Hemab Therapeutics Receives FDA Breakthrough Therapy Designation for Sutacimig in Glanzmann Thrombasthenia

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CAMBRIDGE, MA, USA & COPENHAGEN, Denmark – March 5, 2026 – Hemab Therapeutics, a late stage clinical biotechnology company developing novel prophylactic therapeutics for serious, underserved coagulation disorders, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation (BTD) for sutacimig for the prevention of bleeding episodes in patients with Glanzmann thrombasthenia (GT).

"We are proud to announce this Breakthrough Therapy Designation, which recognizes both the potential for sutacimig to address a significant unmet need, and the urgency of bringing new treatment options to people living with Glanzmann thrombasthenia who have been historically underserved," said Benny Sorensen, MD, PhD, Chief Executive Officer of Hemab. "We look forward to continued collaboration with the FDA, with the goal of bringing the first prophylactic treatment to this patient population."

BTD represents the FDA's formal commitment to facilitating the development and review of drugs targeting serious or life-threatening conditions where preliminary clinical evidence suggests the potential for substantial improvement over existing standard of care.

"In people living with Glanzmann thrombasthenia the impact of frequent bleeding can be life-altering and have an immense impact on quality of life; it results in lost days at school or work and psychological stress. The current therapies inadequately control bleeding let alone prevent it; the unmet need for people living with Glanzmann thrombasthenia is clear," said Suthesh Sivapalaratnam, MD, PhD, Consultant Haematologist at Barts Health NHS Trust and Associate Professor at Queen Mary University of London. "This Breakthrough Therapy Designation is a critical step towards a potentially better therapeutic option for providers and patients who are urgently waiting."

BTD was granted based on a comprehensive data set, including positive results from the completed Phase 2 multiple ascending dose portion of Hemab's Phase 1/2 clinical trial of sutacimig (HMB-001-CL101). The data showed consistent and clinically meaningful reductions in bleeding, including the most severe bleeding events requiring high-intensity treatments (defined as those requiring recombinant Factor VIIa, platelet transfusions, plasma, cryoprecipitate, or medical procedures). Sutacimig has also received Fast Track Designation and Orphan Drug Designation from the FDA.

About Glanzmann Thrombasthenia

Glanzmann thrombasthenia (GT) is a severe bleeding disorder marked by debilitating, sometimes life-threatening bleeding episodes. Results from an international Glanzmann's 360 (GT360) natural history study revealed the substantial burden of this disease: 88% of the 117 participants reported at least one bleed in the previous week with 65% requiring a bleed-related hospital visit in the prior six months. These bleeding episodes significantly impacted patients' mental health and quality of life, with over 80% having missed work or school, over 50% facing limitations in attending social events, and over 50% experiencing restrictions in travel. To date, there are no effective prophylactic treatment options for GT.

About Sutacimig (formerly HMB-001)

Sutacimig is a subcutaneously administered bispecific antibody that is designed to bind and stabilize endogenous Factor VIIa with one antibody arm and bind to TLT-1 on activated platelets with the other arm. This mechanism is designed to allow for the accumulation of endogenous Factor VIIa in the body and recruitment of Factor VIIa directly to the surface of the activated platelets, where it facilitates hemostatic plug formation. Sutacimig is designed to be a first-in-class prophylactic treatment for Glanzmann thrombasthenia (GT) with the potential to treat other debilitating bleeding disorders. The U.S. Food and Drug Administration has granted Fast Track Designation, Orphan Drug Designation, and Breakthrough Therapy Designation to sutacimig for the treatment of GT, and the UK Medicines and Healthcare products Regulatory Agency has awarded sutacimig designation under the Innovative Licensing and Access Pathway (ILAP); it has been designated as an orphan medicinal product in the European Union for the treatment of GT. For more information regarding Hemab's Phase 1/2 clinical trial of sutacimig in GT, please visit clinicaltrials.gov (NCT06211634).

About Hemab Therapeutics

Hemab is a multiple clinical-asset biotechnology company developing novel prophylactic therapeutics for serious, underserved bleeding and thrombotic disorders. Based in Cambridge, MA, and Copenhagen, Denmark, Hemab is progressing a pipeline of innovative therapeutic candidates, leveraging a variety of cutting-edge technologies and approaches to transform the treatment paradigm for patients with blood coagulation disorders with high unmet need. The company's strategy is to build a pipeline of development programs to deliver long-awaited innovation for people with high unmet need diseases, such as Glanzmann thrombasthenia, Factor VII Deficiency, Von Willebrand Disease, and others. Learn more at hemab.com. Follow us on LinkedIn,

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