

Important milestone for Biotest: Biologics License Application for Fibrinogen submitted to the US Food and Drug Administration (FDA)

- **Biotest's fibrinogen aims to fulfill a high unmet medical need for additional fibrinogen to treat acquired fibrinogen deficiency**
- **US submission follows EU application for marketing authorization submitted in October 2024**
- **Subject to FDA approval, new treatment would bring significant improvement in sales, EBIT and cash flow**

Dreieich, Germany, January 9, 2025. The Biologics License Application (BLA) for Biotest's Fibrinogen has been submitted to the US Food and Drug Administration. Fibrinogen is the second product developed and manufactured by Biotest in Dreieich, Germany, for which a BLA has been submitted to the FDA.

The new application covers both supplementation in patients with acquired fibrinogen deficiency and treatment and prophylaxis of acute bleeding episodes in all patients with congenital fibrinogen deficiency.

The application is now under evaluation by the FDA, with a decision anticipated by the end of 2025. This submission follows Biotest's earlier application for marketing authorization in selected European markets filed in October 2024.

"Clinical data demonstrates efficacy and safety of Biotest's Fibrinogen in various bleeding conditions," said Dr. Christina Erb, Head of Scientific Operations and Innovation. "Fibrinogen deficiency can lead to uncontrolled blood loss potentially resulting in patient's death. Biotest's Fibrinogen can be stored at room temperature and is designed to be more convenient and faster to prepare than alternatives for the treatment of fibrinogen deficiency associated with severe blood loss. As such, it will provide an effective and safe option for the management of bleeding in patients with serious and potentially life-threatening conditions".

In many regions of the world, the use of cryoprecipitate or fresh frozen plasma as a fibrinogen substitute is the standard of care for the management of major surgical bleeding. However, these treatments contain not only fibrinogen, but also additional proteins and components that may exhibit undesired effects for the patient. In addition, they are not subject to the same rigorous pathogen safety protocols as Fibrinogen. Fibrinogen also offers the significant advantages of being readily available and allowing for faster administration, ensuring timely and targeted treatment.

As a member of the Grifols Group, Biotest is committed to playing a leading role in expanding access to this therapy to a broader patient population.

About Biotest's Fibrinogen

The newly developed manufacturing process for fibrinogen results in 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 Fibrinogen (BT524) in patients with acquired fibrinogen deficiency. Patients experiencing high blood loss during planned spinal or abdominal surgery were randomized 1:1 to treatment with Fibrinogen (BT524) or fresh frozen plasma (FFP)/cryoprecipitate. To evaluate the efficacy of BT524, blood loss was compared between the two treatment options. For more information on the trial design and outcomes, please visit www.clinicaltrialsregister.eu (EudraCT number: 2017-001163-20). Full trial results are expected to be published in a medical journal later in 2025.

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 alternatives fresh frozen plasma (FFP) and cryoprecipitate contain variable amounts of fibrinogen and must be thawed prior to administration. The defined amount of fibrinogen in the fibrinogen developed by Biotest will allow a tailor-made, patient specific and highly effective treatment.

About Biotest

Biotest (www.biotest.com) is a provider of biological therapeutics derived from human plasma. With a value-added chain that extends from preclinical and clinical development to worldwide sales, Biotest has specialized primarily in the areas of clinical immunology, hematology, 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 hematopoietic systems. Biotest has more than 2,400 employees worldwide. The ordinary and preference shares of Biotest AG are listed in the Prime Standard on the German Stock Exchange. Since May 2022, Biotest has been a part of the Grifols Group, headquartered in Barcelona, Spain (www.grifols.com).

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