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PRESS RELEASE

PDUFA Action Date for Hansa Biopharma's Imlifidase BLA Set for December 19, 2026

- ***If approved, imlifidase will be the first treatment to address highly sensitized patients awaiting kidney transplantation.***

Lund, Sweden, 4 March 2026. Hansa Biopharma AB, ("Hansa" or "the Company"), (Nasdaq Stockholm: HNSA), today announced that the Food and Drug Administration (FDA) has notified the company that the previously accepted Biologics License Application (BLA) for imlifidase has been assigned a Prescription Drug User Fee Act (PDUFA) action date of December 19, 2026.

Renée Aguiar-Lucander, CEO, Hansa Biopharma said: "*With the PDUFA date now set, we are one step closer to potentially offering imlifidase as a transformative therapy option for patients who today have very limited access to a life-changing kidney transplant. It marks an important milestone for Hansa Biopharma and for highly sensitized patients in the U.S. awaiting kidney transplantation. We look forward to working with the FDA as they complete their review over the coming months.*"

About highly sensitized patients awaiting kidney transplantation

Highly sensitized patients constitute a particularly underserved group in kidney transplantation, representing an estimated 10–15% of individuals on transplant waiting lists. These patients carry high levels of pre-formed donor specific antibodies (DSA) with broad reactivity against human leukocyte antigens (HLA), typically resulting from previous transplants, blood transfusions, or pregnancies. Consequently, they face a substantial immunological barrier to transplantation, as DSAs can trigger an immediate immune response against a donor organ, leading to tissue damage and likely graft rejection. Compatible donors are therefore exceedingly difficult to identify, and highly sensitized patients often endure significantly prolonged — and in some cases indefinite — waiting times, remaining dependent on long-term dialysis while awaiting a viable matched organ.

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.

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 22:08 CET on March 4, 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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