

## PRESS RELEASE

# Hansa Biopharma to attend 2025 J.P. Morgan Healthcare Conference

Lund, Sweden, 7 January 2025. Hansa Biopharma AB, “Hansa” or the “Company” (Nasdaq Stockholm: HNSA), today announced that management will attend the 43<sup>rd</sup> Annual J.P. Morgan Healthcare Conference. If you are interested in a meeting, please contact Hansa Biopharma at [ir@hansabiopharma.com](mailto:ir@hansabiopharma.com).

The Company has achieved several key milestones in the last 12-months across its three key therapeutic areas: Autoimmune, Gene Therapy and Transplantation.

In Autoimmune, the company announced positive data from the 15-HMedIdeS-09 Phase 2 trial in Guillain Barre Syndrome (GBS) and indirect treatment comparison to the International Guillain-Barré Syndrome Outcome Study (IGOS) demonstrating the potential of imlifidase, the Company’s first-generation IgG cleaving molecule, to address a significant unmet need in GBS. Additionally, the GOOD-IDES-02 (Phase 3 trial in anti-GBM) completed enrolment and positive results from the NICE-01 Phase 1 trial and additional 12-month analysis for HNSA-5487, the Company’s second-generation IgG cleaving molecule, demonstrated rapid and robust IgG reduction and redosing potential.

In Gene Therapy, the Company initiated two trials with gene therapy partners: SRP-9001-104 Phase 1b trial in Duchenne Muscular Dystrophy (DMD) with Sarepta Therapeutics, Inc. (Nasdaq: SRPT) and GNT-018-IDES Phase 2 trial in Crigler-Najjar Syndrome with Genethon. In both trials, imlifidase is being evaluated as a pre-treatment to gene therapy in patients with anti-AAV antibodies.

In Transplantation, randomization of the ConfldeS (pivotal US Phase 3 trial in kidney transplantation) trial was completed. The Company had four consecutive quarters of strong IDEFIRIX (imlifidase) sales across Europe with Q3 2024 being the highest ever quarterly IDEFIRIX sales performance (69.5 MSEK/\$6.4M), underscoring the important role that IDEFIRIX can play in desensitization in kidney transplantation.

In 2025, the Company has several key milestones:

- Data read out of the pivotal US Phase 3 ConfldeS trial for imlifidase and submission of a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) in 2H 2025
- Data read out of Sarepta Therapeutics’ Phase 1b trial SRP-9001-104 in DMD (2H 2025)
- Data read out of the GOOD-IDES-02 Phase 3 trial in anti-GBM
- HNSA-5487 development pathway alignment with regulatory agencies in neuro-autoimmune diseases (1H 2025) with an initial focus in myasthenia gravis (MG)

Hansa is developing novel immunomodulating biologic therapies based on its proprietary, first in class IgG cleaving platform and is focused on IgG-driven immune mediated diseases. The Company

has two IgG cleaving compounds including imlifidase, a first generation, first in class, single dose therapy with proven efficacy and safety and HNSA-5487, a second-generation IgG cleaving molecule with redosing potential. Imlifidase is conditionally approved in the EU for desensitization in kidney transplantation, with late-stage trials in autoimmune diseases where IgG is a driver of disease, and as a pre-treatment to gene therapy in patients with anti-AAV antibodies.

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**Notes to editors**

**About Imlifidase**

Imlifidase is a unique antibody-cleaving enzyme originating from *Streptococcus pyogenes* that specifically targets IgG and inhibits IgG-mediated immune response.<sup>1</sup> It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration. Imlifidase is conditionally approved 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.<sup>1</sup> Full product information can be accessed via the initial Summary of Product Characteristics found [here](#).

**About HNSA-5487**

HNSA-5487 is Hansa Biopharma's second-generation IgG-cleaving enzyme with the potential to prolong the IgG-low window and redosing potential. In the NICE-01 Phase 1b trial, HNSA-5487 demonstrated rapid and highly robust reduction of IgG levels by more than 95 percent within a few hours post treatment. In a 12-month follow up analysis IgG levels returned to normal range six months after initial dosing. This confirms that HNSA-5487 mirrors the extremely high efficacy of imlifidase, the Company's first-generation IgG-cleaving enzyme, in reducing total IgG levels. No serious adverse events were observed and as previously communicated HNSA-5487 is safe and well tolerated.

**About Hansa and Kidney Transplantation**

Kidney disease can progress to kidney failure or End-Stage Renal Disease (ESRD), identified when a patient's kidney function is less than 15%.<sup>2</sup> ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.<sup>2</sup> 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 U.S. and Europe waiting for a new kidney.<sup>3</sup>

Highly sensitized kidney transplant 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.<sup>4</sup> 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.<sup>5,6</sup> 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.<sup>7,8</sup> Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.<sup>9,10</sup>

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).<sup>11</sup> Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.<sup>4</sup> 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.

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.<sup>10-13</sup> Hansa is collecting further clinical evidence and will submit additional efficacy and safety data based on one observational follow-up study and one post authorization efficacy study (PAES).

### **About Hansa 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.<sup>14-16</sup> 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 the following autoimmune diseases: anti-glomerular basement membrane (anti-GBM) disease and Guillain-Barré Syndrome (GBS). HNSA-5487 is moving quickly into the clinical phase focusing on patients with myasthenia gravis (MG) and potentially other neuro-autoimmune diseases.

### **About Hansa and Gene Therapy**

Imlifidase is currently being evaluated as a pre-treatment to gene therapy in areas of high unmet need. Many gene therapies are based on the use of Adeno Associated Viruses (AAV) vectors.<sup>17-19</sup> In some patients the immune system carries antibodies that counteract the gene therapy treatment preventing its success.<sup>18-24</sup> Pre-treatment with imlifidase prior to AAV-based gene therapy treatment has the potential to inactivate antibodies and thereby enable gene therapy in patients with pre-existing antibodies to AAV-based gene therapies.<sup>23</sup> It is estimated that anti-AAV antibodies on average prevent 1 in 3 people from benefiting from gene therapy treatments.<sup>18-21</sup>

### **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. 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 second-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](http://www.hansabiopharma.com) and follow us on [LinkedIn](#).

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