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 Spain for Idefirix® (imlifidase) as desensitization treatment for highly sensitized patients in kidney transplantation

Lund, Sweden, March 29, 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announced that the Spanish Minister of Health (Ministerio de Sanidad) has granted access and reimbursement to 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 follows the conditional approval granted by EMA in August 2020.[1]

Søren Tulstrup, President and CEO, Hansa Biopharma said, "At Hansa, our mission is to develop innovative treatments and bring them to patients with the highest unmet medical needs, contributing to equitable access to care for those living with rare immunological conditions. The reimbursement approval of Idefirix® in Spain is another important step in this direction, as it now allows highly sensitized patients to be desensitized using Idefirix®, enabling a potentially lifesaving kidney transplant."

Of almost 4000 patients registered on the waiting list for a kidney transplant in Spain at the end of 2021[2], up to one in five (20%)[3] are classified as highly sensitized. More than 3000 kidney transplantations are performed each year in Spain, with approximately 90% of the transplanted organs coming from deceased donors.[2]

With the reimbursement decision in Spain, Idefirix® is now available, among others, in the five most populated countries in Western Europe: Germany, France, UK, Italy, and Spain, which account for around two-thirds of all kidney transplants from deceased donor performed in the continent.[4] Across Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[5,6]

"This is a great news for highly sensitized patients in Spain who struggle to find a compatible organ", says Dr Oriol Bestard, Chair of Nephrology and Kidney Transplantation at Vall d'Hebron University Hospital in Barcelona, and treating physician of the first patient who received Idefirix® in the context of Hansa's post-authorization efficacy study (PAES) in Europe[7]. "Many highly sensitized patients are still disadvantaged and in urgent need of more personalized and innovative desensitization options that can enable incompatible kidney transplantation. Having treated (the first) Idefirix® -enabled kidney transplant patients as part of Hansa's PAES study, I now know first-hand this innovative treatment has the potential to alter the lives of those highly sensitized patients with the highest unmet medical need."

*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 persons set out below, at 3:00pm CET on March 29, 2023.*

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Contacts for more information:

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

Stephanie Kenney, VP Global Corporate Affairs
M: +1 (484) 319 2802
E: stephanie.kenney@hansabiopharma.com

**Notes to editors**

## About highly sensitized patients

Highly sensitized patients have pre-formed antibodies called donor specific antibodies (DSAs) with a broad reactivity against human leukocyte antigens (HLAs), which can cause tissue damage and potentially transplant rejection.[8] The presence of DSAs means that highly sensitized patients tend to have limited or no access to transplant, as finding a compatible donor organ can be particularly challenging.[9,10] The complexity of their immunological profile means that highly sensitized patients spend longer time than average on transplant waiting lists, with evidence showing that this longer time waiting for a suitable donor relates to an increased mortality risk.[9,10] Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[5,6]

## 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.[11]
Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[12] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[13] 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.[12,14-16]
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 European Commission 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.
Full product information can be accessed via the initial Summary of Product Characteristics found here.

## 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%.[17] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[17] 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.[18]

## 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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