

PRESS RELEASE

Hansa Biopharma announces decision by Swedish New Therapies Council to recommend use of Idefirix[®] (imlifidase) as desensitization treatment for highly sensitized kidney transplant patients

- Recommendation to use Idefirix[®] (imlifidase) as defined in indication approved by the European Medicines Agency (EMA)^{1,2}
- Decision provides highly-sensitized patients in Sweden with the opportunity to receive Idefirix[®] as desensitization treatment
- Commercial launch activities for Idefirix[®] in Europe progressing as planned

Lund, Sweden, June 28, 2021. Hansa Biopharma, “Hansa” (Nasdaq Stockholm: HNSA), the pioneer in enzyme technology for rare immunological conditions, today announced that its first-in-class treatment Idefirix[®] (imlifidase) has received recommendation from the Swedish New Therapies Council (NT-rådet) for use in the desensitization of highly sensitized adult patients prior to kidney transplant.¹ This recommendation to the healthcare regions is an important step for transplant clinics across Sweden that would like to introduce Idefirix[®] as a desensitization treatment to enable highly sensitized patients to qualify for potentially lifesaving and life-altering kidney transplant from a deceased donor. The NT-rådet recommendation follows an earlier health-economic assessment by the Swedish Dental and Pharmaceutical Benefits Agency (TLV), which concluded that Idefirix[®] treatment would be cost effective or even cost saving in the patient population specified in the Marketing Authorization received from the European Medicines Agency (EMA).^{2,3}

“Idefirix[®] is the first desensitization treatment to demonstrate positive outcomes in clinical settings. It reduces the risk of hyperacute rejection following transplantation by inactivating the immunoglobulin G in highly sensitized patients,” said Associate Professor Bengt von Zur-Mühlen, senior nephrologist at the Department of Transplantation Surgery at Uppsala University Hospital. “I’m pleased to hear today’s positive news from the Swedish New Therapies Council. It is a big step forward for highly sensitized kidney patients, who will become more compatible for transplants and have an opportunity for a better quality of life.”

Kidney transplant patients are classed as highly sensitized if they have antibodies against many human leukocyte antigens (HLA), which can cause tissue damage and potentially transplant rejection.⁴ Risk factors for developing HLA antibodies that cause sensitization include previous transplantation, blood transfusion and pregnancy.⁵ These patients are unlikely to be offered a kidney transplant and spend a longer time on the waiting list with an increased risk of dying while waiting for a suitable donor.^{6,7}

“Kidney patients with high levels of HLA antibodies 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,” said Håkan Hedman, Chairman of the Swedish Kidney Association. “Availability of the novel treatment imlifidase is very encouraging to the kidney disease community because it will provide certain highly sensitized patients with the opportunity to qualify for a transplant.”

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 and hospitalization.⁷⁻⁹

“At Hansa, our mission is to significantly improve the lives of rare disease patients with serious unmet medical needs, bringing highly innovative medicines from the laboratory to the patients”, said Søren Tulstrup, President and CEO, Hansa Biopharma. “Delivering Idefirix® as a new therapy option for highly sensitized patients who are waiting for a potentially life-saving kidney transplant demonstrates our commitment to improving the lives of patients with rare immunological conditions.”

Hansa Biopharma’s commercial launch activities throughout Europe are underway as planned. Pricing for Idefirix® has been published in the first markets* and the first commercial sales were reported in Q1 2021. Agreements around reimbursement and funding access with healthcare providers and payers are expected to be completed in early-launch countries throughout the course of 2021. The recommendation provided by the Swedish New Therapies Council represents the first such national level decision by a European Union Member State.

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Notes to editors

About Idefirix® (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.¹⁰

IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor-specific antibodies (DSAs).¹¹ Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.⁴ Once they are inactivated with Idefirix®, 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 Idefirix® 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 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.²

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 test 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.²

* Pharmacy purchasing pricing, currently published in Sweden, the Netherlands, Denmark, Finland, the UK, Norway and Germany.

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.¹³ 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.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 <https://hansabiopharma.com>.

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