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PRESS RELEASE

Hansa Biopharma announces temporary marketing authorization in Switzerland for Idefirix® (imlifidase) in kidney transplantation

- Approval by Swissmedic[1] enables highly sensitized patients in Switzerland to receive Idefirix® treatment prior to kidney transplantation
- Idefirix® is now granted marketing authorization within the EU, the U.K.*, Israel and Switzerland

Lund, Sweden May 13, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), pioneer in enzyme technology for rare immunological conditions, today announces that the Swiss Agency for Therapeutic Products (Swissmedic) has granted temporary marketing authorization for Idefirix® in adult patients with a positive crossmatch against an available organ from a diseased donor. The use of Idefirix® in Switzerland is reserved for patients with a low probability of being transplanted within the framework of the current national kidney allocation system.

"We are committed to ensuring access to Idefirix® for highly sensitized patients across the globe awaiting a potentially lifesaving kidney transplant and are pleased that we have now received approval in Switzerland in addition to the already received marketing authorizations in the EU, the U.K. and Israel," says Søren Tulstrup, President and CEO, Hansa Biopharma.

Idefirix® is the first and only medicine authorized for desensitization of highly sensitized patients prior to kidney transplantation, enabling these patients to better access a life-changing kidney transplantation from a deceased donor.

Highly sensitized kidney patients have previously had very limited access to kidney transplants due to the lack of effective desensitization treatments, and they often have no alternative but to remain on long-term dialysis. Long-term dialysis can place a significant burden on patients and on healthcare systems and is associated with a reduction in health-related quality of life and increased risk of mortality, hospitalizations and additional costs.[2-4] In 2021, there where 362 kidney transplantations in Switzerland, with 240 of those being from deceased donors.[5]

The Marketing Authorization Application (MAA) in Switzerland was supported by data from four different Phase 2 open-label, single arm studies evaluating imlifidase in sensitized patients awaiting kidney transplantation.[6]

The temporary marketing authorization by Swissmedic will be available under: www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/new-medicines.html. A pricing and reimbursement dossier has been submitted to the Swiss federal office of public health (BAG).

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*The EU marketing authorization for Idefirix® in August 2020 included the U.K. as a member of the union, and was later automatically transferred to the U.K. separately

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Notes to editors

About imlifidase

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

IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor-specific 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 renewing the depleted antibodies, the patient will be receiving 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.[4, 8,10,11]

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. Imlifidase 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.[12]

Imlifidase 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 test against an available deceased donor. The use of imlifidase should be reserved for patients who are unlikely to be transplanted under the available kidney allocation system, including prioritization programs for highly sensitized patients.[12] 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%.[13] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[10] A kidney transplant is the treatment of choice for suitable patients with ESRD because it offers improved survival and quality of life benefits compared to long-term dialysis. There are approximately 80,000 kidney patients on transplant waiting lists across the European Union.[14]

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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