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PRESS RELEASE

Hansa Biopharma provides business update including certain key financials

- Commercial launch and market access efforts in Europe progressing as planned; New multiregional commercialization partnership with Medison in Central Eastern Europe and Israel
- First patients enrolled into the pivotal U.S. ConfIdeS study; Agreement established with AskBio to evaluate feasibility of imlifidase as pre-treatment ahead of gene therapy in Pompe disease
- Platform strategy: Hansa to explore desensitization treatment in allogeneic hematopoietic stem cell transplantation
- Year-end cash position of SEK 889 million; Hansa financed into 2023, as previously guided

Lund, Sweden January 9, 2022 Hansa Biopharma AB, "Hansa", (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announces a business update for the fourth quarter 2021 and certain preliminary, unaudited key financials for its financial year 2021.

The Company will participate in the virtual J.P. Morgan week from January 10 to 13, 2022. Access to Hansa Biopharma's most recent investor presentation will be available under Events & Presentations in the Investor section of the Company website at www.hansabiopharma.com.

Management will be available for meetings during the J.P. Morgan week. If you wish to schedule a meeting please contact Susan Noonan at susan@sanoonan.com and she will coordinate the schedule on behalf of Hansa Biopharma.

Business Update

Hansa continues to make solid progress in its clinical, commercial and corporate strategy as the Company builds and advances its pipeline of valuable drug candidates for rare immunologic diseases while launching Idefirix® in Europe.

Commercialization in Europe

Idefirix® is the first and only approved drug to enable kidney transplants in highly sensitized patients in the EU, who are incompatible with a deceased donor. Operationally, Hansa's market access activities in Europe continue according to plan in the early launch countries. Pricing and reimbursement have now been secured in four countries: Sweden, the Netherlands as well as on a hospital basis in Finland and Greece.

Market access procedures are ongoing in thirteen countries, including France, Belgium and Greece, initiated during the fourth quarter of 2021. In addition, upon receipt of initiation of procedures from the Ministry of Health in Spain in January 2022, the Health Technology Assessment dossier for Spain is expected to be submitted during the first quarter of 2022, which will complete HTA filings in all of the five largest markets in Europe.

In December 2021, Hansa and Medison Pharma announced a multiregional commercialization partnership for Hansa's desensitization treatment for kidney transplantion covering Israel and major countries in the Central Eastern European region. Commercialization will be based on the current conditional marketing authorization for Europe, and a pending marketing authorization by Israel's Ministry of Health.

The commercial partnership with Medison Pharma represents an important milestone for Hansa as the Company expands access to imlifidase for highly sensitized patients incompatible with a deceased donor.

Lastly, Hansa expects to commence a Post Approval Study (PAS) during 2022 in Europe, in which approximately 50 highly sensitized patients will be treated with imlifidase. The new study will target clinics beyond the first wave of investigators in the Phase 2 programs and will expand to approximately 20 centers across major academic centers in Europe. Each center will enroll about two to five patients, which will build the foundation for a new standard of care in desensitization with imlifidase while we continue to expand our commercial capabilities globally.

Agreement with AskBio to evaluate feasibility of imlifidase ahead of gene therapy in Pompe disease

On January 3, 2022 Hansa announced its agreement with AskBio, a fully integrated AAV gene therapy company and a fully owned subsidiary of Bayer AG dedicated to developing medicines that improve the quality of life for patients with genetic diseases,

The collaboration will evaluate the potential use of imlifidase as a pre-treatment prior to the administration of AskBio's gene therapy in Pompe disease in a pre-clinical and clinical feasibility program for patients with pre-existing neutralizing antibodies (NAbs) to adeno-associated virus (AAV).

Under the terms of the agreement, Hansa will receive a USD 5 million payment upon execution of the agreement and AskBio will have an exclusive option to enter into a full development and commercialization agreement following evaluation of the results from an initial Phase I/II study.

U.S. Randomized Controlled Trial "ConfIdeS"

On December 29, 2021, Hansa announced that the first patient in its pivotal U.S. open-label, randomized, controlled trial "ConfIdeS" was enrolled at the Columbia University Medical Center, New York.

The ConfIdeS study 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.

As of January 8, 2022, two out of a target of 64 patients have been enrolled. Completion of enrollment in the study is expected in the second half of 2022, with a 12-month follow-up study expected to be completed in the second half of 2023, as previously guided. Results from this clinical study could support a potential BLA submission to the FDA under the accelerated approval pathway in the first half of 2024.

Further study details can be found on ClinicalTrials.gov NCT04935177.

Platform strategy - Hansa intends to explore allogeneic hematopoietic stem cell transplantation (HSCT)

As part of Hansa Biopharma's platform strategy and objective to broaden the application of imlifidase as a potential therapy to change the course of IgG-mediated immunological diseases, the Company is exploring high unmet need indications both through Investigator-Sponsored Trials (IST) programs and Hansa-Sponsored trials.

One of the indications Hansa intends to explore further is allogeneic hematopoietic stem cell transplantation (HSCT), also known as "bone-marrow transplantation". Anti-HLA antibodies against the donor may prevent the successful engraftment of donor cells in a patient requiring allogenic HSCT. Allogeneic HSCT is the only curative treatment intervention for most patients with high-risk hematologic malignancies, with over 50,000 transplants performed annually worldwide.

Desensitization treatment of patients with high levels of donor specific antibodies (DSA) prior to allogeneic HSCT transplant is a challenge, and currently there are no approved drugs for managing these patients. Imlifidase may have the potential to transform the standard of care by enabling clinicians to inactivate DSAs prior to transplantation and has thus the potential to enable successful transplantation. Treatment with imlifidase would potentially be a major advancement to currently available treatments.

Clinical pipeline update

GBS (Guillain Barré Syndrome)

As of January 8, 2022, 15 out of a target of 30 patients with Guillain Barré Syndrome, GBS, have been enrolled in a Phase 2 study with imlifidase.

Antibody Mediated Rejection (AMR)

As of January 8, 2022, 23 out of a target of 30 patients with active antibody mediated rejection (AMR) episodes have been enrolled in a Phase 2 study with imlifidase.

Anti-Glomerular Basement Membrane (anti-GBM) antibody disease

On November 15, 2021, Hansa announced plans to initiate a Phase 3 study of imlifidase to treat anti-Glomerular Basement Membrane (anti-GBM) disease after a successful pre-IND meeting with the U.S. FDA.

The planned pivotal Phase 3 clinical study will enroll approximately 50 patients with anti-GBM disease across the U.S. and Europe. The first patient is expected to be enrolled in 2022.

Pre-clinical programs

NiceR next generation enzymes for repeat dosing

Development of Hansa's next generation enzymes for repeat dosing is progressing according to plan. IND-enabling toxicology studies for the lead NiceR candidate were initiated during the second quarter 2021 in preparation for a clinical Phase 1 study. The toxicology studies are expected to be completed in 2022. Upon completion of these studies, Hansa expects to advance the NiceR program into the clinic.

Imlifidase as pre-treatment ahead of gene therapy in DMD and LGMD

In July 2020, Hansa Biopharma entered into an exclusive agreement with Sarepta Therapeutics, Inc. (Sarepta) to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy in Duchenne muscular dystrophy (DMD) and Limb girdle muscular dystrophy (LGMD) in patients with neutralizing antibodies (NAbs) to adeno-associated virus (AAV).

The partnership is progressing as planned with pre-clinical investigations with imlifidase as a potential pre-treatment in the gene therapy setting. For further information regarding Sarepta's gene therapy programs in DMD and LGMD, please refer to www.sarepta.com.

Pre-clinical research collaboration with argenx BV

In March 2021, Hansa Biopharma announced a pre-clinical research collaboration agreement with argenx BV (argenx) to explore the potential of combining imlifidase, Hansa's IgG antibody-cleaving enzyme, and efgartigimod, argenx's FcRn antagonist, to potentially unlock additional therapeutic value in both the acute and chronic setting of autoimmune diseases and transplantation. The pre-clinical collaboration is progressing according to plan.

Key Financials (preliminary, unaudited)

For the financial year 2021, total revenue amounts to approximately SEK 34 million and total operating loss approximately SEK 547 million. As of December 31, 2021, the Company had a cash position (including short-term investments) of approximately SEK 889 million, which is expected to finance Hansa's operations into 2023, as previously guided.

Key Financials (Group level) *SEK million*	Q4 2021	FY 2021
Total Revenue	**15**	**34**
thereof: Product sales	9	15
SG&A expenses	103	328
R&D expenses	68	230
Operating profit/loss	-163	-547
Cash and short-term investments Dec 31, 2021	889	889

The fourth quarter 2021 interim report including condensed financial statements will be published on February 3, 2022.

COVID-19 pandemic

The COVID-19 pandemic is the defining global health crisis of our time. With the emergence of the new Omicron variant Hansa continues to take measures to protect employees and be socially responsible during this global pandemic while working to limit the potential negative effects on its business.

The current guidance for initiation of additional studies, study centers or completion of enrollment in ongoing studies is subject to change depending on the ongoing and potential future negative impact of the COVID-19 pandemic.

Upcoming milestones and news flow

H1 2022	AMR Phase 2 study: Complete enrollment
H1 2022	GBS Phase 2 study: Complete enrollment
2022	Anti-GBM: Initiation of Phase 3 study
2022	NiceR: Completion of GLP tox studies
H2 2022	Kidney transplantation U.S.: Complete enrollment
H2 2022	AMR Phase 2 study: First data read out
H2 2022	GBS Phase 2 study: First data read out
H2 2023	Kidney transplantation U.S.: 12 months follow-up completed
H1 2024	Kidney transplantation U.S.: BLA submission

Updated Financial calendar and events

Jan 9-13, 2022	JPM Week 2022, San Francisco (virtual)
Jan 10-13, 2022	HC Wainwright BioConnect (virtual)
Jan 18, 2022	SEB Nordic Healthcare Seminar, Stockholm/virtual
Feb 3, 2022	**Year-End report for Jan - Dec 2021**
Mar 10, 2022	Erik Penser Bolagsdag, Stockholm
Mar 10, 2022	Redeye Investor Forum, Gothenburg
Mar 15, 2022	Carnegie Healthcare Seminar 2022, Stockholm
Mar 31, 2022	Redeye Investor Forum, Malmo
April 7, 2022	**Annual Report 2021**
April 21, 2022	**Interim Report for January-March 2022**
April 21, 2022	Kempen Life Sciences Conference 2022, Amsterdam
April 27, 2022	Redeye Orphan Drugs 2022, Stockholm
May, 2022	RBC Global Healthcare Conference 2022, New York City
June 16, 2022	**Annual General Meeting 2022**
July 21, 2022	**Half year 2022 report**
Oct 20, 2022	**Interim Report for January-September 2022**

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.

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