

PRESS RELEASE

Hansa Biopharma announces Idefirix PAES late-breaking abstract selected for oral presentation in High-Impact Clinical Trials session at ASN Kidney Week

Lund, Sweden, October 20, 2026. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), today announced that the European Post-Authorization Efficacy and Safety (PAES) study of Idefirix® (imlifidase) has been selected by the Committee for an oral abstract presentation in the High-Impact Clinical Trials session at ASN Kidney Week in Denver, US.

Friday, October 23, 10:30 a.m. – 12:30 p.m. MT High-Impact Clinical Trials

11:15 AM ET 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 – Oriol Bestard, Amado Andres, Marta Crespo, Fritz Diekmann, Ondrej Viklicky, Dominique Bertrand, Lucrezia Furian, Torbjörn Lundgren, Annelies de Weerd, Rainer Oberbauer, Aiko P. De Vries, Dany Anglicheau, Umberto Maggiore, Fabian Halleck, Miha Arnol, Atul Bagul, Stefan P. Berger, Dirk R. Kuypers, Lutz Renders, Lionel Rostaing, Lina Nilsson, Anna Runström, Jan G. Tollemar, Tomas Lorant.

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Contacts for more information:

Adam Cutler, CFO
IR@hansabiopharma.com

Kerstin Falck, VP Global Corporate Affairs
media@hansabiopharma.com

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 HLAs 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 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 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.

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 as well as 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](#).

Hansa Biopharma has exclusively licensed Idefirix to SERB Pharmaceuticals for transplantation in the EU, UK, Switzerland, Norway, Liechtenstein, Iceland, and the Middle East and North Africa (MENA), effective 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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