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PRESS RELEASE

Hansa Biopharma announces study design for a US randomized, controlled trial of imlifidase in highly sensitized kidney transplant patients

First patient expected to be included in second half of 2021 with results expected to support a submission of a Biologics License Application (BLA) under the accelerated approval pathway in the first half of 2024.

Lund, Sweden June 23, 2021 Hansa Biopharma AB "Hansa", (Nasdaq Stockholm: HNSA), the pioneer in enzyme technology for rare immunological conditions, today announces the study design for a randomized, controlled clinical trial to investigate imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a compatible deceased donor kidney in the context of the US Kidney Allocation System. This group of patients has an insurmountable immunologic challenge with very limited access to transplantation and the only available therapy today is chronic dialysis treatment as they wait for a compatible donor kidney.

In the study, 64 highly sensitized kidney patients with a cPRA score of ≥99.9% will be enrolled, representing a subset of very highly sensitized patients that continue to be disadvantaged despite prioritization under the US 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 compatible kidney offer or receiving an experimental desensitization treatment). A surrogate endpoint measured in the form of eGFR (kidney function) at 12-months after randomization will be used to demonstrate the clinical benefit of imlifidase compared to the control group.

"We are pleased to move forward with this study that could support a Biologics License Application (BLA) in the United States under the accelerated approval pathway", said Søren Tulstrup, President & CEO of Hansa Biopharma. "This is an important milestone for Hansa and, more importantly, it brings hope to highly sensitized patients on dialysis in the United States, who are waiting for a potentially life-saving and life altering kidney transplant, and who without the availability of an effective desensitization treatment may never be able to access this."

Hansa Biopharma is preparing to engage with 12-15 leading transplantation centers in the US to conduct the study. Robert A. Montgomery, M.D. Professor of Surgery and Director, NYU Langone Transplant Institute, New York City is appointed to be the principal investigator. Among the centers are Northwestern Memorial Hospital in Chicago, IL and University of Alabama (UAB) Hospital in Birmingham, AL.

"Our team looks forward to participating in this innovative study, enabling some of our most disadvantaged sensitized patients to gain access to life-saving kidney organ offers and transplants. This therapy has the potential to bring hope to a group of people who have very few options to get a kidney transplant", says John J Friedewald, MD, Professor of Medicine in Nephrology and Hypertension and Surgery in Organ Transplantation at Northwestern Memorial Hospital in Chicago, IL.

"The organ shortage for kidney transplantation remains a challenging issue worldwide. There is an established survival benefit for positive crossmatch transplant recipients compared with remaining on the transplant waitlist and we look forward to this trial for our sensitized patients who would face long waiting times and may never be able to achieve compatible transplantation", says Professor Jayme Locke, MD, MPH, FACS, FAST, Director, UAB Comprehensive Transplant Institute, Associate Chief Medical Offer for Inpatient Quality & Patient Safety at UAB Hospital in Birmingham, AL.

The first patient is expected to be included in the second half of 2021. Completion of enrollment is expected in the second half of 2022 with a 12-month follow up completed in the second half of 2023. Results from this clinical study could support a potential BLA submission in the first half of 2024. Imlifidase has already received conditional Marketing Authorization in Europe for the desensitization treatment of highly sensitized kidney transplant patients with positive crossmatch against an available deceased donor.

Further details around the study design can be found on ClinicalTrials.gov Link NCT04935177.

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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