Hemab Therapeutics to Present Clinical and Preclinical Data from Multiple Bleeding Disorder Programs at the ISTH 2025 Congress

June 10, 2025

Sutacimig (formerly HMB-001) continues to demonstrate promising interim safety, PK, and efficacy Phase 2 results in Glanzmann thrombasthenia and is granted its International Non-Proprietary Name designation by WHO

HMB-002 shows promise in Von Willebrand disease with initial proof of mechanism clinical data from patients in ongoing VELORA Pioneer study, supported by comprehensive non-clinical package including in vivo proof-of-concept data

Natural history insights from Glanzmann thrombasthenia, Factor VII Deficiency, and Von Willebrand disease to highlight critical unmet medical needs

COPENHAGEN, DENMARK AND CAMBRIDGE, MASS., US – June 10, 2025 – Hemab Therapeutics, a clinical-stage biotechnology company developing novel prophylactic therapeutics for serious, underserved bleeding and thrombotic disorders, today announced a total of 11 presentations from multiple programs across its pipeline at the upcoming International Society on Thrombosis and Haemostasis (ISTH) 2025 Congress in Washington, DC, on June 21-25, 2025.

Hemab also announced that the Non-Proprietary Name (INN) Expert Committee of the WHO has selected “sutacimig” for the nonproprietary name of the Company’s investigational drug for Glanzmann thrombasthenia (GT) and Factor VII Deficiency, previously known as HMB-001.

“We’re excited to attend ISTH 2025. Updated results from our sutacimig Phase 2 study and late-breaking initial clinical data from our HMB-002 program demonstrate our commitment to developing transformative therapies for people living with underserved diseases like GT, Factor VII Deficiency, and Von Willebrand disease,” said Benny Sorensen, MD, PhD, CEO of Hemab. “Carefully listening to patients is fundamental to Hemab’s culture, and we are therefore pleased to also share data from multiple natural history studies that outline the lived-disease experience and unmet medical need, emphasizing the necessity for modern preventative treatments.”

Details of Presentations and Abstracts:

The abstracts are now available through the ISTH conference website.

Presentation Number: OC 55.4
Title: Interim Data from Phase 2 study of HMB-001 for Prophylactic Treatment in Glanzmann Thrombasthenia

Presentation Number: LB 01.4
Title: VELORA Pioneer: First-In-Human Safety and PK/PD Study of HMB-002 in Type 1 Von Willebrand Disease

Presentation Number: OC 08.4
Title: HMB-002: Elevating Von Willebrand Factor for Prophylactic Treatment of Von Willebrand Disease

Presentation Number: OC 59.5
Title: Favorable Nonclinical Safety Profile of HMB-002 for Prophylactic Treatment of Von Willebrand Disease

Abstract Number: PB1594
Title: Unveiling the Unmet Need in Glanzmann Thrombasthenia: Insights from the ATHN Transcends GT Module Natural History Study

Abstract Number: PB1543
Title: HMB-001 in Glanzmann Thrombasthenia: Breakthrough Bleed Control with Reduced Platelet and rFVila Use

Abstract Number: PB1432
Title: Living with von Willebrand Disease: An interim report from the VWD 360 study

Abstract Number: PB1460
Title: Prospective Observational Analysis of Bleeding in People with VWD: Insights from the VWD360 Study

Abstract Number: PB1373
Title: A Prospective, Screening Study of Bleeding and Treatment in Participants with Von Willebrand Disease: The VELORA Discover Study

Abstract Number: PB1545
Title: Impact of Iron Deficiency Anaemia & Heavy Menstrual Bleeding in Glanzmann Thrombasthenia

Abstract Number: PB1518
Title: Clinical history and management of Glanzmann Thrombasthenia: A retrospective chart review

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 34% of those bleeds requiring medical treatment. These bleeding episodes significantly impact patients' mental health and quality of life, with 67% reporting low mood, 52% reporting emotional problems, and 46% experiencing social isolation. Additionally, 81% of participants reported missing school or work due to bruising or bleeding. To date, there are no effective prophylactic treatment options for GT.

About Sutacimig (formerly HMB-001)

Sutacimigis a subcutaneously administered bispecific antibody that binds and stabilizes endogenous Factor VIIa with one antibody arm and binds to TLT-1 on activated platelets with the other arm. This mechanism allows 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. Sutacimigis 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 granted Fast Track Designation and Orphan Drug Designation to Sutacimigfor the treatment of GT while the UK Medicines and Healthcare products Regulatory Agency has awarded it designation under the Innovative Licensing and Access Pathway (ILAP). For more information, please visit clinicaltrials.gov (NCT06211634).

About Von Willebrand Disease

Von Willebrand Disease (VWD) is the most common inherited bleeding disorder, characterized by quantitative or qualitative defects in Von Willebrand Factor (VWF), often resulting in frequent mucocutaneous bleeding events and heavy menstrual bleeding in women. The severity of bleeding ranges from low-volume events to potentially life-threatening hemorrhages. Chronic blood loss frequently leads to iron deficiency anemia, exacerbating the disease burden and reducing quality of life, particularly for those with clinically understated subtypes. Despite its prevalence, current treatment options for VWD primarily focus on managing symptoms rather than addressing the underlying defect in VWF production or function.

About HMB-002

HMB-002 is a monovalent human antibody developed as the first-in-class prophylactic treatment for Von Willebrand Disease targeting the underlying root cause of the disease, a condition driven by a deficiency or defect in Von Willebrand Factor (VWF), a key regulator of hemostasis. By specifically targeting the C-terminal CK domain of VWF, which is distinct from regions critical to its essential interactions, HMB-002 shields the protein from degradation, boosting endogenous levels without compromising its function. Clinical and nonclinical data suggest strong potential for meaningful therapeutic benefit. For more information, please visit clinicaltrials.gov (NCT06610201 and NCT06754852).

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 solutions, leveraging a variety of cutting-edge technologies and approaches to transform the treatment paradigm for patients with high unmet need. The company's strategic guidance, Hemab 1-2-5 ™, targets building a pipeline of development programs to deliver long-awaited innovation for patients with high unmet need diseases like Glanzmann thrombasthenia, Factor VII Deficiency, Von Willebrand Disease, and others. Learn more at hemab.com. Follow us on LinkedIn, Facebook, Instagram, and X.

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