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PRESS RELEASE

Hansa provides update on Pivotal Phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease

Lund, Sweden, 16 December 2025. Hansa Biopharma AB, “Hansa” (Nasdaq Stockholm: HNSA), today announced that GOOD-IDES-02, a global pivotal Phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease, did not meet its primary endpoint. The endpoint was renal function at 6 months, evaluated by estimated glomerular filtration rate (eGFR).

Approximately 60% of patients treated with imlifidase followed by the standard of care (SoC) protocol defined in the trial did not require dialysis at 6 months, which represented a substantial improvement and clinical benefit compared to what has been observed in historical control cohorts. Outcomes generally observed in these patients reflect only 20-25% who do not require dialysis at 6 months, which also was the basis for powering the trial. However, the treatment response was similar in patients in the control arm treated with the defined SoC alone.

In the trial, SoC was defined as immediate and intense plasma exchange (PLEX) together with cyclophosphamide (CYC) and glucocorticoids.

The administration of imlifidase in combination with SoC proved to be well tolerated with an acceptable safety profile, in keeping with what has been observed in other imlifidase clinical trials.

Renée Aguiar-Lucander, CEO, Hansa Biopharma said “We are disappointed not to be able to provide a new treatment option for this patient group, who to date have experienced poor outcomes. Despite the deep and rapid reduction of anti-GBM antibodies following imlifidase treatment, it did not result in a statistically significant outcome in this setting. We are, however, delighted to see the overall very strong results where approximately 60% of patients did not require dialysis at 6 months, which is almost three-fold that of typically reported outcomes for this disease. I want to thank the patients, investigators and care givers who participated in the trial.” She added: “We remain very excited by imlifidase’ consistent effect, potential in the gene therapy area and that we are on track to file our BLA with the FDA, related to desensitization of highly sensitized patients on the waitlist for kidney transplant, before the year end.”

Professor Mårten Segelmark, International Coordinating Investigator in GOOD-IDES-02 said ”Although the trial did not meet the primary endpoint, the overall outcome, in terms of avoiding dialysis dependency, is encouraging as it shows that anti-GBM patients clearly benefit from receiving a more aggressive treatment compared to what has previously been achieved in clinical practice.”

A total of 50 adult patients were enrolled in the trial, with 25 randomized to receive imlifidase in combination with SoC and 25 receiving SoC treatment only.

GOOD-IDES-02 (Trial ID: 21-HMedIdeS-24) is an open label, multi-centre Phase 3 trial involving over 50 sites in 14 countries in the EU, US and the UK. The primary objective of the study was to assess the effect on kidney function of imlifidase in combination with SoC versus SoC alone in the treatment of patients with severe anti-GBM disease. The primary and key secondary endpoints were assessed at 6 months through the evaluation of renal function as measured by estimated glomerular filtration rate (eGFR) and need for dialysis. Other outcomes include effects of treatment on anti-GBM antibody and ANCA levels, other measures of kidney function, health-related quality of life and safety. Patients continue to be followed up until 24 months after randomisation; long-term outcomes will be reported separately.

More information about the trial is available at ClinicalTrials.gov under NCT05679401.

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 above, at 23:07 CET on December 16, 2026.

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Notes to editors

About anti-GBM disease

Anti-glomerular basement membrane (anti-GBM) disease, also known as Goodpasture disease, is a rare, severe autoimmune condition affecting around 1.6 people per million annually[1] with majority of patients losing their kidney function.[2,3] In anti-GBM disease, the immune system mistakenly develops antibodies against an antigen intrinsic to the glomerular basement membrane, resulting in an acute immune attack of the kidneys and, in around half of the patients, also the lungs. Approximately two thirds of anti-GBM patients will experience kidney failure and require long-term dialysis while awaiting potential kidney transplantation.[4] Some patients may also experience bleeding from the lungs. In one out of six patients, anti-GBM disease can become fatal during the acute phase.

Imlifidase has been granted orphan drug designation for the treatment of anti-GBM disease by both the U.S. FDA and the European Medicinal Agency (EMA).

About imlifidase

Imlifidase is a unique antibody-cleaving enzyme originating from Streptococcus pyogenes that specifically targets IgG and inhibits IgG-mediated immune response.[5] It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration. Imlifidase has conditional marketing approval in the EU, UK, Switzerland and Australia 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 .[5]

About imlifidase, HNSA-5487 and autoimmune diseases

Autoimmune diseases form a group of serious diseases caused by the immune system attacking the body. In many autoimmune diseases the immune system mistakenly recognizes the body's own proteins, as foreign and mounts an immune response, creating antibodies to attack the body's own cells and tissues.[6-8] Pathogenic IgG can contribute to a broad spectrum of autoimmune diseases.

Hansa Biopharma is exploring how imlifidase and HNSA-5487 may be able to prevent or slow the progression of these diseases and their debilitating, life-threatening symptoms. Imlifidase is currently being studied in anti-glomerular basement membrane (anti-GBM) disease. HNSA-5487 is progressing into the clinical phase, with an initial focus on Guillain-Barré Syndrome (GBS).

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 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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