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PRESS RELEASE

Hansa Biopharma announces positive reimbursement decision for Idefirix (imlifidase) in Belgium as desensitization treatment for highly sensitized patients in kidney transplantation

Lund, Sweden, June 1, 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announced that it has attained reimbursement in Belgium for its first-in-class treatment, Idefirix, for the desensitization treatment of highly sensitized adult patients prior to kidney transplant from a deceased donor. Idefirix is available for eligible highly sensitized patients starting today, June 1, 2023. Idefirix is the first and only product approved for use in highly sensitized patients waiting for a kidney transplant in Belgium.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "This is an important moment for highly sensitized patients in Belgium in urgent need of a kidney transplant that so far have had no choice other than to wait and hope for a compatible donor organ to become available. Including Belgium, we now have positive access and reimbursement decisions in twelve countries in Europe – a testament to our commitment to ensure access to Idefirix for highly-sensitized patients waiting for a kidney transplant. With Idefirix, we are changing the approach to desensitization and organ allocation and advancing a treatment regime from one that has been solely focused on compatibility, to one that is more patient-centric and that can accommodate transplants for incompatible patients".

A total of 419 kidney transplantations were performed in 2021 in Belgium, with the majority (86%) from deceased donors.[1] Of more than 1,100 patients waiting for a kidney transplant in Belgium, it is estimated that one in ten are classified as highly sensitized, with limited or no access to a suitable donor organ. As of 2022, almost 11% of all patients on waiting list in Belgium have been on dialysis for more than 5 years [2], which relates to an increased mortality risk. [3,4]

Professor Dirk Kuypers, Chair of the Department of Nephrology and Director of the Renal Transplantation Program at the University Hospitals Leuven, said, "Currently, a growing group of patients, classified as highly sensitized, have very few to no options to receive an offer for a donor kidney due to their immunological status and especially the presence of multiple anti-HLA antibodies (Including donor specific antibodies), which may cause an acute rejection of the donor organ. Idefirix represents a new opportunity as it allows us to consider less immunologically compatible kidney transplantation as a viable option for highly sensitized patients that have an urgent unmet medical need and would otherwise face very long waiting times".

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

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.[8] 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.[8]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[9] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[10] 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.[9,11-13] 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%.[14] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[14] 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]

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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