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Grifols receives expanded indication for THROMBATE III® (antithrombin III [human]) label in U.S., strengthening treatment options for pediatric patients

- ***THROMBATE III is now the only antithrombin concentrate (ATc) approved for hereditary antithrombin deficiency (hATd) in both adult and pediatric patients***

- ***FDA approval was based on submitted data extrapolation from two clinical trials in adult patients addressing critical gaps in the clinical comprehension and treatment of pediatric hATd***

- ***The expanded label for THROMBATE III indicates it can be safely and effectively used in pediatric patients with hATd, a rare patient population***

Barcelona, Spain, November 18, 2025 – Grifols (MCE:GRF, MCE:GRF.P, NASDAQ:GRFS), one of the world's leading producers of plasma-derived medicines, today announced that the United States Food and Drug Administration (FDA) has approved an expanded indication for THROMBATE III®, the company's antithrombin III [human concentrate], to include pediatric patients diagnosed with hereditary antithrombin deficiency (hATd).

With this expansion, THROMBATE III becomes the first and only antithrombin concentrate (ATc) approved for adults and pediatrics with hATd, a frequently undiagnosed blood clotting disorder that may affect up to 700,000 people in the U.S. People with this condition have a higher-than-average risk of developing abnormal blood clots.

Considering that hATd has one of the highest thrombotic risks of all of the inherited thrombophilias[1] and 85% of patients with hATd will have at least one thrombotic episode by age 50[2], this approval represents a significant step forward for patients and families impacted by hATd.

"This label expansion helps close a long-standing gap in the treatment of pediatric patients with hereditary antithrombin deficiency," said George M. Rodgers, III, M.D., Ph.D., Professor of Medicine in the Division of Hematology and Hematologic Malignancies at the University of Utah School of Medicine. "It gives clinicians added confidence that ATc can be appropriately used in children."

FDA approval was supported by the extrapolation of data from two clinical studies in adult patients, concluding that ATc – which has been successfully used for treatment in adults with hATd for over three decades – can be safely and effectively used in pediatric patients with

[1] Patnaik MM, Moll S. Inherited antithrombin deficiency: a review. Haemophilia. 2008;14(6):1229-1239
[2] Kottke-Marchant K, Duncan A. Antithrombin deficiency: issues in laboratory diagnosis. Arch Pathol Lab Med. 2002;126(11):1326-1336

hATd.

“Expanding the indication to include pediatric patients provides a new option for children and families facing hereditary antithrombin deficiency,” said Roland Wandeler, president of Grifols Biopharma. “This is another example of Grifols’ continuing work to provide more patients with medicines to enhance their health and well-being.”

Treatment and prevention of thromboembolism in patients with hATd typically requires anticoagulation, with replacement of antithrombin (AT) with antithrombin sources like ATc or fresh frozen plasma (FFP) administration in certain high-risk situations.

THROMBATE III has been approved in the U.S. for treatment of adults with hATd since 1991.

About THROMBATE III®
Clinical studies have shown that THROMBATE III is an effective choice for patients with hereditary antithrombin deficiency (hATd) and for the treatment and prevention of thromboembolism, including before, during, and after surgery and childbirth.

THROMBATE III (antithrombin III [human]) is indicated in adult and pediatric patients with hereditary antithrombin deficiency for treatment and prevention of thromboembolism and for prevention of perioperative and peripartum thromboembolism.

Important Safety Information
Hypersensitivity reactions may occur. Should evidence of an acute hypersensitivity reaction be observed, promptly interrupt the infusion and begin appropriate treatment.

Because THROMBATE III is made from human blood, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent. There is also the possibility that unknown infectious agents may be present in the product.

Perform coagulation tests to avoid excessive or insufficient anticoagulation and monitor for bleeding or thrombosis. Measure functional plasma AT levels with amidolytic or clotting assays; do not use immunoassays.

In clinical studies, the most common adverse reactions (≥ 5% of patients) were dizziness, chest discomfort, nausea, dysgeusia, and pain (cramps).

The anticoagulant effect of heparin is enhanced by concurrent treatment with THROMBATE III in patients with hereditary AT deficiency. Thus, in order to avoid bleeding, the dosage of heparin (or low molecular weight heparin) may need to be reduced during treatment with THROMBATE III.

Please see accompanying full Prescribing Information for THROMBATE III®.

Product information, including indications, safety warnings, and prescribing details, may vary by country. For information specific to your region, please consult your local regulatory authority or healthcare provider.

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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 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