

## PRESS RELEASE

# Hansa Biopharma announces reimbursement in the Netherlands of Idefirix<sup>®</sup> (imlifidase) as desensitization treatment for highly sensitized kidney transplant patients

- Idefirix<sup>®</sup> ▼ (imlifidase) for enabling kidney transplantation in highly sensitized patients is now reimbursable and available for use in the Netherlands
- Idefirix<sup>®</sup> is the first and only approved medicine by the European Commission for the desensitization of highly sensitized patients prior to kidney transplantation<sup>1</sup>

Lund, Sweden, August 2, 2021. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), the pioneer in enzyme technology for rare immunological conditions, today announces that its first-in-class treatment Idefirix<sup>®</sup> ▼ (imlifidase) is, as of August 1, reimbursable and available for use in the Netherlands. Idefirix<sup>®</sup> is the first and only treatment approved for use in the European Union for desensitization of highly sensitized patients prior to kidney transplantation, allowing them to be considered for a life-altering kidney transplantation from a deceased donor.<sup>1</sup>

"Highly sensitized patients have high levels of immunoglobulin G against many human leukocyte antigens that can cause tissue damage and potentially transplant rejection." says Dr Annelies de Weerd, nephrologist at the Erasmus Medical Center in Rotterdam. "Idefirix is the first medicine to desensitize immunized kidney transplant candidates. It works by inactivating immunoglobulin G, then reduces the risk of hyperacute rejection following transplantation."

Hansa Biopharma's commercial launch activities throughout Europe are underway as planned. Pricing for Idefirix<sup>®</sup> has been published in the first markets\* and the first commercial sales were reported in Q1 2021. The first agreements around reimbursement and funding access with healthcare providers and payers have been completed, and more are expected in the early-launch countries over the course of 2021.

"At Hansa, our mission is to significantly improve the lives of rare disease patients with serious unmet medical needs, bringing highly innovative medicines from the laboratory to patients", said Henk Doude van Troostwijk, Senior Vice President and Chief Commercial Officer, Hansa Biopharma. "We are excited to be able to partner with the healthcare community in the Netherlands to offer a new therapy option for highly sensitized patients waiting for a potentially life-saving kidney transplant. This reimbursement announcement shows how we are delivering on our commitment to improve the lives of patients with rare immunological conditions."

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\* Pharmacy purchasing pricing, currently published in Sweden, the Netherlands, Denmark, Finland, the UK, Norway and Germany

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### About Idefirix® (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.<sup>2</sup>

IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor specific antibodies (DSAs).<sup>3</sup> Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ, damaging the transplant.<sup>4</sup> Once they are inactivated with Idefirix®, 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 continue to reduce the risk of organ rejection.

The efficacy and safety of Idefirix® as a pre-transplant treatment to reduce donor-specific IgG was studied in four phase 2 open-label, single-arm, six-month clinical trials.<sup>3,5-7</sup>

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 PRiority MEdicines (PRIME) program, which supports medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options.<sup>1</sup>

Idefirix® was granted conditional marketing authorization from the European Commission (EC) 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 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.<sup>1</sup> Conditional approval allows the Commission 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%.<sup>8</sup> ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.<sup>7</sup> 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.<sup>9</sup>

### 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>.

### References

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