Hemab Therapeutics Announces First Patient Dosed in Phase 1/2 Study of HMB-001 to Treat Bleeding Disorder Glanzmann Thrombasthenia

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Bispecific antibody HMB-001 positioned as the first prophylactic treatment for rare bleeding disorders

CEO Benny Sorensen, MD, PhD, delivered the update during a corporate overview presented at the 41st Annual JP Morgan Healthcare Conference

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Hemab Therapeutics, a clinical-stage biotechnology company developing next-generation therapeutics for serious, underserved bleeding and thrombotic disorders, today announced the first patient has been dosed in a Phase 1/2 study evaluating HMB-001 for the treatment of the severe bleeding disorder Glanzmann Thrombasthenia (Glanzmann). The update was provided during a corporate overview presented at the 41st Annual J.P. Morgan Healthcare Conference held this week in San Francisco. HMB-001 is a bispecific antibody that binds, stabilizes, and recruits endogenous factor VIIa (FVIIa) to the site of vascular injury to overcome the body's inability to form healthy clots.

"HMB-001 is the first candidate of our emerging pipeline to reach clinical stage as we realize our mission to deliver functional cure medicines to people living with serious blood clotting disorders," said Benny Sorensen, MD, PhD, CEO of Hemab. "This milestone is supported by preclinical data showing HMB-001 potentiates FVIIa-dependent fibrin formation on platelets in Glanzmann and accumulates FVIIa to levels that are considered therapeutically effective. We are confident clinical evaluation will confirm HMB-001's potential and look forward to its continued clinical advancement as the first prophylaxis treatment for Glanzmann and other severe bleeding disorders."

The Phase 1/2 first-in-human open-label study in patients with Glanzmann was designed to evaluate HMB-001 for safety, tolerability, biomarkers such as FVII levels and bleeding time before and after HMB-001, and efficacy based on assessment of changes in bleeding frequency. Facilitated in collaboration with the UK-based clinical research organization Richmond Pharmacology, the trial is expected to expand into the US and other EU countries. Initial data are expected 2H 2023.

"Many patients with Glanzmann suffer from frequent and potentially life-threatening bleed events. Despite that, we have concerningly few effective and no prophylactic treatment options to offer them, often relying on platelet transfusions, antifibrinolytics, or acute use of recombinant factor VIIa," said Suthesh Sivapalaratnam, MD, PhD MRCP FRCPath, Consultant of Paediatric and Adult Haemostasis and Thrombosis at The Royal London Hospital, Barts Health NHS Trust. "I am eager to see HMB-001 progress through clinical evaluation toward validating its potential as a much-needed bleed-preventative treatment for patients with Glanzmann all over the world."

In partnership with UK specialist research consultancy Haemnet, Hemab announced in mid-2022 that it had commenced a natural history study to better understand the realities of living with Glanzmann and expects to share new data from the study in early 2023.

The company is continuing to advance its strategic guidance, Hemab 1-2-5™, to develop five clinical assets by 2025 to transform treatment for rare bleeding and thrombotic disorders with high unmet need, including Glanzmann, Factor VII Deficiency, Bernard Soulier Syndrome, Von Willebrand Disease, Hereditary Hemorrhagic Telangiectasia (or Osler-Weber-Rendu disease), Congenital Antithrombin III Deficiency.

About Hemab Therapeutics

Hemab is a clinical-stage biotech company developing next generation therapeutics for serious, underserved bleeding and thrombosis disorders. Based in Denmark and the US and backed by Novo Holdings, RA Capital, and HealthCap, Hemab aims to progress its pipeline of monoclonal and bispecific antibody-based therapeutics with the vision of transforming the treatment paradigm for patients with bleeding and thrombotic disorders with high unmet need. Learn more at hemab.com.

About HMB-001

HMB-001 is bispecific antibody that binds and stabilizes endogenous factor VIIa (FVIIa) with one antibody arm and TLT-1 on activated platelets with the other arm. This allows for accumulation of FVIIa in the body, recruitment of FVIIa directly to the surface of the activated platelets where it is known to facilitate clotting, and avoidance of clotting activity in the absence of tissue damage. HMB-001 was designed to be a first-in-class prophylactic treatment for Glanzmann Thrombasthenia with potential for other debilitating rare bleeding disorders. It entered Phase 1/2 clinical evaluation in late 2022, with initial data expected in 2H 2023.

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