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PRESS RELEASE

Hansa Biopharma Completes Randomization in Pivotal Phase 3 US ConfIdeS Trial

Lund, Sweden, 31 May, 2024. Hansa Biopharma AB, ("Hansa" or the "Company") (Nasdaq Stockholm: HNSA), today announced recruitment and randomization in its US ConfIdeS trial is complete. ConfIdeS is a pivotal Phase 3 open label, randomized, controlled trial of imlifidase in kidney transplantation. Data from the trial is expected to support a Biologic License Application (BLA) submission under the accelerated approval pathway to the US Food and Drug Administration (FDA) in the second half of 2025.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "The randomization of 64 patients in the ConfIdeS trial is an important step in bringing imlifidase to the US to help address the significant unmet need faced by highly sensitized kidney transplant patients. Our hope is that the ConfIdeS trial will help further validate the role imlifidase may play as a desensitization treatment that enables HLA-incompatible kidney transplantation. We look forward to sharing the data from the ConfIdeS trial in due course."

The ConfIdeS trial is evaluating kidney function in 64 highly sensitized (cPRA ≥99.9%) kidney transplant patients with positive crossmatch against a deceased donor, comparing desensitization using imlifidase with standard of care. A total of 24 US sites are participating in the trial and its primary endpoint is kidney graft function at 12 months, measured by eGFR (estimated Glomerular Filtration Rate).

Imlifidase has been granted conditional marketing approval in Europe 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. Imlifidase is also being studied in autoimmune conditions including anti-glomerular basement membrane (anti-GBM) disease and Guillain-Barré syndrome (GBS) and as a pre-treatment to gene therapy in rare disease patients with pre-existing antibodies.

This is information that Hansa Biopharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the contact person set out below, at 13:30 CEST on 31 May 2024.

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Notes to editors

About highly sensitized patients
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Highly sensitized patients have pre-formed antibodies called donor specific antibodies (DSAs) with a broad reactivity against human leukocyte antigens (HLAs), which can cause tissue damage and potentially transplant rejection.[1] The presence of DSAs means that highly sensitized patients tend to have limited or no access to transplant, as finding a compatible donor organ can be particularly challenging.[2,3] The complexity of their immunological profile means that highly sensitized patients spend longer time than average on transplant waiting lists, with evidence showing that this longer time waiting for a suitable donor relates to an increased mortality risk.[2,3] Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[4,5]

About IDEFIRIX® (imlifidase)

Imlifidase is an antibody-cleaving enzyme originating from Streptococcus pyogenes that specifically targets and cleaves immunoglobulin G (IgG) antibodies and inhibits IgG-mediated immune response.[6] 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. The use of IDEFIRIX should be reserved for patients who are unlikely to be transplanted under the available kidney allocation system, including prioritization programs for highly sensitized patients.[6] IDEFIRIX was reviewed as part of the European Medicines Agency's (EMA) Priority Medicines (PRIME) program, which supports medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options.[6]

Imlifidase is an effective strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[7] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[8] Once they are inactivated with imlifidase, there is a window of opportunity for the transplant to take place. By the time the body starts to synthesize new IgG, the patient will be receiving post-transplant immunosuppressive therapy to reduce the risk of organ rejection.

The efficacy and safety of imlifidase as a pre-transplant treatment to reduce donor-specific IgG was studied in four phase 2 open-label, single-arm, six-month clinical trials.7,9-11 Hansa is collecting further clinical evidence and will submit additional efficacy and safety data based on one observational follow-up study and one post-approval efficacy study.

Full product information can be accessed via the initial Summary of Product Characteristics found here.

About kidney failure

Kidney disease can progress to kidney failure or End-Stage Renal Disease (ESRD), identified when a patient's kidney function is less than 15%.[12] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[12] A kidney transplant is the treatment of choice for suitable patients with ESRD because it offers improved survival and quality of life benefits, and is cost savings compared to long-term dialysis. There are approximately 170,000 kidney patients on transplant waiting lists across the U.S., European Union and United Kingdom.[13]

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 Biopharma 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 Biopharma 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 and follow us on LinkedIn.

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