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PRESS RELEASE

Hansa Biopharma announces U.S. FDA acceptance of Investigational New Drug (IND) application for Phase 3 study of imlifidase in anti-GBM disease

- Pivotal Phase 3 study to commence in 2022 and is expected to enroll 50 patients across the U.S. and Europe
- Scientific advice on protocol obtained from both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) with the aim of conducting a global study
- Clinical Phase 2 data suggests that deactivation of autoantibodies by imlifidase could alter the course of this serious autoimmune disease

Lund, Sweden, April 19, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), pioneer in enzyme technology for rare immunological conditions, today announces the acceptance by U.S. FDA of Hansa's Investigational New Drug (IND) application to proceed with a Phase 3 study of imlifidase for the treatment of anti-Glomerular Basement Membrane (anti-GBM) disease.

As previously communicated, Hansa held a successful pre-IND meeting with FDA late last year on the study design of its planned Phase 3 study. In parallel, Hansa has also obtained scientific advice from EMA on the corresponding protocol earlier this year with the aim of conducting a global study. The advice from both authorities has been included in the Phase 3 study design.

The pivotal Phase 3 clinical study will enroll 50 patients with anti-GBM disease across the U.S. and Europe and the first patient is expected to be enrolled this year. Patients in this study will be randomised 1:1 to receive either Standard of Care (SoC) or imlifidase plus SoC. The planned primary endpoint of the study is renal function by means of eGFR at six months. Patients will also be evaluated for other parameters related to kidney function during a six-month follow-up period.

The recently completed investigator-initiated Phase 2 study by Professor Mårten Segelmark (GOOD-IDES-01 ClinicalTrials.gov Identifier: NCT03157037) showed that kidney function at 6 months was significantly better than in previously published cohorts, without any safety concerns. Of the 15 patients included, 10 were dependent on dialysis at enrollment. At 6 months, a total of 67% (N=10) of the included patients were dialysis independent, which is significantly better than in the historical control cohort, where only 18% had functioning kidneys. All patients that were dialysis-independent at baseline remained so during the study. This positive outcome has been recognized for its significance, as it suggests that deactivation of autoantibodies by imlifidase could alter the course of an autoimmune disease.[1]

"Acceptance of our IND for this pivotal Phase 3 program in anti-GBM, a devastating disease, is an important milestone that will allow us to begin reaching out to patients soon," says Christian Kjellman, Chief Scientific Officer at Hansa Biopharma. "Today, most anti-GBM patients suffer terminal damage to their kidneys as their condition progresses. The potential for imlifidase to positively alter the course of the disease is, therefore, very promising and gives hope to these patients, who currently have very few treatment options."

Imlifidase was granted Orphan Drug Designation in anti-GBM disease by both the FDA[2] and the European Commission in 2018[3].

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Notes to Editors

About anti-GBM disease

Anti-GBM disease, also known as Goodpasture's disease, is a rare severe kidney disease affecting around 1.5 in a million people annually.[4] The condition causes the immune system to mistakenly attack a specific part of the kidneys called the glomerular basement membrane (GBM) with IgG-antibodies, severely damaging the kidneys and in some cases the lungs. Many patients with anti-GBM disease lose kidney function and require chronic dialysis and kidney transplantation.[5] In severe cases, anti-GBM disease may lead to death.

About imlifidase

Imlifidase is a unique antibody-cleaving enzyme originating from Streptococcus pyogenes that specifically targets IgG and inhibits IgG-mediated immune response. It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration. Imlifidase has conditional marketing approval in Europe and is marketed under the trade name, Idefirix® (imlifidase) for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.[6]

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.

References

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