

PRESS RELEASE

Hansa Biopharma announces first commercial kidney transplant patient treated with Idefirix in Australia

Lund, Sweden, August 18, 2026. Hansa Biopharma AB, “Hansa” (Nasdaq Stockholm: HNSA), today announced that the first commercial patient in Australia has received a living donor kidney transplant following treatment with Idefirix® (imlifidase), consistent with the indication approved by the Therapeutic Goods Administration (TGA).

“This first commercial living donor transplant patient in Australia represents an important milestone for Hansa and for patients facing significant barriers to transplantation,” said Renée Aguiar-Lucander, CEO of Hansa Biopharma. *“We look forward to continued collaboration with the Australian transplant community to build experience with Idefirix across both living and deceased donor transplantations.”*

Patient outcomes will be documented through an established registry in Australia. Data from real-world clinical use will be collected and may contribute to future scientific publications, and help to further the understanding of the use of Idefirix in living donor transplants.

Idefirix is approved in Australia as a desensitization treatment of highly sensitized adult kidney transplant candidates who have a positive cross-match against a living or deceased donor.

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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.^{4,5} Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.^{6,7}

About imlifidase

Imlifidase is conditionally approved in the European Union, Norway, Liechtenstein, Iceland and the UK under the tradename Idefirix® for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive cross-match against an available deceased donor. Idefirix® is also approved in Australia, Israel and Switzerland.

Information about the trial is available at ClinicalTrials.gov: [NCT04935177](https://clinicaltrials.gov/ct2/show/study/NCT04935177)

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.⁸ 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 cross-match 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.⁸ 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.⁸

The efficacy and safety of imlifidase as a pre-transplant treatment to reduce donor-specific IgG antibodies was studied in four phase 2 single-arm, studies in EU and US as well as a randomized, controlled Phase 3 study in US.^{5,7,10-11} 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.

In the US, the Food and Drug Administration (FDA) accepted the Biologics License Application (BLA) for imlifidase in February of 2026 and assigned a Prescription Drug User Fee Act (PDUFA) action date of December 19, 2026.

Full EU 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 170,000 kidney patients in the U.S. and Europe waiting for a new kidney.¹³

About Hansa Biopharma

Hansa Biopharma AB is a pioneering commercial-stage biopharmaceutical company developing and commercializing novel immunomodulatory therapies to transform care for patients with acute or complex immune disorders. Hansa's proprietary IgG-cleaving enzyme technology platform addresses serious unmet medical needs in transplantation, gene therapy and autoimmune diseases. 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 that will be developed for Guillain-Barré Syndrome (GBS). 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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Forward-Looking Statements

This press release contains forward-looking statements relating to the business of Hansa, including, without limitation, statements regarding Hansa's commercial activities in Australia. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties, and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release. Hansa cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Hansa disclaims any obligation to publicly update or revise any such

statements to reflect any change in expectations or in events, conditions, or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Hansa's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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 RR, et al. The mode of sensitization and its influence on allograft outcomes in highly sensitized kidney transplant recipients. *Nephrol Dial Transplant*. 2016 Oct;31(10):1746-53. doi: 10.1093/ndt/gfw099.
3. Lonze BE, et al. IdeS (Imlifidase): A Novel Agent That Cleaves Human IgG and Permits Successful Kidney Transplantation Across High-strength Donor-specific Antibody. *Ann Surg*. 2018 Sep;268(3):488-496. doi: 10.1097/
4. Alelign T, Ahmed MM, Bobosha K, Tadesse Y, Howe R, Petros B. Kidney Transplantation: The Challenge of Human Leukocyte Antigen and Its Therapeutic Strategies. *J Immunol Res*. 2018 Mar 5;2018:5986740. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5859822/>
5. Heidt S, et al. Highly Sensitized Patients are Well Served by Receiving a Compatible Organ Offer Based on Acceptable Mismatches. *Front Immunol*. 2021;12:687254. Available at: <https://pubmed.ncbi.nlm.nih.gov/34248971/>
6. Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR). OPTN/SRTR 2022 Annual Data Report. U.S. Department of Health and Human Services, Health Resources and Services Administration; 2024. Accessed [June 2024].
7. Jordan SC, et al. Imlifidase Desensitization in Crossmatch-positive, Highly Sensitized Kidney Transplant Recipients: Results of an International Phase 2 Trial (Highdes). *Transplantation*. 2021 Aug 1;105(8):1808-1817. doi: 10.1097/TP.0000000000003496.
8. European Medicines Agency. Idefix® summary of product characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/idefix-epar-product-information_en.pdf.
9. Jordan SC, et al. IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation. *N Engl J Med*. 2017;377:442-453. DOI: 10.1056/NEJMoa16125
10. Winstedt L, et al. Complete Removal of Extracellular IgG Antibodies in a Randomized Dose-Escalation Phase I Study with the Bacterial Enzyme IdeS—A Novel Therapeutic Opportunity. *PLoS One*. 2015 Jul 15;10(7):e0132011. doi: 10.1371/journal.pone.0132011. PMID: 26177518; PMCID: PMC4503742.
11. Lorant T, et al. Safety, immunogenicity, pharmacokinetics, and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients. *Am J Transplant*. 2018 Nov;18(11):2752-2762. doi: 10.1111/ajt.14733.
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 2022. International figures on donation and transplantation. Available at: Newsletter Transplant - latest edition | Freepub (edgm.eu) Accessed: May 2024