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PRESS RELEASE

Hansa Biopharma to present data at 2024 American Transplant Congress annual meeting

Lund, Sweden, 21 May, 2024. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), today announced data featuring imlifidase will be presented at the American Transplant Congress (ATC), the joint annual meeting of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (ATS). Imlifidase is Hansa's unique antibody-cleaving enzyme that specifically targets IgG and inhibits IgG-mediated immune response.[1]

Søren Tulstrup, CEO and President, Hansa Biopharma, said: "ATC is a valuable opportunity for Hansa to share the latest science and data around imlifidase and its role in enabling transplantation for those patients who are highly sensitized. We are excited to attend ATC and showcase the progress we are making across our Transplantation therapy area and these data underscore our continued commitment to advancing innovative new approaches to transplantation care."

Imlifidase has conditional marketing approval in Europe 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 Company is conducting an open label, randomized controlled Phase 3 trial in the US in kidney transplantation and plans to submit a Biologic License Application (BLA) to the US Food and Drug Administration (FDA) in 2025. The molecule is also being studied as a pre-treatment to gene therapy in rare disease patients with pre-existing antibodies and in autoimmune conditions including anti-GBM and Guillain Barre Syndrome (GBS).

Key abstracts at ATC include:

Abstract Title and Location	**Presentation Details**
Reestablishment of COVID-Specific IgG Antibodies After Imlifidase Treatment Abstract B058 Poster Hall, Exhibit Hall A, Level 2	Poster Presentation Sunday 2 June 9:15 am – 10:00 am EST
A Phase II Study Investigating DSA Rebound in Highly Sensitized Living Donor Kidney Transplant Recipients Treated with Imlifidase 107-AB, Level 1	Late Breaking Abstracts: Clinical Rapid Fire Oral Abstract Monday 3 June 1:40 – 1:50 pm ET
Imlifidase for Highly Sensitized Kidney Transplant Recipients with a Positive Crossmatch Against a Deceased Donor: Results of Kidney Transplantations Performed in Accordance to the French Guidelines Abstract D092 Poster Hall, Exhibit Hall A, Level 2	Poster Presentation Tuesday 4 June 9:15 – 10:00 am ET
Five Years of Imlifidase: Clinical Outcomes and Donor-Specific Antibodies 118-ABC, Level 1	Rapid Fire Oral Abstract Tuesday 4 June 10:15 – 10:25 am ET

Long-Term Follow Up of Imlifidase Desensitized Kidney Transplant Recipients: 5 Year Pooled Analysis 108-AB, Level 1	Rapid Fire Oral Abstract Wednesday 5 June 9:40 – 9:50 am ET

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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.[1] 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.[2,3] 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.[2,3] Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[4,5]

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.[6] 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 patiensts who are unlikely to be transplanted under the available kidney allocation system, including prioritization programs for highly sensitized patients.[6] 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.[6]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[7] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[8] 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.[7,9-11] 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%.[12] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.12 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 and United Kingdom.[13]

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 Biopharma 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 Biopharma 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 and follow us on LinkedIn.

References

1. Eurostam Report (A Europe-wide strategy to enhance transplantation of highly sensitized patients on the basis of acceptable HLA mismatches.) Available at https://cordis.europa.eu/project/id/305385/reporting.
2. Redfield R, et al. Nephrol Dial Transplant 2016; 31:1746–1753
3. Lonze BE, et al. Ann Surg 2018; 268(3):488–496
4. EDQM. (2020). International figures on donation and Transplantation 2019
5. SRTR Database and individual assessments of allocation systems 6_European Medicines Agency. Idefirix® summary of product characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf.
6. European Medicines Agency. Idefirix® summary of product characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf.
7. Jordan SC, et al. N Engl J Med 2017; 377(5):442-453.
8. Manook M, et al. Lancet 2017; 389(10070):727-734.
9. Winstedt L, et al. PLoS One 2015; 10(7): e013201
10. Lorant T, et al. Am J Transplant 2018;18(11):2752-2762.
11. Jordan SC, et al. Transplantation October 21 2020 - volume online first issue
12. NIH (2018). What is kidney failure? Available at: https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/what-is-kidney-failure.
13. Newsletter Transplant. Available at: https://freepub.edqm.eu/publications.