Hemab Therapeutics Initiates SOLARA, a Pivotal Phase 3 Trial of Sutacimig in Glanzmann Thrombasthenia

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Hemab's first Phase 3 trial to evaluate once-weekly subcutaneous sutacimig in approximately 75 participants with Glanzmann thrombasthenia

Single-arm design with a 24-week run-in followed by 48 weeks of treatment; primary endpoint is annualized treated bleed rate

CAMBRIDGE, Mass. and COPENHAGEN, Denmark, Nov. 09, 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 the initiation of SOLARA, a pivotal Phase 3 trial evaluating sutacimig (HMB-001) as a potential prophylactic treatment for people with Glanzmann thrombasthenia (GT). The first participants have been consented and are scheduled to enter the trial's run-in period in the fourth quarter of 2026. GT is a serious, inherited platelet function disorder for which no prophylactic therapy is currently approved. Sutacimig is an investigational, once-weekly subcutaneous bispecific antibody designed to help form stable hemostatic plugs at the site of bleeding, compensating for platelet dysfunction.

"Starting SOLARA, our first pivotal Phase 3 trial, is a transformative moment for the sutacimig program and for Hemab," said Benny Sørensen, MD, PhD, Chief Executive Officer of Hemab Therapeutics. "People living with Glanzmann thrombasthenia face unpredictable, and sometimes severe, bleeding yet have no approved prophylactic option to prevent it. Sutacimig has the potential to offer new hope as a once-weekly preventive therapy. We are grateful to the patients, families, investigators and regulators whose engagement shaped this trial."

SOLARA builds on the Phase 2 data presented at the International Society on Thrombosis and Haemostasis (ISTH) 2026 Congress. In the long-term extension, 34 participants were treated for a median of 6.9 months and up to 15.9 months of exposure. Treated bleed rates fell in 92% of participants who had bled during the run-in, and the mean high-intensity annualized treated bleed event rate was reduced by 62% over the treatment and extension period among participants who reported high-intensity bleeding events within 12 months prior to receiving sutacimig. Most adverse events were mild or moderate, with no related Grade 3 or higher 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, and all were managed with routine anticoagulation and were resolved or resolving at the data cut-off date. The SOLARA dose and regimen were chosen to optimize bleed reduction while avoiding the high peak exposures linked to those events.

"SOLARA is the first pivotal trial of a subcutaneous prophylactic treatment in Glanzmann thrombasthenia," said Kate Madigan, MD, Chief Medical Officer of Hemab. "We designed SOLARA with these patients in mind, with the hope that prevention can reduce the bleeds that interrupt work, school and daily life and improve quality of life. This is a significant moment for a community that has long managed bleeding after it happens."

Phase 3 SOLARA Clinical Trial Design

SOLARA is an open-label, single-arm, multicenter Phase 3 trial enrolling approximately 75 participants aged 12 to 70 years with GT. Adolescent enrollment will be gated by the data safety monitoring committee. Participants must have had at least four treated bleeding events in the 12 months before screening.

The trial has two consecutive periods, so that each participant serves as their own control:

- **24-week run-in period:** participants continue their current on-demand standard of care, without sutacimig while treated bleeding events are prospectively recorded.
- **48-week treatment period:** participants receive sutacimig 0.2 mg/kg by subcutaneous injection once weekly.

Participants who complete the treatment period will have the opportunity to continue sutacimig treatment in a separate open-label extension study.

The primary endpoint is the annualized treated bleed rate (ATBR) during sutacimig prophylaxis compared with the run-in period. Secondary endpoints include high-intensity ATBR, annualized treated bleed days, ATBR by bleed type and cause, the proportion of participants with reductions in ATBR, and safety, tolerability, immunogenicity and pharmacokinetics. The trial is being conducted at sites in the United States and other countries.

SOLARA is being conducted under Hemab's active Investigational New Drug (IND) application. SOLARA is designed as a

single-arm trial using intra-participant comparisons. The U.S. Food and Drug Administration (FDA) recommended that Hemab consider a randomized controlled design. However, the FDA acknowledged Hemab's concerns about the feasibility of randomization in GT. In light of the substantial variability in treated bleeding rates, the heterogeneity of the patient population, and the practical challenges of randomized trials in a rare disease, Hemab has determined to proceed with a single-arm trial.

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 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.

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.

Cautionary Note Regarding 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 the planned initiation, conduct, design and timing for the Phase 3 SOLARA trial; the ability of SOLARA to proceed in accordance with its current protocol and anticipated timelines; the suitability of SOLARA's single-arm, intra-participant trial design for evaluating sutacimig in GT; the potential for the design and results of SOLARA to support regulatory approval of sutacimig; Hemab's plans to engage with the FDA and other regulatory authorities regarding the design and conduct of SOLARA and the development of sutacimig for GT; the potential clinical benefits, safety, tolerability and prophylactic treatment profile of sutacimig, including its potential to reduce treated bleeding events, high-intensity treated bleeding events and the burden of Glanzmann thrombasthenia; the potential for the selected dose and regimen for SOLARA to reduce the risk of thromboembolic and other adverse events while providing clinical benefit; the potential for results from Hemab's Phase 2 trial of sutacimig to be predictive of results from SOLARA; and the potential for sutacimig to become an approved prophylactic treatment for Glanzmann thrombasthenia, 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: the risk that Hemab may experience delays or difficulties in initiating, enrolling, conducting or completing the SOLARA trial; the risk that SOLARA may not enroll the anticipated number of participants or be completed on the anticipated timeline; the risk that the SOLARA protocol may be modified or the trial may be delayed, suspended or terminated as a result of safety findings, recommendations of the data safety monitoring committee, regulatory feedback, enrollment challenges or other factors; the possibility that sutacimig may not demonstrate a clinically meaningful reduction in treated bleeding events or may otherwise fail to meet the primary or secondary endpoints of the SOLARA trial; the possibility that variability in bleeding frequency, differences in standards of care, changes in participant behavior or treatment practices, missing data, or other limitations inherent in a single-arm trial using intra-participant comparisons may complicate the interpretation of SOLARA's results; the risk that the FDA or other regulatory authorities may not agree that SOLARA's single-arm, intra-participant design is adequate to establish the safety or effectiveness of sutacimig for GT, may not accept the results of SOLARA as substantial evidence supporting approval, or may require Hemab to conduct one or more additional clinical trials, including a randomized controlled trial, before submitting or obtaining approval of a marketing application

for sutacimig; the risk that Hemab's decision to proceed with the current SOLARA design notwithstanding the FDA's recommendation that Hemab consider a randomized controlled design could result in delays in, additional costs associated with, or the inability to obtain regulatory approval for sutacimig on the timeline anticipated or at all; the risk that safety or tolerability findings, including thromboembolic events or other adverse events observed in prior or future clinical trials, could affect the conduct or results of SOLARA, limit the dose or patient population for sutacimig, result in clinical holds or other regulatory actions, or adversely affect the approvability or commercial potential of sutacimig; the possibility that the dose and regimen selected for SOLARA may not provide the anticipated balance of efficacy and safety or may not avoid the exposures or adverse events observed in earlier-stage clinical trials; the risk that results from preclinical studies or earlier-stage clinical trials, including the Phase 2 trial of sutacimig, may not be predictive of results from SOLARA or any other later-stage clinical trial of sutacimig; uncertainties regarding the FDA's and other regulatory authorities' interpretation of clinical data and the requirements for approval; 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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