

PRESS RELEASE

Hansa Biopharma announces positive Idefirix PAES results presented in the High-Impact Clinical Trials session at ASN Kidney Week

- The 1-year graft failure-free survival at 12 months post-transplant was 90%, which is clinically meaningful
- Graft and patient survival were 92% and 98%, respectively
- Idefirix was generally well tolerated with a safety profile consistent with previous clinical trial experience

Lund, Sweden, October 23, 2026. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), today announced that data from the European Post-Authorization Efficacy and Safety (PAES) study of Idefirix® (imlifidase) were presented during the High-Impact Clinical Trials oral session at the American Society of Nephrology (ASN) Kidney Week 2026 in Denver, Colorado. The abstract "FR-OR103 Post-Authorization Efficacy and Safety (PAES): An Open-Label Post-Authorization Trial of 50 Imlifidase Crossmatch-Positive Deceased-Donor Kidney Transplants in Europe" was selected as a Late-Breaking Abstract at the congress.

Renée Aguiar-Lucander, CEO of Hansa Biopharma, said: *"The presentation of the PAES study in the High-Impact Clinical Trials session highlights the scientific and clinical relevance of these findings and the potential of imlifidase to address a significant unmet need for highly sensitized patients awaiting kidney transplantation. We are encouraged by the continued interest from the transplant community in the growing body of evidence supporting imlifidase."*

Oriol Bestard MD PhD, Vall d'Hebron University Hospital, Barcelona, Spain and investigator for the trial said: *"The successful completion of the PAES study provides important evidence in a patient population that continues to face significant challenges in accessing kidney transplantation. These findings add to the clinical evidence supporting the use of imlifidase to enable transplantation in highly sensitized patients with a positive crossmatch against a deceased donor."*

ASN Kidney Week is one of the world's leading scientific meetings in nephrology and transplantation, bringing together researchers and clinicians to present the latest advances in kidney disease and transplantation medicine. The High-Impact Clinical Trials session features selected studies considered to represent some of the most clinically relevant and impactful research presented at the congress.

The abstract was presented by Oriol Bestard MD PhD, Vall d'Hebron University Hospital, Barcelona, Spain, on behalf of the PAES study investigators.

Summary of the Abstract

Background

Imlifidase have a conditional approval in Europe since 2020. PAES (NCT05369975) is a controlled, non-randomized, open-label post-authorization efficacy and safety trial, designed to provide comprehensive data to support a full marketing authorisation of imlifidase (Idefix®) in Europe.

Methods

Fifty highly sensitized (HS) patients who received crossmatch positive kidney offers received imlifidase treatment in line with the mode-of-action i.e. conversion of a positive crossmatch to a negative crossmatch and thereby enabling transplantation. All patients were unlikely to be transplanted under available kidney allocation systems, including prioritization programs for HS patients.

The primary trial objective was to assess graft failure-free survival at 1 year after transplantation. Secondary outcomes at 1 year includes kidney function assessed by eGFR, patient survival, graft survival, delayed graft function (DGF), antibody-mediated rejection (AMR) and safety.

Results

- The graft failure-free survival was 90% at 1 year after transplantation in patients desensitized with imlifidase (n=50).
- Graft and patient survival were 92% and 98%, respectively.
- The mean eGFR calculated by MDRD was 51.04 mL/min/1.73 m² (n=45).
- DGF was seen in 40% of patients with a median duration of 14 days.
- AMR occurred in 56% of recipients; however, no allograft loss was associated with AMR.
- There were no new or additional safety signals found, and no imlifidase infusions were stopped due to infusion reactions.

Conclusion

Imlifidase enables kidney transplantation with a successful kidney function measured as eGFR at 1 year in patients desensitized. Imlifidase was well tolerated, with a safety profile consistent with prior experience and no unexpected or unacceptable risks observed.

Information about the trial is available at ClinicalTrials.gov: [NCT05369975](https://clinicaltrials.gov/ct2/show/study/NCT05369975)

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Notes to editors

About highly sensitized patients

Highly sensitized patients have pre-formed antibodies with a broad reactivity against human leukocyte antigens (HLAs). Those antibodies can cause damage to a transplanted organ and potentially graft loss.¹ The presence of HLA antibodies means that highly sensitized patients have limited or no access to transplantation, as finding a compatible donor organ

is particularly challenging.^{2,3} The immunological complexity of highly sensitized patients make them spend a longer time on transplant waiting lists, with an increased risk of dying while waiting for a suitable donor organ.^{4,5} Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of all patients on transplant waiting lists.^{6,7}

About Idefirix® (imlifidase)

Imlifidase is an antibody-cleaving enzyme originating from *Streptococcus pyogenes* that specifically cleaves and inactivates all immunoglobulin G (IgG) antibody subclasses, including HLAs. It has a rapid onset and inactivates IgG-antibodies within hours after administration. The decrease in antibody levels creates a temporal antibody-free window of opportunity for highly sensitised patients to undergo transplant, thus enabling successful transplantation from an otherwise incompatible donor.

Imlifidase received a conditional marketing authorization valid throughout the European Union on 25 August 2020 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.

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, a controlled Phase 3 study in US and in this European Post-Authorization Efficacy and Safety (PAES) study.^{5,7,10-11}

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

Idefirix is exclusively out-licensed for transplantation in EU, UK, Switzerland, Norway, Liechtenstein, Iceland and Middle East and North Africa (MENA) to SERB Pharmaceuticals since July 1, 2026.

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.

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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