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PRESS RELEASE

Hansa Biopharma announces positive early access decision by French Haute Autorité de Santé to use Idefirix® (imlifidase) as desensitization treatment for highly sensitized kidney transplant patients

- Decision to use commercially supplied Idefirix® (imlifidase) in approved indication by the European Medicines Agency (EMA)[1,2]
- Decision provides highly sensitized patients in France with the opportunity to immediately receive Idefirix® as desensitization treatment
- Commercial launch activities for Idefirix® in Europe continue to progress

Lund, Sweden, February 25, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), the pioneer in enzyme technology for rare immunological conditions, today announces that its first-in-class treatment Idefirix® (imlifidase) has been granted early access post marketing authorization (*Autorisation d'accès précoce*) in France by French HAS (*Haute Autorité de Santé*) for use in the desensitization of highly sensitized adult patients prior to kidney transplant, in accordance with the patient population specified in the Marketing Authorization received from the European Medicines Agency (EMA).[1,2]

The aim of early access programs in France is to accelerate access to innovative medicines before (AP1) or after (AP2) marketing authorization (and before completion of the full P&R process), as in the case of Idefirix® when all the following conditions stipulated in article L.5121-12 of the French Public Health Code (*CSP*) are met:

- There is no appropriate treatment available on the market;
- The initiation of the treatment cannot be deferred;
- The efficacy and safety of the medicinal product are strongly presumed based on the results of clinical trials; and
- The medicinal product is presumed to be innovative, notably compared with a clinically relevant comparator.

The approval of this early access program for Idefirix® is valid for a year from the date of decision, funded through the National Security System, and is effective across kidney transplant centers in France. The authorization has been granted based on Hansa's dossier submitted in December 2021, which rendered a positive opinion of the Transparency Commission. Full details of the early access program can be found at the HAS website.

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 hyperimmune patients represented 11.1% of kidney transplant recipients, while the proportion of hyperimmune patients on the active renal transplant waiting list was 23.7%.

"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," says Søren Tulstrup, President and CEO, Hansa Biopharma. "Delivering Idefirix® as a new therapy option for highly sensitized kidney patients in France demonstrates our commitment to improving the lives of patients with rare immunological conditions."

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.[4-6]

Commercial launch and market access efforts for Idefirix® in Europe continue to progress. Pricing and reimbursement processes have been completed in Sweden and the Netherlands, as well as on an individual hospital basis in Finland and Greece. Market access procedures are ongoing in 14 countries including Germany, France, Italy and the United Kingdom (U.K.). A Health Technology Assessment (HTA) dossier for Spain was submitted in January 2022, which completed HTA filings in all of the five largest markets in Europe.

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 23:50 CET on February 25 2022.

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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.[6, 8,11,12]

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.[2]

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.[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%.[13] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[11] 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 https://hansabiopharma.com.

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