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PRESS RELEASE

Hansa Biopharma and German payer head association agree on reimbursement price for Idefirix® (imlifidase) as desensitization treatment for highly sensitized kidney transplant patients

- Hansa Biopharma completes the AMNOG reimbursement process for Idefirix® in Germany
- Hansa and National Association of Statutory Health Insurance Funds (GKV-SV) agree on reimbursement price
- German hospitals can receive extra funding for the final reimbursement price based on a positive NUB status 1 decision

Lund, Sweden, March 15, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), the pioneer in enzyme technology for rare immunological conditions, today announces having reached an agreement on the reimbursement for Idefirix in Germany with the National Association of Statutory Health Insurance Funds, GKV-Spitzenverband (GKV-SV) effective March 15. The agreement for reimbursement covers the entire statutory health insurance system and is also adopted by private health insurances in Germany.

This completes, within the foreseen 12 month timeline, the AMNOG (Medicines Market Reorganization Act) process for Idefirix® in Germany.

Additionally, German hospitals can receive extra funding for the final reimbursement price based on a positive decision (NUB status 1) as communicated in January by the InEK- institute for the hospital remuneration system.[1] For Idefirix®,12 hospitals applied for the NUB status in October 2021 which entitles them to extra budgetary funds for the agreed reimbursement price.

Roughly 2,000 kidney transplantations are carried out annually in Germany, with more than 75% transplanted from deceased donors.[2,3] There are more than 11,000 patients on waitlist for a kidney transplantation in Germany.[2,3]

"We are very pleased to have reached this agreement with GKV-SV. At Hansa, our commitment is to significantly improve the lives of highly sensitized patients in Germany who are waiting for a potentially life-saving kidney transplant," says Søren Tulstrup, President and CEO, Hansa Biopharma. "Highly sensitized kidney patients 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."

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, hospitalizations and additional costs.[4-6]

Commercial launch and market access procedures for Idefirix® in Europe continue to progress according to plan. Beyond the new agreement in Germany, pricing and market access procedures have now been completed in Sweden and the Netherlands as well as on an individual hospital basis in Finland and Greece, while early access including full funding was secured in France end of February. Market access procedures are ongoing in 10 countries, including the 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 15:25 CET on March 15, 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.[13]

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.[13] 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.[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.[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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