Hansa Biopharma
Scheelevägen 22
SE- 223 63 Lund, Sweden
Phone: +46 46 16 56 70

www.hansabiopharma.com

PRESS RELEASE

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

- Idefirix® is granted full access and reimbursement in line with the indication approved by the European Medicines Agency (EMA).[1]
- The decision by the Italian Medicine Agency (AIFA) provides highly sensitized patients in Italy with the opportunity to receive Idefirix® to enable kidney transplantation.

Lund, Sweden, December 8, 2022. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announces that the Italian Medicine Agency (AIFA) has granted full access and reimbursement for the use of Idefirix®, the company's first-in-class treatment, for the desensitization of highly sensitized adult patients prior to kidney transplant from a deceased donor. The positive reimbursement decision is aligned with the conditional approval granted by EMA in August 2020.[1]

Approximately 2,000 kidney transplantations are performed each year in Italy, with the majority (86%) from deceased donors.[2] Of more than 6,000 patients waiting for a kidney transplant in Italy, it is estimated that one in ten are classified as highly sensitized, with limited or no access to a suitable donor. Kidney transplant patients are classified as highly sensitized when they have pre-formed antibodies with a broad reactivity against human leukocyte antigens (HLAs), which can cause tissue damage and potentially transplant rejection.[3] Due to the presence of these antibodies, finding a suitable donor organ for highly sensitized patients can be particularly difficult.[4,5] As a result, highly sensitized patients spend longer than average on transplant waiting lists, and therefore have an increased risk of dying while waiting for a suitable donor.[4,5]

"The positive decision by AIFA provides highly sensitized patients in Italy with an important opportunity to access a potentially lifesaving kidney transplant", says Søren Tulstrup, President and CEO, Hansa Biopharma. "This decision is another step forward as we pursue our mission to develop innovative, lifesaving and life-altering therapies for patients with rare immunological diseases and conditions and generate value to society at large".

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For more information:

Klaus Sindahl, *Head of Investor Relations*
M: +46 (0) 709 298 269
E: klaus.sindahl@hansabiopharma.com

Notes to editors

About Idefirix® (imlifidase)

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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.[6]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[7] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[8] 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.[7,9-11]

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. 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.[1]

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.[1] 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%.[12] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[12] 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.[13]

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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