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PRESS RELEASE

Imlifidase successfully meets primary endpoint in pivotal US Phase 3 ConfIdeS trial in kidney transplantation

- *At 12 months, mean eGFR was 51.5 mL/min/1.73m^2 in the imlifidase arm versus 19.3 mL/min/1.73m^2 in the control arm with a statistically significant and clinically meaningful difference of 32.2 mL/min/1.73m^2 (p<0.0001)*
- *Imlifidase was generally well tolerated with a safety profile consistent with previous clinical trial experience*
- *Submission of a Biologic License Application (BLA) under accelerated approval pathway planned for end of 2025*

Lund, Sweden, 24 September 2025. Hansa Biopharma AB, ("Hansa" or "the Company"), (Nasdaq Stockholm: HNSA), today announced positive topline results from the US Phase 3 ConfIdeS trial of imlifidase, evaluating 12-month kidney function in highly sensitized (cPRA ≥99.9%) adult kidney transplant patients with positive crossmatch against a deceased donor, versus the control arm. The trial was well conducted, with patient retention in excess of 90%, and met the primary endpoint of kidney function at 12 months as measured by mean estimated Glomerular Filtration Rate (eGFR) with a p-value of <0.0001. The Company plans to submit a BLA under the accelerated approval pathway to the US Food and Drug Administration (FDA) by the end of 2025.

Renée Aguiar-Lucander, CEO, Hansa Biopharma said: "We are excited to share the data from the US ConfIdeS trial, which clearly shows the clinically meaningful benefit of imlifidase in kidney transplantation of highly sensitized patients, and the role it can play in shaping future standard of care. These results corroborate the existing clinical and real-world evidence of the use of imlifidase as an effective desensitization therapy in kidney transplantation. We look forward to sharing this body of data with the FDA in our mission to bring this medicine to these patients who today have very limited options. I would like to thank all the patients, their families, as well as the investigators and the site staff who continue to participate in the trial."

Robert Montgomery, MD, PhD, New York University Langone Health, said: "There have been few major breakthroughs in desensitization strategies in kidney transplantation for the last 30 years. The unmet need remains high for kidney transplant patients who are considered highly sensitized, with many remaining on the wait list with little to no hope of receiving a suitable match for transplantation. The result from the US ConfIdeS trial are highly encouraging and demonstrate the significant potential for imlifidase to transform standard of care for highly sensitized kidney transplant patients."

Patients who were randomized to receive imlifidase showed superior kidney function at 12 months of 51.5 mL/min/1.73m^2, compared to patients randomized to the control arm of 19.3 mL/min/1.73m^2. In the trial, the control arm allowed for a range of treatment options, including remaining on dialysis awaiting a more compatible organ offer, transplantation using off-label desensitization approaches, or transplantation with a compatible organ.

A key secondary outcome relating to dialysis independence at 12 months was also statistically significant in favor of imlifidase (p=0.0007). Imlifidase was generally well tolerated with a safety profile consistent with previous clinical trial experience.

Full results from the Phase 3 ConfIdeS trial will be submitted to a medical congress in 2026.

About ConfIdeS

ConfIdeS is a pivotal Phase 3 open label, randomized, controlled trial of imlifidase in kidney transplantation. The trial evaluated kidney function at 12 months in 64 highly sensitized (cPRA ≥99.9%) kidney transplant patients with positive crossmatch against a deceased donor, comparing desensitization using imlifidase with a control arm. A total of 25 US sites participated in the trial and its primary endpoint is kidney graft function at 12 months, measured by mean eGFR (estimated glomerular filtration rate). The total trial duration is five years which includes a long-term follow-up as agreed to with the FDA as part of the accelerated approval pathway.

About imlifidase

Imlifidase is conditionally approved in the European Union, Norway, Lichtenstein, Iceland and the UK under the brand name 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 and Switzerland.

Information about the trial is available at ClinicalTrials.gov: NCT04935177

Hansa Biopharma will host a telephone conference on September 25, 2025 at 14:30 CET.

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

Participant Dial In (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.

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 18:21 CET on September 24, 2025.

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Notes to editors

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.[1] 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.[1] 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.[1]

The efficacy and safety of imlifidase as a pre-transplant treatment to reduce donor-specific IgG was studied in four Phase 2 open-label, single-arm, six-month clinical trials.[2,3-5] 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.

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%.[6] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[6] 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 US and Europe waiting for a new kidney.[7]

About Hansa Biopharma

Hansa Biopharma AB is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life-altering treatments for patients with rare immunological conditions. The company has a rich and expanding research and development program based on its proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in autoimmune diseases, gene therapy and transplantation. 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 with redosing potential. Hansa Biopharma is based in Lund, Sweden, and has operations in Europe and the US The company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com and follow us on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements relating to the business of Hansa, including, without limitation, statements regarding Hansa's strategy, commercialization efforts, business plans, regulatory submissions, clinical development plans, revenue and product sales projections or forecasts and focus. 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, including, without limitation, any related to Hansa's business and operations, the presumed mechanism of action of imlifidase, the safety and efficacy of imlifidase in the patient population above or

other potential indications, market acceptance of imlifidase, competitive products, anticipated timelines and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. 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.

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