GRIFOLS

Grifols' positive fibrinogen phase 3 trial results published in *The Lancet's eClinicalMedicine*

- ***The data will also be presented as part of three abstracts at the upcoming International Society on Thrombosis and Haemostasis (ISTH) 2025 Congress***

- ***The Phase 3 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***

Barcelona, Spain, June 19, 2025 - Grifols (MCE: GRF, MCE: GRF.P NASDAQ: GRFS), a global healthcare company and leading producer of plasma-derived medicines, today announced that the positive Phase 3 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 was developed by Biotest, a Grifols Group company.

"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, Grifols Chief Scientific Innovation Officer. "We look forward to finalizing regulatory approval processes in Europe and the United States as soon as possible."

---

[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.

Niels Rahe-Meyer, M.D., Hannover Medical School, Department of Anesthesiology and Intensive Care Medicine, Germany, 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 upcoming International Society on Thrombosis and Haemostais (ISTH) 2025, to be held 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 3 AdFIrst Trial
Presenter: Silke Aigner
Session Date and Time: June 24, 10:50 – 11:10

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

Abstract Number: PB1219
Title: Efficacy and Safety of Fibrinogen Concentrate During Major Spinal Surgery: Phase 3 Randomized Trial
Presenter: Maria José Colomina
Session Date and Time: June 24, 13:45 – 14:45

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).

Grifols’ experience with fibrinogen medicines to manage surgical bleeding also includes a fibrinogen-based fibrin sealant the company launched five years ago.

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.

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 is focused on treating conditions across four main therapeutic areas: immunology, infectious diseases, pulmonology and critical care.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with close to 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 23,800 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

MEDIA CONTACTS:

Grifols Press Office
media@grifols.com
Tel. +34 93 571 00 02

LEGAL DISCLAIMER

The facts and figures contained in this report that do not refer to historical data are 'projections and future hypotheses'. Words and expressions such as 'believe', 'expect', 'anticipate', 'predict', 'hope', 'intend', 'should', 'will try to achieve', 'is estimated', 'future' and similar expressions, insofar as they refer to the Grifols group, are used to identify future projections and hypotheses. These expressions reflect the assumptions, hypotheses, expectations and predictions of the management team at the time of writing this report, and these are subject to a series of factors that mean that the real results may be materially different. The future results of the Grifols group could be affected by events related to its own activities, such as shortages of supplies of raw materials for the manufacture of its products, the appearance on the market of competing products, or changes in the regulatory framework of the markets in which it operates, among others.

At the date of preparation of this report, the Grifols group has adopted the necessary measures to mitigate the potential impact of these events. Grifols, S.A. assumes no obligation to publicly report, revise or update the projections or future hypotheses to adapt them to facts or circumstances after the date of writing of this report, except when expressly required by applicable legislation. This document does not constitute an offer or invitation to purchase or subscribe shares in accordance with the provisions of Law 6/2023, of 17 March, on the Securities Markets and Investment Services, and any regulations implementing said legislation. Furthermore, this document does not constitute an offer to purchase, sell or exchange, or a solicitation of an offer to purchase, sell or exchange any securities, or a solicitation of any vote or approval in any other jurisdiction. The information contained in this document has not been verified or revised by the external auditors of the Grifols group.