Grifols receives expanded indication for THROMBATE III® (antithrombin III [human]) label in US, 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[1]**
- **FDA approval was based on submitted data extrapolation from 2 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**

The US Food and Drug Administration (FDA) has approved an expanded indication for THROMBATE III® antithrombin III [human], 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 US.[2,3] People with this condition have a higher-than-average risk of developing abnormal blood clots.[2]

Considering that hATd has one of the highest thrombotic risks of all inherited thrombophilias and 85% of patients with hATd will have at least one thrombotic episode by age 50, this approval represents a significant step forward for patients and families impacted by hATd.[2,4]

FDA approval was supported by the extrapolation of data from 2 clinical studies in adult patients, concluding that ATc – which has been successfully used for treatment in adults with hATd for more than 3 decades – can be safely and effectively used in pediatric patients with hATd.

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 US for treatment of adults with hATd since 1991.

Please see Important Safety Information on the next page and refer to accompanying full Prescribing Information for THROMBATE III.

Important Safety Information

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.

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®.

References: 1. THROMBATE III® (antithrombin III [human]) Prescribing Information. Grifols. **2.** Patnaik MM, Moll S. Inherited antithrombin deficiency: a review. *Haemophilia*. 2008;14(6):1229-1239. **3.** US Census Bureau, Population Division. US and world population clock. Accessed April 10, 2025. http://www.census.gov/popclock/. **4**. Kottke-Marchant K, Duncan A. Antithrombin deficiency: issues in laboratory diagnosis. *Arch Pathol Lab Med*. 2002;126(11):1326-1336.

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