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PRESS RELEASE

Hansa Biopharma completes enrolment in European Phase 3 20-HMedIdeS-19 Post Authorization Efficacy and Safety study in highly sensitized kidney transplant patients

Lund, Sweden, 11 March 2025. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), announced today that it has completed enrolment of its 20-HMedIdeS-19 Post Authorization Efficacy and Safety (PAES) study, an open-label Phase 3 confirmatory study in Europe investigating the one-year patient and graft survival in highly sensitized patients who have undergone HLA-incompatible kidney transplantation following desensitization treatment with imlifidase. Imlifidase is the Company's first generation, first-in-class, one-time treatment, conditionally approved in Europe as desensitization treatment in kidney transplantation with the brand name IDEFIRIX®.[1] Imlifidase is also being evaluated in late-stage trials in autoimmune diseases where immunoglobulin G (IgG) antibodies are a driver of disease, and as a pre-treatment to gene therapy in patients with anti-AAV antibodies.

The Company anticipates data readout in the second half of 2026 followed by submission to the European Medicines Agency to seek full authorization. The 20-HMedIdeS-19 or PAES study is an obligation following conditional authorization by the European Commission for IDEFIRIX® (imlifidase) in 2020.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "The PAES study is an important part of Hansa's continued commitment to ensuring access to potentially lifesaving IDEFIRIX therapy for highly sensitized kidney transplant patients, as we believe that the evidence generated will support the submission for full authorization in the European Union. Those considered highly sensitized and waiting for a transplant continue to face very long wait times due to their immunological status which poses a significant barrier to finding a compatible organ. We believe the PAES study will underscore the strong efficacy and safety data supporting the use of IDEFIRIX as a desensitization treatment in the pre-transplant setting, and look forward to sharing data from the study in the second half of 2026, following the completion of a 12-month follow-up period".

The PAES study is a controlled, open-label post-authorization efficacy and safety study to determine the one-year graft failure-free survival in highly sensitized kidney transplant patients with positive crossmatch against a deceased donor who received desensitization treatment with imlifidase followed by an HLA-incompatible kidney transplantation. In addition to the 50 highly sensitized adult kidney transplant patients enrolled in the study, a total of 64 patients who underwent kidney transplantation without the need for desensitization were included in a concurrent reference cohort and as part of the study design. The reference cohort was included in the trial to account for the center-to-center variability in post-transplant management of patients. The study also includes a non-comparative registry of historical data. A total of 22 sites across Europe were included.

Thomas Lorant, transplant surgeon at Uppsala University and the coordinating investigator for the trial said, "Imlifidase is transforming transplantation care for highly sensitized patients in Europe. Creating an IgG-free window by inactivating the donor-specific antibodies, it makes desensitization-enabled HLA-incompatible kidney transplantation a viable option for those considered highly sensitized and who were previously left on transplant waiting list for extended, often indefinite time. I am confident that imlifidase can play a key role in allowing us to treat those kidney transplant patients with the highest need."

Further details of the trial (EudraCT number 2021-002640-70) can be found on the EU Clinical Trials Register.

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Notes to editors

About highly sensitized patients

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.[2] 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.[3,4] 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.[5,6] Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[7,8]

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.[1] It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration.

Imlifidase has conditional marketing authorization 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.[1] 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.[1]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[10] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[2] 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,[8-11] and in a long-term observational follow-up study.[12] Hansa is collecting further clinical evidence and will submit additional efficacy and safety data based on one post-authorization safety and efficacy study, and a related long-term follow up study.[13,14]

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%.[15] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[15] 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 in the U.S. and Europe waiting for a new kidney.[16]

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. The company has a rich and expanding research and development program based on its proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in autoimmune diseases, gene therapy and transplantation. The company's portfolio includes imlifidase, a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients and HNSA-5487, a second-generation IgG cleaving molecule with redosing potential. 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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