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PRESS RELEASE

Idefirix (imlifidase) receives provisional approval in Australia as desensitization treatment in highly sensitized patients prior to kidney transplantation

Regulatory milestone marks the first time Idefirix has been approved in kidney transplantation from both living and deceased donors

Lund, Sweden, July 11, 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announced that the Australian Therapeutic Goods Administration ("TGA") has provisionally approved Idefirix (imlifidase) as desensitization treatment for highly sensitized patients prior to kidney transplantation from both living and deceased donors. The provisional approval has a duration of two years and was based on data from Hansa's phase 2 studies[1-4] that included highly sensitized patients who received a kidney from either a living (17%) or deceased donor (83%) following desensitization treatment with imlifidase.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "With nearly 28 percent[5] of kidney transplant candidates in Australia considered highly sensitized, the approval of Idefirix represents an important innovation in kidney transplantation care for patients and clinicians. Hansa applauds the TGA for being the first regulatory body to approve the use of Idefirix in transplants from both living and deceased donors, thus ensuring comprehensive access for highly sensitized patients in Australia to this important therapy."

There is a high unmet need for very highly sensitized kidney transplant candidates in Australia. Of the more than 1,000 patients on the deceased donor kidney transplant waiting list as of end of 2020,[6] 21% are classified as very highly sensitized against a donor organ having a calculated Panel Reactive Antibody ("cPRA") of 95% or higher. Even under the Australian allocation system, which gives priority to candidates with cPRA >80%, and the Australian and New Zealand Paired Kidney Exchange, very highly sensitized patients continue to have markedly reduced rates of transplantation[5] and are forced to wait for very protracted times, or indefinitely, for a suitable match to become available. Of a total of 875 kidney transplantations performed in Australia in 2021, 202 (24%) were from living donors and 644 (76%) were from deceased donors.[7] Enabling transplantation from living donors expands the number of potential organs available to patients and increases the chances for these patients to receive a life altering transplant.

University of Sydney Clinical Professor Kate Wyburn said, "Innovation in kidney transplantation has been quite limited for highly sensitised patients. With the approval of this new desensitisation treatment in Australia, we now have an opportunity to potentially help these immunologically complex patients who may otherwise never receive a transplant offer."

Data submitted to the Australian TGA was generated in Hansa's phase 2 studies that demonstrated the efficacy and safety of imlifidase as a desensitization treatment to enable incompatible kidney transplantation for highly sensitized patients.[1-4] The submitted data included a sub analysis of highly sensitized patients that received a kidney transplant from a living donor following desensitization treatment using imlifidase. In line with the EMA's conditional approval, full approval in Australia will require submission to the TGA of further safety and efficacy data from studies that are currently underway.[8-10]

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 persons set out below, at 12:00 CET on July 11, 2023.

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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.[11] 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.[12,13] The level of a patients sensitivity can be gauged by a calculated Panel Reactive Antibody (cPRA) percentage. This is an estimate of the percentage of donors expected to be crossmatch incompatible to the transplant candidate. 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.[12,13]

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

Imlifidase has conditional marketing approval in the EU, the UK, Switzerland, Israel and now provisional approval in Australia. Imlifidase 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.[14] 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.[14] In July 2023 the Australian Therapeutic Goods Administration ("TGA") included Idefirix (imlifidase) on the Australian Register of therapeutic Goods as desensitization treatment for highly sensitized adult kidney transplant candidates prior to kidney transplantation from a donor against whom there is a positive cross-match. This indication allows transplants from either living or deceased donor kidneys.

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[1] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[15] 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.[1-4] 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.

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%.[16] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[16] 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. In Australia there were approximately 28,000 kidney patients needing renal replacement therapy in 2021.[17,18]

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.

Full Australian product information can be accessed from the TGA via this link here.

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