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Grifols submits Biologics License Application for its new fibrinogen solution to U.S. FDA

- ***Key step in U.S. follows submission of marketing authorization application in Europe in October 2024, backed by successful phase 3 clinical trial data to treat acquired fibrinogen deficiency***

- ***Commercial rollout of new potential therapeutic scheduled for Europe in H2 2025, followed by U.S. in H1 2026***

- ***Grifols fibrinogen, designed to be more convenient and faster to prepare than alternatives, treats fibrinogen deficiency associated with severe blood loss***

Barcelona, Spain, Jan. 9, 2025 - Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), a global healthcare company and leading manufacturer of plasma-derived medicines, today announced it has submitted a Biologics License Application (BLA) for its new potential fibrinogen treatment to the United States Food and Drug Administration (FDA).

The European equivalent, a Marketing Authorization Application (MAA), was submitted for several countries in October 2024. Grifols expects to begin treating patients in Europe starting in the second half of 2025, with rollout in the U.S. planned for the first part of 2026.

In February 2024, Grifols and Biotest, a Grifols Group company, announced that the fibrinogen had achieved positive topline results in a phase 3 clinical trial. The study met its primary endpoint of being as effective as standard of care in reducing intraoperative blood loss in patients with acquired fibrinogen deficiency, while also maintaining an excellent safety profile.

“A fibrinogen deficit impedes the body’s ability to arrest bleeding, which can lead to death in severe situations,” said Dr. Jörg Schüttrumpf, Grifols Chief Scientific Innovation Officer. “Grifols developed its new fibrinogen to be more convenient, faster to prepare and storable at room temperature, an advantage over alternatives such as cryoprecipitate or fresh frozen plasma when time is of the essence. We’re excited to get this innovative solution to patients.”

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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. Grifols is focused on treating conditions across a broad range of therapeutic areas: immunology, hepatology and intensive care, pulmonology, hematology, neurology, and infectious diseases.

A pioneer in the plasma industry, Grifols continues to grow its network of donation centers, the world's largest with over 390 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 23,000 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 grifols.com

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