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PRESS RELEASE

Hansa Biopharma announces ConfIdeS Phase 3 Abstract Selected for 'What's Hot, What's New' Plenary at ATC 2026

Lund, Sweden, June 24, 2026. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), today announced that the ConfIdeS Phase 3 abstract titled "Superior 1-year eGFR Among Highly Sensitized Patients Desensitized with Imlifidase Compared to Control" has been selected to be highlighted at the closing plenary session "What's Hot, What's New" at the American Transplant Congress (ATC) 2026, taking place in Boston on June 24, 2026.

Renée Aguiar-Lucander, CEO of Hansa Biopharma, said: *"This recognition highlights the strength and clinical relevance of the ConfIdeS data and the potential of imlifidase to address a significant unmet need in highly sensitized transplant patients. Being selected for the 'What's Hot, What's New' plenary session underscores the novelty and importance of these findings for the transplant community*."

ATC is the leading annual meeting in transplantation, bringing together experts to share the latest scientific and clinical advances in the field. The "What's Hot, What's New" closing plenary session showcases a select group of abstracts considered to represent some of the most notable and impactful scientific contributions presented at the congress.

The inclusion of the ConfIdeS abstract in this session follows its prior selection as a late-breaking oral presentation at ATC 2026, further emphasizing the growing scientific and clinical interest in imlifidase and its potential role in enabling kidney transplantation in highly sensitized patients.

The presentation includes detailed 12-month results from the ConfIdeS trial, including the primary endpoint eGFR, key secondary endpoints as well as safety results. The presentation was delivered by Dr. Robert Montgomery, MD PhD, New York University Langone Transplant Institute, on behalf of the ConfIdeS study group.

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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] 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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