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PRESS RELEASE

Hansa Biopharma enrolls first patient in U.S. randomized, controlled pivotal trial of imlifidase in highly sensitized kidney transplant patients

- Hansa expects to complete enrollment in the second half of 2022 with a 12-month follow up completed in the second half of 2023
- The U.S. randomized, controlled trial is expected to support a potential Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) under accelerated approval pathway in the first half of 2024

Lund, Sweden December 29, 2021. Hansa Biopharma AB "Hansa", (Nasdaq Stockholm: HNSA), the pioneer in IgG-cleaving enzyme technology for rare immunological conditions, today announces that the first patient in its U.S. open-label, randomized, controlled pivotal trial ("ConfIdeS") has been enrolled at the Columbia University Medical Center, New York. The ConfIdeS trial is evaluating imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a deceased donor kidney through the U.S. kidney allocation system.

"We are pleased to have enrolled the first patient in ConfIdeS, as it brings us one step closer to making this potentially life-saving therapy available to highly sensitized patients in the U.S. who are currently ineligible for kidney transplantation without an effective desensitization treatment," said Søren Tulstrup, President & CEO of Hansa Biopharma. "We are encouraged by the strong interest shown by leading U.S. transplant centers to participate in this important trial, as it underscores the considerable unmet medical need and highlights the potential of imlifidase to successfully expand access to kidney transplantation for highly sensitized patients in the U.S."

The trial is expected to randomize 64 highly sensitized kidney transplant patients with a cPRA of ≥99.9%, representing a subset of very highly sensitized patients that continue to be disadvantaged despite prioritization under the U.S. kidney allocation system. When a donor organ becomes available and a positive crossmatch with the intended recipient indicates that the organ is not compatible, the patient will be randomized to either imlifidase desensitization treatment or to a control arm that will receive standard of care (i.e. waiting for a more compatible kidney offer or receiving an experimental desensitization treatment). The study's primary endpoint for imlifidase to evaluate benefit in transplanting highly sensitized patients is kidney graft function at 12 months, measured by eGFR (estimated Glomerular Filtration Rate).

The goals of the ConfIdeS trial are aligned with the "Advancing American Kidney Health" ("AAKH") U.S. Executive Order (https://kidney360.asnjournals.org/content/1/6/557), which is centered around three broad goals: (1) reducing the risk of kidney failure; (2) improving access to and the quality of person-centered treatment options; and (3) increasing access to kidney transplants, with the latter two directly tied to expanding transplantation.

"We are very excited about participating in this imlifidase study. Access to organ transplantation truly can make the difference between life and death. Those patients in need of kidney transplantation who are highly sensitized (i.e. immunologically incompatible with the majority of the population) have extremely limited access to transplantation and as a result imlifidase has the potential to be a total 'game changer' in access to transplantation for patients with the most challenging problems. Preliminary data from prior studies indicate that mlifidase has the potential to eliminate the antibodies that are responsible for these immunologic incompatibilities. Thus, we are very optimistic that imlifidase may enable kidney transplantation, increase access to transplantation, improve equity, and offer renewed hope to the thousands of highly sensitized patients with end-stage renal disease" said Lloyd E. Ratner, M.D., M.P.H., Professor of Surgery and Director of Renal and Pancreatic Transplantation at Columbia University, New York. "We anxiously await the outcome of this study."

Robert A. Montgomery, M.D., Professor of Surgery and Director, NYU Langone Transplant Institute in New York City, has been appointed National Coordinating Investigator for the ConfIdeS trial. The trial will enroll patients at 12 to 15 leading transplantation centers in the U.S.

Completion of enrollment in the trial is expected in the second half of 2022, with a 12-month follow-up study period expected to be completed in the second half of 2023. Results from this pivotal trial are expected to support a potential BLA submission to the FDA under the accelerated approval pathway in the first half of 2024.

Imlifidase has already received conditional marketing approval in Europe for the desensitization treatment of highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor.

Further study details can be found on ClinicalTrials.gov NCT04935177.

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® for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

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.

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