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PRESS RELEASE

Hansa Biopharma to initiate Phase 3 study of imlifidase to treat anti-Glomerular Basement Membrane (anti-GBM) disease after successful pre-IND meeting with U.S. FDA

- Pivotal Phase 3 study to commence in 2022 and is expected to enroll approximately 50 patients across the U.S. and Europe
- Advice procedure also initiated with the European Medicines Agency
- Marks important milestone in the expansion of imlifidase into autoimmune diseases

Lund, Sweden November 15, 2021. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), today announces its decision to initiate a pivotal Phase 3 clinical study of imlifidase to treat anti-GBM disease, following a successful pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA).

The recently completed investigator-initiated Phase 2 study by Professor Mårten Segelmark (GOOD-IDES-01 ClinicalTrials.gov Identifier: NCT03157037) showed that two thirds (67%) of patients (10 out of 15 patients) achieved dialysis independence at six months after imlifidase treatment. As a comparison the overall renal survival over 12 trials has been reported to be 26% with current Standard of Care (SoC)[1]. This positive outcome served as Proof of Concept (PoC) for the potential of imlifidase to treat IgG-mediated serious autoimmune diseases.

Through the pre-IND meeting with the FDA, advice was sought on the design of a pivotal Phase 3 study. The FDA generally indicated alignment with Hansa's proposed study design, including proposed primary and secondary endpoints and intended patient population. Hansa will now submit an IND for anti-GBM disease prior to initiation of the Phase 3 trial and expects additional feedback and input from the FDA. Hansa has also initiated an advice procedure with the European Medicines Agency (EMA) on the regulatory path forward for anti-GBM disease in Europe.

The planned pivotal Phase 3 clinical study is expected to enroll approximately 50 patients with anti-GBM disease across the U.S. and Europe and is expected to enroll the first patient in 2022. Patients in this study will be randomised 1:1 to receive either 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 months follow up period.

"The FDA's valuable insight and guidance at the pre-IND meeting paves the way for Hansa to potentially bring a new treatment to patients with anti-GBM disease, a devastating autoimmune condition," says Christian Kjellman, Chief Scientific Officer at Hansa Biopharma. "The successful outcome of the meeting with the FDA marks an important milestone for Hansa Biopharma's efforts to develop potentially lifesaving and life-altering therapies for patients with rare immunological diseases where there is a significant unmet medical need. Anti-GBM disease is the first IgG-mediated disease outside transplantation where imlifidase has been shown to halt an ongoing autoimmune injury."

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 https://hansabiopharma.com.

References

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