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PRESS RELEASE

Hansa Biopharma granted added benefit ASMR 3 by French Transparency Commission for Idefirix® (imlifidase) as desensitization treatment for highly sensitized kidney transplant patients

- Idefirix® is among a few selected medicines to be granted ASMR 3 (Amélioration du service médical rendu) by the French Transparency Commission, which represents a level of clinical added benefit, and has also received SMR Important[1]
- The opinion by the Transparency Commission follows after Idefirix® was granted a funded Early Access Program by the French Haute Autorité de Santé (HAS) in February this year
- Commercial launch activities for Idefirix® in Europe continue to progress

Lund, Sweden, April 20, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), pioneer in enzyme technology for rare immunological conditions, today announces that its treatment Idefirix® has been granted an ASMR 3 rating by the Transparency Commission (TC) of the French National Authority for Health (HAS) as part of the ongoing pricing and reimbursement process.

ASMR is a grading system based on seriousness of a disease, evidence of efficacy, added benefit versus comparators, safety, treatment landscape and relevance for public health. The ASMR 3 status granted to Idefirix® could enable faster price and reimbursement. Idefirix® has also received SMR Important (Service Médical Rendu), which is reflecting the product's actual medical benefit. Important is the highest level of reimbursement possible. Of all ASMR ratings granted in 2020, only 5,8% received ASMR level 3.[2]

"Receiving ASMR 3 is a rare event and a testament to both the level of innovation represented by Idefirix® and the high degree of unmet need among highly sensitized patients in France," says Søren Tulstrup, President and CEO, Hansa Biopharma.

The TC opinion has been adopted by the French Ministry of Health and comes after Idefirix® was granted early access post marketing authorization (Autorisation d'accès précoce) earlier this year by French HAS for the use as desensitization treatment of highly sensitized adult patients prior to kidney transplant. This early access program will be in effect until the standard pricing and reimbursement process is completed.

Approximately 3,600 kidney transplantations are carried out annually in France, with more than 80% transplanted from deceased donors.[3] According to the Agence de Biomédecine, in 2020 highly sensitized patients represented 11.1% of kidney transplant recipients, while the proportion of highly sensitized patients on the active renal transplant waiting list was 23.7%.

Commercial launch and market access efforts for Idefirix® in Europe continue to progress. Pricing and reimbursement processes have been completed in Sweden, the Netherlands and Germany, as well as on an individual hospital basis in Finland and Greece. Market access procedures are ongoing in 11 countries, including Spain, Italy and the U.K.

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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.[4]

IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor-specific antibodies (DSAs).[5] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[6] 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.[7,5,8,9]

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.[10]

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.[10] 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%.[11] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[8] 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.[12]

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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