

PRESS RELEASE

Hansa Biopharma announces encouraging high-level results for first-in-human trial of HNSA-5487

HNSA-5487 is a next-generation IgG-cleaving enzyme and the lead candidate in the NiceR development program

Lund, Sweden, October 9, 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announced high-level results from NICE-01, the first-in-human trial for HNSA-5487. Results showed the molecule was safe and well tolerated. Fast and complete depletion of immunoglobulin G (IgG) antibodies was observed at increasing doses in all subjects. Pharmacokinetics (PK) was in line with expectations and pharmacodynamics (PD) (efficacy on IgG cleavage) showed a fast and complete cleavage of IgG to F(ab')₂- and Fc-fragments with increasing doses.

NICE-01 is a double blind, randomized, placebo-controlled trial evaluating safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of single ascending doses of HNSA-5487 administered as a single intravenous (IV) infusion. The trial included a total of 36 healthy male and female adult participants.

HNSA-5487 is the company's lead candidate in the Novel Immunoglobulin Cleaving Enzymes for Repeat Dosing (NiceR) program. The NiceR program aims to develop next-generation enzymes with lower immunogenicity that would potentially allow for repeat dosing in a range of indications including IgG-driven autoimmune diseases where patients experience flares, transplantation where repeat dosing would be beneficial, gene therapy and oncology.

Søren Tøllstrup, President and CEO, Hansa Biopharma said, "This is encouraging data as we continue to explore the potential for HNSA-5487 and better understand how this powerful, new enzyme could benefit patients and clinicians. An enzyme with lower immunogenicity would potentially enable repeat dosing, allowing a prolonged effect by flexibly extending the IgG-free window depending on the number of repeated infusions. This could enable innovative treatment approaches in a broad range of indications, and benefit patients with diseases where a prolonged IgG-free window is needed".

Analysis of additional exploratory endpoints on IgG recovery and immunogenicity is now being conducted, with follow up on all subjects for 12 months. This analysis will serve as key input in determining the further clinical development program, including selection of indications.

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About Hansa Biopharma

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life-altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden, and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.