Hemab Therapeutics Announces First Participant Dosed in Phase 1 Clinical Trial of HMB-003, an Investigational Therapy for the Management of Heavy Menstrual Bleeding

September 17, 2026

Heavy menstrual bleeding is reported in approximately 1 in 3 reproductive-aged women, according to the American College of Obstetricians and Gynecologists, with approximately 23 million seeking care from a healthcare professional in the U.S. last year.

It is the leading cause of iron deficiency and anemia among premenopausal women, and the primary symptom driving hysterectomies in the U.S.

CAMBRIDGE, Mass. and COPENHAGEN, Denmark, Sept. 17, 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 announced that the first healthy volunteer has been dosed in its Phase 1 clinical trial evaluating HMB-003, an investigational therapy for the management of heavy menstrual bleeding.

HMB-003 is a novel fatty-acid-conjugated peptide antifibrinolytic, designed to stabilize clots and reduce bleeding. Engineered to directly inhibit plasmin at its active site, HMB-003 blocks fibrinolysis independently of the plasminogen activation pathway. In preclinical studies, HMB-003 demonstrated greater activity over tranexamic acid in the models evaluated. In minipigs, a single subcutaneous dose achieved peak plasma levels within hours and sustained antifibrinolytic activity for approximately one week, supporting the potential for cycle-matched, once-per-cycle dosing. Such a dosing profile would represent a significant improvement over current short-acting therapies.

Heavy menstrual bleeding is “The Missed Vital Sign”. According to data compiled by Wellcome Leap’s international health initiative:

- *Reported in approximately 1 in 3 reproductive-aged women (American College of Obstetricians and Gynecologists)*
- *10 times more prevalent than asthma and diabetes in the same population*
- *Leading cause of anemia and iron deficiency, which cause fatigue, shortness of breath and difficulty concentrating*
- *Primary symptom driving a significant portion of the roughly 600,000 hysterectomies conducted in the U.S annually*
- *3.6 weeks of work missed annually per affected woman, costing the U.S. economy more than $94 billion*
- *11 academic weeks in total lost across the formative teenage years*
- *Nearly 23 million women seeking care from a healthcare professional for heavy menstrual bleeding each year*

“Millions of women and girls live with heavy menstrual bleeding and have no approved non-hormonal, long-acting treatment option,” said Benny Sørensen, MD, PhD, CEO of Hemab. “Dosing our first participant with HMB-003, purpose-built for the management of heavy menstrual bleeding, is the first step toward resetting the standard of care for these women. Beyond heavy menstrual bleeding, we believe HMB-003 has the potential to become a cornerstone therapy for underserved patients across several large indications. We look forward to sharing results that will inform our clinical development plans for heavy menstrual bleeding and provide insights into HMB-003’s potential for other bleeding conditions, no later than the middle of 2027.”

The Phase 1 study (NCT07798505) is a randomized, placebo-controlled, single-ascending-dose escalation trial designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of HMB-003 in healthy adult volunteers. Results from this study are expected to inform dose selection and clinical development plans for HMB-003 across additional high-unmet-need bleeding conditions.

About Heavy Menstrual Bleeding
Heavy menstrual bleeding is a common condition characterized by excessive menstrual blood loss that disrupts a person’s physical, emotional, social, and daily life, affecting an estimated one in three reproductive-age women, or more than 23 million women in the U.S. alone. The condition is frequently associated with pain, iron-deficiency anemia, and fatigue, and carries a significant social burden, including stigma and substantial lost days from work and school. Current treatment options are limited. Tranexamic acid (TXA), the primary non-hormonal therapy, has a short half-life that requires frequent dosing throughout menstruation, limiting adherence. Hormonal therapies are not suitable, or not preferred, for many women. To date, there remains no approved non-hormonal, customized hemostatic treatment option for heavy menstrual bleeding.

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. For more information, please visit clinicaltrials.gov (NCT07798505).

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 antifibrinolytic targeting plasmin inhibition in clinical development for heavy menstrual bleeding.

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 clinical potential of HMB-003 for heavy menstrual bleeding and other indications and Hemab's timeline for providing an update on its clinical development plans for HMB-003, 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 Hemab'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 Hemab'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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