Hemab Therapeutics Presents Clinical and Preclinical Data from Sutacimig in Glanzmann Thrombasthenia and Factor VII Deficiency at the ISTH 2026 Congress

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Sutacimig Phase 2 long-term extension (LTE) data show sustained bleed reduction and manageable safety and tolerability; Phase 3 initiation planned 2H 2026

Preclinical data for sutacimig in Factor VII deficiency (FVIID) demonstrate restoration of thrombin generation under disease-mimicking conditions and support its potential as a pan-hemostatic agent

Natural history studies in Glanzmann thrombasthenia (GT) confirm lifelong bleeding burden and critical underutilization of prophylaxis, underscoring the urgent need for preventive treatment

ISTH 2026 included nine total Hemab-led presentations delivering new clinical and preclinical data across sutacimig, HMB-002, and HMB-003

CAMBRIDGE, Mass. and COPENHAGEN, Denmark, July 14, 2026 (GLOBE NEWSWIRE) -- Hemab Therapeutics (Nasdaq:COAG), a clinical-stage biotechnology company developing therapies that reimagine the treatment of blood coagulation disorders to sustain life and human resilience, today presented clinical and preclinical data from sutacimig in GT and FVIID at the International Society on Thrombosis and Haemostasis (ISTH) 2026 Congress in Paris, France. This follows the presentation of new clinical data from HMB-002 in Von Willebrand disease and the announcement of the HMB-003 program on Sunday, July 12.

"People living with GT and FVIID face a stark reality: no approved prophylaxis, a lifetime of unpredictable bleeds, and treatment options that have changed little in decades," said Benny Sørensen, MD, PhD, CEO of Hemab. "The data we've presented at ISTH 2026 show how we're closing that gap: sutacimig's Phase 2 LTE results demonstrate sustained bleed reduction alongside a manageable safety and tolerability profile that has enabled FDA alignment on a Phase 3 dose and regimen. What underscores the relevance of these data is the real-world context supporting them. Natural history data from our GT360 and ATHN Transcends studies confirm that patients continue to bleed well into adulthood, prophylaxis remains critically underutilized, and the profound psychological toll—anxiety, isolation, diminished quality of life—extends far beyond bleed frequency."

"The Phase 2 LTE data establish that sutacimig's prophylactic benefit is durable, with a marked reduction in bleed events requiring high-intensity treatment and the first successful management of surgical cases on study," said Quentin Van Thillo, MD, Department of Cardiovascular Diseases, Hemophilia Centre, University Hospitals Leuven, Belgium. "Together with natural history data documenting persistent bleeding burden and limited prophylaxis use, these findings support sutacimig's advancement toward Phase 3 and the broader shift from reactive treatment to preventive care."

Program Presentation

Sutacimig Phase 2 LTE data—reflecting treatment of 34 patients at a median of 6.9 months and up to 15.9 months of exposure —demonstrate a sustained prophylactic effect and reinforce the potential to shift people living with GT from reactive, IV-dependent treatment to subcutaneous prophylaxis, with regulatory alignment to proceed to Phase 3 with an agreed weekly regimen.

- **Clinically meaningful annualized treated bleeding rate (ATBR) reduction:** 92% of participants who had bled during the run-in experienced reductions in treated bleed rates on sutacimig, and among participants who reported bleeding events that required transfusions, rFVIIa or hospitalization (high intensity bleeding events) within 12 months prior to receiving sutacimig, the mean high intensity annualized treated bleed event rate was reduced by 62% over the treatment and extension period. In all dose cohorts, the mean ATBR was reduced over the treatment and extension period, and in the low dose weekly regimen cohort, the mean ATBR was reduced by approximately 84%.
- **First surgical use data:** Three participants underwent procedures (two invasive surgeries and one dental procedure), all with successful hemostatic outcomes; one required a single post-procedure dose of recombinant Factor VIIa (rFVIIa).
- **Safety:** Adverse events were predominantly mild to moderate. There were no Grade 3 or higher related adverse events. Three participants experienced Grade 2 thromboembolic events. These occurred in participants assigned to dose cohorts associated with higher exposure and/or with multiple concurrent risk factors; all were managed with routine anticoagulation and were resolved or resolving at the datacut.
- **Robust Phase 1/2 data:** Enabled identification of a weekly Phase 3 dose with potential to optimize ATBR reduction while avoiding high peak exposures associated with TE in Phase 1/2. FDA has endorsed the clinical data package as sufficient to proceed to Phase 3 with a dose of 0.2mg/kg Q1 week.

Other Data Highlights

- **Preclinical data for sutacimig in FVIID:** Demonstrate restoration of thrombin generation under disease-mimicking conditions and support its potential across multiple indications, with retained binding expected for >90% of severe-to-moderate FVIID database variants and confirmed binding across 22 of 25 tested variants (88%), supporting broad patient applicability for the ongoing Phase 2 study.
- **Lifelong GT bleeding burden (GT360, N=117):** Over 90% of pediatric, adolescent, and young adult patients experience at least one bleed per week; 72% of those aged 40 and older still bleed weekly. Prevalence of depressive symptoms is 3-4x for the general population (32% vs. ~8–10%), with a stepwise relationship between bleeding frequency and psychological burden.
- **Prophylaxis critically underutilized (ATHN Transcends, N=49):** In 16.6 prospective patient-years of follow-up, mean ABR was 25.9 among participants experiencing bleeds and 44% of bleeds went untreated. Only 14% of patients received any prophylaxis.

About Glanzmann Thrombasthenia
Glanzmann thrombasthenia (GT) is a severe bleeding disorder marked by debilitating, sometimes life-threatening bleeding episodes. Results from an international natural history study (Glanzmann's 360) 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 approved prophylactic treatment options for GT.

About Factor VII Deficiency
Factor VII deficiency (FVIID) is a congenital severe bleeding disorder characterized by reduced levels of Factor VII, a naturally circulating blood coagulation protein. Patients with clinically severe FVIID suffer from recurrent, unpredictable, life-threatening or potentially disabling bleeding at critical sites, such as in the central nervous system, gastrointestinal tract and intra-articular locations, as well as recurrent mucocutaneous bleeds of the nose and gums with additional risks for female patients, consisting of heavy menstrual bleeding and potentially life-threatening post-partum hemorrhage.

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 amplifies thrombin generation at the platelet surface. 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, and the European Medicines Agency (EMA) has granted sutacimig access to the Priority Medicines (PRIME) scheme. 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 biology of the disease.

About HMB-002
HMB-002 is a monovalent human antibody being developed as the first-in-class subcutaneous prophylactic treatment for Von Willebrand Disease targeting the underlying 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 HMB-003
HMB-003 is a subcutaneously administered peptide-based plasmin inhibitor with a durable half-life — a proven therapeutic target in coagulation medicine — being developed as a novel antifibrinolytic designed to reduce bleeding across multiple settings. Engineered to directly inhibit plasmin at its active site, HMB-003 blocks fibrinolysis independently of the plasminogen activation pathway. HMB-003 is optimized to provide sustained bleed protection across multiple high-unmet-need conditions, ranging from heavy menstrual bleeding and hereditary hemorrhagic telangiectasia to peri-operative bleeding management.

About Hemab Therapeutics
Hemab Therapeutics Holdings, Inc. is a clinical-stage biotechnology company developing therapies that reimagine the treatment of blood coagulation disorders to sustain life and human resilience. Hemab’s mission is to discover, develop, and commercialize innovative therapies for the millions of patients worldwide suffering from serious bleeding and thrombotic diseases. Hemab is

building a franchise of innovative therapeutics designed to address critical gaps in the treatment of coagulation disorders, including sutacimig (HMB-001), a bispecific antibody in clinical development for the prophylactic treatment of Glanzmann thrombasthenia and Factor VII deficiency, HMB-002, a monovalent antibody in clinical development for the prophylactic treatment of Von Willebrand Disease, and HMB-003, an anti-fibrinolytic targeting plasmin inhibition in preclinical development for multiple high-unmet-need conditions, ranging from heavy menstrual bleeding, hereditary hemorrhagic telangiectasia to peri-operative bleeding management.

Learn more at hemab.com. Follow us on LinkedIn, Facebook, Instagram, and X.

Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Hemab's strategy, future operations, prospects and plans, objectives of management, the anticipated timelines for reporting data from Hemab's clinical trials, the anticipated timelines for initiating a Phase 3 clinical trial of sutacimig and first-in-human studies of HMB-003, the clinical potential of sutacimig, HMB-002 and HMB-003, Hemab's plans to expand its pipeline, and the sufficiency of Hemab's cash resources for the period anticipated, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Hemab may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; the timing of and Hemab's ability to initiate and enroll patients in clinical trials; whether results from preclinical studies and earlier clinical trials will be predictive of the results of later clinical trials; whether Hemab's cash resources will be sufficient to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Hemab's filings with the Securities and Exchange Commission (SEC), including the Company's most recent Form 10-Q and in subsequent filings Hemab may make with the SEC. In addition, the forward-looking statements included in this press release represent Hemab's views as of the date of this press release. Hemab anticipates that subsequent events and developments will cause its views to change. However, while Hemab may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Hemab's views as of any date subsequent to the date of this press release.

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