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PRESS RELEASE

Hansa Biopharma's Biologics License Application (BLA) for imlifidase accepted by the FDA

Lund, Sweden, 18 February 2026. Hansa Biopharma AB, ("Hansa" or "the Company"), (Nasdaq Stockholm: HNSA), today announced that its Biologics License Application (BLA) for imlifidase has been accepted by the U.S. Food and Drug Administration (FDA).

FDA's filing review was completed on day 60 which is meant to verify that the submission is substantially complete and meets the requirements for a full evaluation.

Renée Aguiar-Lucander, CEO, Hansa Biopharma said: "*We now look forward to receiving the 74-Day Letter which will provide details regarding review plan, timelines and other pertinent information and start working with the FDA as they go through their review over the coming months.*"

Imlifidase is a unique IgG-cleaving enzyme that rapidly inactivates > 95% of donor-specific antibodies within 2–6 hours of administration, providing a crucial window to enable HLA-incompatible kidney transplantation.

The BLA submission for imlifidase is supported by the previously communicated highly statistically significant outcome of the pivotal U.S. Phase 3 ConfIdeS trial, which evaluated 12-month kidney function in highly sensitized adult kidney transplant patients (cPRA ≥99.9%) with a positive crossmatch against a deceased donor, compared to a control arm. The trial successfully met its primary endpoint, demonstrating significantly improved kidney function in the imlifidase arm at 12 months as measured by mean estimated glomerular filtration rate (eGFR) ($p < 0.0001$). A key secondary endpoint—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.

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 U.S. sites participated in the trial, and the primary endpoint was 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 agreed 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 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 and Switzerland.

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

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 19:53 CET on February 18 2026.

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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 tradename 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 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%.[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 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 to address 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.

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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