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PRESS RELEASE

Hansa Biopharma presents positive outcomes of five-year follow-up study of imlifidase in kidney transplantation at ESOT Congress 2025 in London

Lund, Sweden, June 30, 2025. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), announced today the presentation of its five year extended pooled analysis including data from the 17-HMedIdeS-14 study, an international long-term follow-up study of patients who have received a kidney transplant following desensitization with imlifidase, at the 2025 International Transplant Congress of the European Society for Organ Transplantation (ESOT), taking place in London, June 29 – July 2.

Massimo Mangiola, PhD, NYU Langone Transplant Institute, will present the outcomes of the extended pooled analysis including data from the 17-HMedIdeS-14 study, presented at the American Transplant Congress (ATC) 2024, and published as a letter to the editor in the *American Journal of Transplantation*.[1]

The extended pooled analysis, including data from the 17-HMedIdeS-14 study, showed sustained positive outcomes out to five years of highly sensitized patients who received an imlifidase-enabled kidney transplant. After five years, the patient survival rate was 90% (reflecting three deaths occurring between six months and one year) and graft survival (death censored) was 82%, in line with outcomes seen at three-years.[2] At five years, mean estimated glomerular filtration rate (eGFR) or kidney function was 50 mL/min/m^2 in the imlifidase treated patients.

eGFR is a measure of how well the kidneys are working in the body – higher eGFR indicates better kidney function.[3] For many kidney transplant recipients three years post-transplant the mean eGFR is anywhere between 40-60 ml/min per 1.73 m^2 with continued decline of eGFR function at five years post-transplant.[4]

Hitto Kaufmann, Chief R&D Officer, Hansa Biopharma said, "We are very pleased to see that the 17-HMedIdeS-14 extended pooled analysis data continue to excite the clinical community. This study demonstrated for the first time that HLA-incompatible transplantation following desensitization with imlifidase is a viable option for patients who need it, with long term benefit comparable to standard kidney transplants, providing a life changing alternative to remaining on dialysis."

Speaker	Abstract Title	Presentation Details
Massimo Mangiola, PhD	"Five years follow up of imlifidase desensitized kidney transplant recipients" – Oral presentation	Monday 30 June, 11:10 - 11:20 BST. Part of the FOS_04 session: Innovation in solid organ transplantation

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

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.*[1]

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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.[5] 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.[6,7] 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.[8,9] Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[10,11]

About IDEFIRIX® (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.[12] It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration.

Imlifidase has conditional marketing approval in Europe and is marketed under the trade name IDEFIRIX 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.[12] 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.[12]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[13] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[5] 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.[11,13-15] Hansa is 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.

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%.[16] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[16] 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 170,000 kidney patients in the U.S. and Europe waiting for a new kidney.[17]

About Hansa Biopharma

Hansa Biopharma AB 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. The company has a rich and expanding research and development program based on its proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in autoimmune diseases, gene therapy and transplantation. The company's portfolio includes imlifidase, a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients and HNSA-5487, a next-generation IgG cleaving molecule with redosing potential. 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 and follow us on LinkedIn.

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