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PRESS RELEASE

Hansa Biopharma reports positive efficacy and safety results from Idefirix® European post authorization study in kidney transplantation

- **The 1-year graft failure-free survival was 90%, which is clinically meaningful and supports full marketing authorization submission**
- **Idefirix was generally well tolerated with a safety profile consistent with previous clinical trial experience**
- **Submission to EMA for conversion to full marketing authorization planned for Q4 2026**

Lund, Sweden, May 27, 2026. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), today announced positive topline results from the European 20-HMedIdeS-19 Post Authorization Efficacy Study (PAES), an open-label confirmatory study investigating one-year graft failure-free survival* and patient survival in highly sensitized patients who have undergone HLA-incompatible kidney transplantation following desensitization treatment with Idefirix (imlifidase).

Renée Aguiar-Lucander, CEO, Hansa Biopharma said**,** *"These positive results represent a significant milestone for Idefirix and for Hansa. The one-year graft failure-free survival observed in this highly sensitized patient population confirms the clinical benefit of Idefirix and demonstrates expected efficacy outcomes supported by a safety profile consistent with prior clinical experience. With this post-authorization requirement fulfilled, we look forward to submitting an application for conversion to full marketing authorization to the EMA by the end of 2026."*

Tomas Lorant, Associate Professor, transplant surgeon at Akademiska Hospital, Uppsala University and the coordinating investigator for the trial said, "*Imlifidase is transforming transplantation care for highly sensitized patients in Europe, by enabling kidney transplantation for patients who would otherwise have remained on the transplant waiting list for an extended, often indefinite period. The PAES study results confirm the key role of imlifidase in allowing us to treat those kidney transplant patients with the highest unmet need.*"

Imlifidase is conditionally approved in the European Union under the brand name Idefirix as a desensitization treatment for highly sensitized adult patients prior to kidney transplantation from deceased donors. As part of the conditional marketing authorization, the European Medicines Agency (EMA) requested a post-authorization efficacy study (PAES) for Idefirix.

The first patient was enrolled in May 2022. In total, 22 transplant centers across 11 countries in the EU and the UK participated in the study. A total of 51 patients were enrolled and treated with Idefirix in the study.

* Permanent return to dialysis for at least 6 weeks, retransplantation, transplantectomy or death

The primary objective of the PAES was met, with 90% of highly sensitized kidney transplant patients achieving one-year graft failure-free survival following Idefirix pre-treatment to convert a positive crossmatch against a deceased donor to negative prior to transplantation.

Secondary objectives included evaluation of renal function one year after transplantation, assessed by estimated glomerular filtration rate (eGFR), as well as patient and graft survival at one year.

In patients treated with Idefirix, at one year, mean estimated glomerular filtration rate (eGFR) was 52.4 mL/min/1.73 m², graft survival was 92%, and patient survival was 98%.

The study was well conducted with patient retention greater than 94%. Idefirix was generally well tolerated, with a safety profile consistent with previous clinical trial experience.

The obligation to complete a post-authorization efficacy study, as defined under the conditional marketing authorization, is now considered fulfilled and an application for conversion to full marketing authorization to EMA is planned to be submitted by the end of 2026.

Full results from the PAES will be submitted for presentation at an upcoming medical congress.

Information about the trial is available at ClinicalTrials.gov: NCT05369975.

Conference Call

Hansa Biopharma will host a telephone conference today, Wednesday 27 May, 2026 at 8:00 AM EDT / 14:00 PM CEST. The event will be hosted by Renée Aguiar-Lucander, CEO, and Richard Philipson, CMO. The call will be held in English.

Slides used in the presentation will be live on the webcast during the call and will also be made available online after the call under Events and presentations | Hansa Biopharma.

To participate in the telephone conference, please use the dial-in details provided below:

Participant Dial In (USA/Canada Toll Free): +1-833-821-3542
Participant International Dial In: +1-412-652-1248
*Please ask to be joined into the Hansa Biopharma call.

Join the webcast here: Webcast | Hansa Biopharma Conference Call

This is information that Hansa Biopharma AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, at 07:12 AM CEST on May 27, 2026.

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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 crossmatch against an available deceased donor. Idefirix® is also approved in Australia, Israel and Switzerland.

Information about the trial is available at ClinicalTrials.gov: 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 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.[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].

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 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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