NEWS RELEASE

NICE recommends use of Hansa Biopharma's Idefirix® (imlifidase) as desensitization treatment for highly sensitized kidney transplant patients

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- Idefirix® becomes the first and only product recommended by NICE for the desensitization of highly sensitized patients waiting for a kidney transplant[1]
- NICE considers Idefirix® to be a clinically and cost-effective treatment within current clinical practice
- The positive recommendation will enable access to this novel therapy for highly sensitized patients in England, Wales and potentially Northern Ireland

Lund, Sweden, June 16, 2022. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), pioneer in enzyme technology for rare immunological conditions, today announces the recommendation by the National Institute for Health and Care Excellence (NICE) for its first-in-class treatment Idefirix® in the desensitization of highly sensitized adult patients prior to kidney transplant from a deceased donor. NICE considers Idefirix® to be a clinically and cost-effective treatment.

The recommendation marks an important milestone for patients in England, Wales and Northern Ireland, as appropriate specialized transplant centres will be able to use Idefirix® to enable transplantation for highly sensitized patients, currently highly unlikely to receive a lifesaving compatible kidney transplant. The Medicines and Healthcare products Regulatory Agency's (MHRA) granted conditional approval of imlifidase from the European Commission conditional approval in August 2020.[2] The NICE recommendation builds upon this approval by considering the cost-effectiveness of Idefirix® in addition to its clinical efficacy and the significant unmet need of the patient population it

treats.[1]

Kidney transplant candidates are classified as highly sensitized if they have pre-formed antibodies against available donors known as human leukocyte antigens (HLA). These antibodies can carry the risk of causing damage to the transplanted kidney and potentially lead to rejection.[3] Risk factors for becoming highly sensitized include previous transplantation, blood transfusion and pregnancy.[4] Finding a match for these patients can be particularly difficult, meaning they spend a longer average time on transplant waiting lists, and therefore have an increased risk of dying while waiting for a suitable donor.[5,6] The annual average number of kidney transplants in the U.K. over the last five years are 2,400 from deceased donors and 926 from living donors.[7]

“A lack of effective desensitization approaches has meant that until now, people who are classed as highly sensitized kidney patients in England have struggled to find a donor match, and have often had no alternative but to remain on long-term dialysis with a very poor quality of life,” says Dr Adnan Sharif, trustee at Kidney Research UK. “We welcome this decision, which will allow new opportunities for certain highly sensitized patients to qualify for a life-altering transplant, and gain freedom from dialysis. Decision making around who has access to the treatment is key, and the lifespan of the transplanted kidneys will need to be carefully monitored.”

Long-term dialysis places a significant burden on both patients and healthcare systems, reducing health-related quality of life and increasing the risk of mortality and hospitalization.[6,8-9]

“We are thrilled that NICE has recommended Idefirix® as the first licensed therapy for highly sensitized kidney patients. These patients have serious disease burden and unmet needs and this recommendation is a significant milestone for them”, says Søren Tulstrup, President and CEO, Hansa Biopharma. “For Hansa, this recommendation is also encouraging as we continue to pursue our vision: A world where patients with rare immunologic diseases can lead long and healthy lives”.

Hansa will work with national health service commissioners in England, Wales and Northern Ireland to support the implementation of the service in line with the NICE’s recommendations.

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 person set out below, at 07:00 CET on June 16, 2022.

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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 all classes of immunoglobulin G (IgG) antibodies.[10]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) 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 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 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 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 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] 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 **www.hansabiopharma.com**.

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