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PRESS RELEASE

# Update on ConfIdeS Phase 3 trial of imlifidase in highly sensitized kidney transplant patients

## Biologic License Application submission expected for 2025

Lund, Sweden, 11 October, 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announced randomization for the US ConfIdeS trial is expected to conclude in mid-2024. The ConfIdeS trial is an open-label, controlled, randomized Phase 3 trial evaluating 12-month kidney function in highly sensitized (cPRA ≥99.9%) kidney transplant patients with positive crossmatch against a deceased donor, comparing desensitization using imlifidase with standard of care.[1] Hansa plans to submit a Biologics License Application (BLA) under the accelerated approval pathway to the U.S. Food and Drug Administration (FDA) in 2025.

To accelerate randomization, Hansa has increased overall site activation up to 25 sites, continued enrollment beyond the targeted 64 patients, and amended the trial protocol to potentially facilitate a broader set of donors for organ allocation. Currently, 87 patients are enrolled in the trial at 16 activated trial sites with nine additional sites being initiated.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "What we now know is that identifying and screening patients for this trial can take anywhere from one week to several months based on patient, donor and site-specific factors including overall patient health and proximity to the site. And, unlike other trials that can progress once patients meet certain criteria, this trial is largely dependent on allocation of suitable organs to consented patients. Organ allocation in the U.S. is managed by an independent third party. With this in mind, randomization is taking weeks and even months in most instances. We appreciate the ongoing commitment and dedication of participating trial centers and are committed to advancing this important clinical trial."

The ConfIdeS trial is evaluating imlifidase as a potential desensitization therapy to enable kidney transplants in highly sensitized patients waiting for a deceased donor kidney through the U.S. kidney allocation system. The study's primary endpoint is kidney graft function at 12 months, measured by eGFR (estimated Glomerular Filtration Rate) in highly sensitized kidney patients following an imlifidase-enabled kidney transplant. The trial design requires randomization of 64 highly sensitized kidney transplant patients with a cPRA of ≥99.9%, representing a subset of very highly sensitized patients.

**Clinical pipeline update**
Hansa has made good progress on patient enrollment in two key trials in autoimmune diseases.

- **GOOD-IDES-02**: Nine of 50 targeted patients enrolled in this global pivotal phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease[2]
- **Investigator-initiated trial in ANCA-associated vasculitis**: Three of 10 targeted patients enrolled in this single-center, single arm Phase 2 trial[3]

Hansa also expects to achieve several milestones by the end of 2023, as previously guided.

- **17-HMedIdeS-14 (Long-term follow-up study in kidney transplantation) 5-year data read-out**: An extended pooled analysis from the 17-HMedIdeS-14 study, a long-term follow-up study of patients who have received a kidney transplant following desensitization with imlifidase[4]

- **15-HMedIdeS-09 (Guillain-Barré Syndrome - GBS) results**: A phase 2 open-label, single arm, multi-centre, study investigating safety, tolerability, efficacy, pharmacodynamics and pharmacokinetics of imlifidase in patients with GBS, in comparison with matched control patients[5]
- **16-HMedIdes-12 (Antibody-Mediated Rejected – AMR) results**: A phase 2 randomized, open-label, multi-center, controlled study evaluating safety, tolerability, and efficacy of imlifidase compared to plasma exchange (PE) in removal of donor-specific antibodies (DSAs) in patients experiencing active and chronic active antibody mediated rejection episodes[6]
- Sarepta Duchenne Muscular Dystrophy (DMD) pre-treatment Phase 1b: Commencement of a clinical trial evaluating imlifidase as pre-treatment in patients with pre-existing IgG antibodies to delandistrogene moxeparvovec, Sarepta's AAV-based gene therapy for the treatment of DMD

**Commercial update**
Total revenue in third quarter (Q3) is SEK 22.8 million, of which SEK 16.5 million is product sales. September year to date (YTD) revenue is SEK 83.7 million, of which SEK 60.4 million is product sales.

During the third quarter several new supply agreements with leading transplant centers in Europe have been secured, which is expected to translate into increased commercial sales in the fourth quarter and the periods to come, supported by new markets such as U.K., Germany, and Belgium where patient identification is ongoing as organs become available.

Total cash and equivalents stood at SEK 908 million (USD 83m) end of September 2023 which is expected to finance Hansa's operations into 2025, as previously guided.

**Hansa to publish its interim report for January-September 2023 at 8:00 CET on October 26, 2023**
All interested parties are invited to participate in a telephone conference, which will include a presentation of the interim results and a business update, on the same date at 14:00 CET/8:00am EST. The event will be hosted by Hansa Biopharma's CEO, Søren Tulstrup, CCO and US President, Matthew Shaulis and CFO, Donato Spota. The presentation will be held in English.

Slides used in the presentation will be live on the company website during the call under "Events & Presentations" and will also be made available online after the call. Link to presentation

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

Sweden: +46 812 410 952

United Kingdom: +44 203 769 6819

United States: +1 646 787 0157

Participant access code: 765135

The webcast will be available on https://hansabiopharma.eventcdn.net/events/q3-2023-conference-call

*This is information that Hansa Biopharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the contact person set out above, at 18:35 CET on October 11 2023.*

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## 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.[7] It has a rapid onset of action, cleaving IgG-antibodies and inhibiting its activity within hours after administration. 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.[8-11]

Imlifidase is conditionally approved in Europe and 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 imlifidase should be reserved for patients who are unlikely to be transplanted under the available kidney allocation system, including prioritization programs for highly sensitized patients.[7] Imlifidase 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.[7]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[8] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[12] Once they are inactivated with imlifidase, there is a window of opportunity for the transplant to take place. By the time the body starts to synthesize new IgG, the patient will be receiving post-transplant immunosuppressive therapy to reduce the risk of organ rejection.

## HMedIdes Clinical Trial Program

17-HMedIdeS-14 is part of the HMedIdeS clinical program for imlifidase. The program includes four global phase 2 trials (13-HMedIdeS-02, 13-HMedIdeS-03, 14-HMedIdeS-04 and 15-HMedIdeS-06), one US open-label phase 3 trial (ConfIdeS), a long-term follow up study (17-HMedIdeS-14) and a post-authorization efficacy and safety study in Europe (PAES).

## About kidney failure and highly sensitized patients

Kidney disease can progress to kidney failure or End-Stage Renal Disease (ESRD), identified when a patient's kidney function is less than 15%.[13] 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 has cost savings compared to long-term dialysis. There are approximately 80,000 kidney patients on transplant waiting lists across the European Union.[13]

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.[14] 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.[15,16] 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.[15,16] Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[17,18]

## About Hansa Biopharma

Hansa Biopharma 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. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and

development program based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. 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.

Full product information can be accessed via the initial Summary of Product Characteristics found here.

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