

## PRESS RELEASE

# Imlifidase demonstrated 90% patient survival and 82% graft survival at five years in extended pooled analysis with data from 17-HMedIdeS-14 study

Lund, Sweden, 17 October 2023. Hansa Biopharma, “Hansa” (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announced results from an extended pooled analysis using data from the 17-HMedIdeS-14 study,<sup>1</sup> an international long-term follow-up study of patients who have received a kidney transplant following desensitization with imlifidase, showing sustained positive outcomes out to 5 years in the majority of highly sensitized patients who received an imlifidase-enabled kidney transplant. After 5 years, the patient survival rate was 90% (three deaths occurring between six months and one year, and no deaths occurring between one and five years) and graft survival (death censored) was 82%, in line with outcomes seen at 3-years post-transplant.<sup>2</sup> At five years, mean estimated glomerular filtration rate (eGFR) was 50 mL/min/m<sup>2</sup>. eGFR is a measure of how well the kidneys are working in the body.<sup>3</sup>

Søren Tulstrup, President and CEO, Hansa Biopharma said, “The results from this study confirm the important role imlifidase plays in desensitization in kidney transplantation and further supports the clinical benefit of enabling HLA-incompatible kidney transplantation with imlifidase. Conditionally approved and marketed in Europe as Idefix® (imlifidase), we believe it is a paradigm shifting treatment in kidney transplantation – one that will positively impact patient outcomes and ensure that highly sensitized patients waiting for a kidney have access to transplantation.”

The 17-HMedIdeS-14 study included patients who consented to long-term follow-up and had previously received an imlifidase-enabled transplant in Hansa’s phase 2 studies. The 5-year extended pooled analysis is a continuation of the analysis at 3-years of crossmatch positive only patients published in the *American Journal of Transplantation*. Hansa is continuing to analyze the data from 17-HMedIdeS-14 along with the extended pooled analysis and plans to share further data in 2024.

Tomas Lorant, MD PhD, Associate Professor of Transplant Surgery, Uppsala University Hospital, Uppsala, Sweden, said, “It is encouraging to see the outcome of patients five years out from an incompatible kidney transplant and its consistency with the 3-year data that was published in 2021. Despite the high-risk immunological profile of these patients, we see stable long-term outcomes both on graft survival and patient survival, not different from what we otherwise see in compatible kidney transplantation.”<sup>4</sup>

Stanley Jordan, MD, FASN, FAST, Professor of Pediatrics & Medicine and Director of Nephrology & Transplant Immunology, Cedars-Sinai Medical Center, Los Angeles, CA, said, “These results reinforce the case for HLA-incompatible transplantation following desensitization with imlifidase being a viable and concrete option for patients on the waitlist who are highly sensitized and predicted to have low likelihood to access a compatible kidney offer, removing their dependency on dialysis treatment.”

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).<sup>11</sup> Highly sensitized patients have high levels of preformed antibodies that can damage the transplant.<sup>12</sup> Once they 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.

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## Imlifidase

Imlifidase is an antibody-cleaving enzyme originating from *Streptococcus pyogenes* that specifically targets and cleaves immunoglobulin G (IgG) antibodies and inhibits IgG-mediated immune response.<sup>10</sup> It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration.

Imlifidase is conditionally approved in Europe and marketed under the trade name Idefix® for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch 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.<sup>10</sup> 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.<sup>10</sup>

## HMedldeS Clinical Trial Program

17-HMedldeS-14 is part of the HMedldeS clinical program for imlifidase. The program includes four global phase 2 trials (13-HMedldeS-02, 13-HMedldeS-03, 14-HMedldeS-04 and 15-HMedldeS-06), one US open-label phase 3 trial (ConfldeS), a long-term follow up study (17-HMedldeS-14) and a post-authorization efficacy and safety study in Europe (PAES).

## About kidney failure and highly sensitized patients

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>14</sup> ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.<sup>15</sup> A kidney transplant is the treatment of choice for suitable patients with ESRD because it offers improved survival and quality of life benefits, and has cost savings compared to long-term dialysis. There are approximately 80,000 kidney patients on transplant waiting lists across the European Union.<sup>17</sup>

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.<sup>4</sup> 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.<sup>6,7</sup> 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.<sup>6,7</sup> Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.<sup>8,9</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 [www.hansabiopharma.com](http://www.hansabiopharma.com).

Full product information can be accessed via the initial Summary of Product Characteristics found [here](#).

## References

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