

## PRESS RELEASE

# Hansa Biopharma provides update on business and key financials ahead of the JP Morgan Healthcare Conference

- Strong revenue generation in Q4 2023, including SEK 43m in Idefirix® product sales supported by growth in new markets such as U.K., Germany, and Spain
- Encouraging first results from first-in-human trial of HNSA-5487, Hansa's lead candidate from the NiceR program for repeat dosing
- Initiation of phase 1b trial of imlifidase as pre-treatment to Sarepta's SRP-9001 in DMD

Lund, January 6, 2024. Hansa Biopharma today announced a business update for the fourth quarter of 2023 and certain preliminary, unaudited key financials for the fourth quarter and full year 2023.

Søren Tulstrup, President and CEO, Hansa Biopharma said: "Hansa enters 2024 in a strong position to successfully execute on our key priorities. I am particularly encouraged by the strong commercial performance of Idefirix® in the fourth quarter of 2023 and the continued progress we have achieved across our pipeline, with positive phase 2 data read-outs in several potential new indications for imlifidase as well as a positive first-in-human trial of HNSA-5487, Hansa's lead candidate in the Novel Immunoglobulin Cleaving Enzymes for Repeat Dosing (NiceR) program. We also continue to expand access to imlifidase for highly sensitized kidney transplant patients through a new commercial partnership with NewBridge in the MENA region. Finally, in December 2023 the first clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in Duchenne Muscular Dystrophy (DMD) was initiated."

Management will be available for meetings in San Francisco during the J.P. Morgan Conference week, January 8-11, 2024. Susan Noonan is coordinating the schedule on behalf of Hansa Biopharma and can be reached at [susan@sanoonan.com](mailto:susan@sanoonan.com).

The latest investor presentation can be downloaded through following link  
<https://www.hansabiopharma.com/investors/presentations/>

### Business Update

#### Strong commercial performance in the fourth quarter of 2023

Hansa expects to report total fourth quarter revenue of SEK 50m consisting of SEK 43m in product sales and SEK 7m in revenue recognition mainly under the agreement with Sarepta Therapeutics. Product sales is driven by growth in new markets such as U.K., Germany, and Spain.

#### Commercial partnership with NewBridge in the MENA region

Hansa and NewBridge Pharmaceuticals have formed a partnership to enable supply of Hansa's novel treatment Idefirix® to kidney transplant patients in the Middle East and North Africa (MENA) through NewBridge's capabilities. The new collaboration is rooted in the existing European conditional marketing authorization for Idefirix and pending application for marketing authorization in the respective MENA markets for desensitization treatment in kidney transplantation.

### Clinical pipeline update

- US ConfIdeS phase 3 trial (kidney transplantation): 101 patients have been enrolled with close to 2/3 of 64 targeted patients randomized in the pivotal U.S. open label, randomized, controlled trial of imlifidase in kidney transplantation.
- GOOD-IDES-02 phase 3 (anti-GBM disease): 16 of 50 targeted patients enrolled in this global pivotal phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease. Completion of enrollment is expected in 2025.

- Investigator-initiated phase 2 trial (ANCA-associated vasculitis): 3 of 10 targeted patients enrolled.
- NICE-01 phase 1 (HNSA-5487): Following positive results from the first-in-human trial of HNSA-5487, the lead candidate from the NiceR program for repeat dosing, analysis of additional exploratory endpoints on IgG recovery and immunogenicity is being conducted. The analysis is expected to be complete in 2024 and will help determine further clinical development, including selection of indications.
- SRP-9001-104 phase 1b trial (Duchenne Muscular Dystrophy, DMD): The first clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD was initiated mid-December 2023. First patient is expected to be dosed in due course.

## Key Financials (preliminary, unaudited)

<i>SEK million</i>	Q4 2023	FY 2023
Total Revenue	50	134
Product sales	43	103
SG&A expenses	-107	-452
R&D expenses	-108	-411
Operating profit/loss	-177	-790
Cash and short-term investments Dec 31, 2023	732	732

The fourth quarter 2023 interim report including a comprehensive business update and complete condensed financial statements will be published on February 2, 2024.

## Upcoming milestones and news flow

2024	First high level data read-out from phase 1b study in DMD with Sarepta (NEW)
2024	GBS Phase 2: Outcome of the comparative efficacy analysis to IGOS data
2024	Genethon Crigler-Najjar Phase 1/2: Initiate clinical study with imlifidase prior to GNT-0003
2024	HNSA-5487: Further analysis around endpoints in FIH trial
2024	U.S. ConfIdes (Kidney tx) Phase 3: Complete randomization
2025	U.S. ConfIdes (Kidney tx) Phase 3: BLA submission
2025	Anti-GBM disease Phase 3: Completion of enrollment (NEW)

## Conference call details

Hansa Biopharma will host a telephone conference Friday February 2, 2024, 14:00 CET / 8:00am EST.

The event will be hosted by Hansa Biopharma's CEO, Søren Tulstrup, CCO and U.S. 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.

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

Sweden: +46 8 12 41 0952

UK: +44 203 769 68 19

USA: +1 646 787 0157

Participant access code: 765135

The webcast will be available on <https://hansabiopharma.eventcdn.net/events/fullyear2023>

*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 persons set out below, at 14:00 CET on January 6, 2024.*

--ENDS--

**For more information:**

Klaus Sindahl, *VP Head of Investor Relations*

**M:** +46 (0) 709–298 269

**E:** [klaus.sindahl@hansabiopharma.com](mailto:klaus.sindahl@hansabiopharma.com)

Stephanie Kenney, *VP Global Corporate Affairs*

**M:** +1 (484) 319 2802

**E:** [stephanie.kenney@hansabiopharma.com](mailto:stephanie.kenney@hansabiopharma.com)

**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 <https://hansabiopharma.com>.