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PRESS RELEASE

Hansa Biopharma announces positive reimbursement decision for Idefirix® (imlifidase) in the Czech Republic

- Idefirix® is the first and only product approved for use in highly sensitized patients waiting for a kidney transplant in the Czech Republic[1,2]
- Availability of Idefirix® for eligible highly sensitized patients to begin January 1, 2023

Lund, Sweden, January 2, 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announces that it has attained reimbursement in the Czech Republic for its first-in-class treatment, Idefirix®, for the desensitization treatment of highly sensitized adult patients prior to kidney transplant from a deceased donor.[1,2]

Between January and October 2022, a total of 386 kidney transplants from deceased donors were performed in the Czech Republic, while approximately 400 patients remained on the kidney transplant waiting list.[3] Highly sensitized patients have antibodies with a broad reactivity against a wide pool of potential donors,[4] so finding a matched organ for these patients is particularly challenging. As a result, highly sensitized patients end up spending a longer than average time on transplant waiting lists with an increased risk of dying while waiting for a compatible donor.[5,6] The decision to implement Idefirix® marks an important milestone for highly sensitized patients in the Czech Republic as they may now be desensitized using Idefirix® to enable kidney transplantation.

"We welcome this important decision and look forward to the positive impact that Idefirix® is expected to now make in clinical practice" says Professor Ondrej Viklicky, Head Transplant Center, Institute for Clinical and Experimental Medicine, Prague. "Highly sensitized patients are often left with no option but to remain on long-term dialysis, which lowers their quality of life and increases the risk of mortality and hospitalization. For those less likely to receive an organ offer due to their immunological status, there is now the opportunity to be treated with Idefirix® to enable kidney transplant, freeing them from dialysis".

"We are very pleased to see that Idefirix® is now reimbursed in the Czech Republic for the treatment of highly sensitized kidney patients. These patients have a serious disease burden and unmet needs and this decision is a significant milestone for them", says Søren Tulstrup, President and CEO, Hansa Biopharma. "For Hansa, this decision is well aligned with our vision: A world where patients with rare immunologic diseases can lead long and healthy lives".

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About Idefirix® (imlifidase)

Imlifidase is an enzyme derived from the bacterium *Streptococcus pyogenes* and has the ability to specifically target and cleave all classes of immunoglobulin G (IgG) antibodies.[7]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[8] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[9] 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.[8,10-12]

Hansa is now 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. 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.[13]

Idefirix® was granted conditional European Marketing Authorization from the EMA in August 2020 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.[13] Conditional approval allows the Agency to recommend a medicine for marketing authorization in cases where the benefit of a medicine's immediate availability to patients outweighs the risk that not all the data are available yet.

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%.[14] 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 80,000 kidney patients on transplant waiting lists across the European Union.[15]

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

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 www.hansabiopharma.com.

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