Hansa Biopharma provides business update incl. certain key financials ahead of the JP Morgan Global Healthcare Conference

- Commercial launch activities for Idefirix® progressing as planned
- Patient recruitment in the two phase 2 studies in AMR and GBS was reinitiated in December 2020
- Year-end cash position of SEK 1.4 billion

Lund, Sweden January 11, 2021. Hansa Biopharma, the leader in immunomodulatory enzyme technology for rare IgG mediated diseases, today announced a business update for the fourth quarter 2020 and certain preliminary, unaudited key financials for its financial year 2020.

The Company will be participating in the JP Morgan Global Healthcare Conference in San Francisco from January 11 to 14, 2021, with a corporate presentation on Thursday, January 14, at 7:30am EST/13:30 CET.

COVID-19 pandemic

Hansa has an exciting year ahead with the Company's first product being launched in Europe. However, the global COVID-19 pandemic may still adversely impact Hansa Biopharma's operational business and trial activities.

Hansa Biopharma continues to take measures to protect employees and take social responsibility during this global healthcare crisis, while working to limit the potential negative effects on its business.

"Hansa enters the new year well positioned to execute successfully on our key priorities and objectives for 2021, which are to ensure the successful launch of Idefirix® in leading transplantation centres in select European markets, initiate a randomized, controlled clinical study in the US to support a future filing of a BLA in the US, and continue the strong current momentum behind our efforts to advance our pipeline of drug candidates within auto-immune diseases and gene therapy" states **Søren Tulstrup, President and CEO, Hansa Biopharma.**

Business Update

Commercialization in Europe

Hansa Biopharma's evolution into a fully integrated, commercial stage biopharmaceutical company took a major step forward in the third quarter 2020 following the conditional approval of Idefirix® (imlifidase) by the European Commission for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

Commercial launch activities are underway as planned. Depending on the impact of the escalating COVID-19 pandemic, it is expected that the first commercial patient will be treated with Idefirix® during the first quarter of 2021.

During the fourth quarter of 2020, pricing for Idefirix® was published in the first markets and agreements around reimbursement with healthcare providers and payers are expected to be completed in the early launch countries throughout the course of 2021.

The information was submitted for publication, through the contact person set out below, at 08:00 a.m. (CET) on January 11, 2021.

Contact information

Klaus Sindahl
Head of Investor Relations
Hansa Biopharma
M: +46 (0) 709–298 269
E: klaus.sindahl@hansabiopharma.com

Katja Margell
Head of Corporate Communications
Hansa Biopharma
M: +46 (0) 768-198 326
E: katja.margell@hansabiopharma.com

About Hansa Biopharma

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer.

The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications.

Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in both Europe and the U.S.

Hansa Biopharma
Scheelevägen 22
SE- 223 63 Lund, Sweden
Phone: +46 46 16 56 70
www.hansabiopharma.com

Nasdaq OMX Stockholm

Randomized Controlled Trial in the US

Hansa is in ongoing discussions with the U.S. Food and Drug Administration (FDA) around a proposed study protocol for a new, randomized controlled study of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients.

Depending on the development of the escalating COVID-19 pandemic in the United States and on the resulting impact on enrollment, the Company expects to complete enrollment of this study in 2022 enabling a potential Biologics License Application (BLA) submission by 2023 under the accelerated approval pathway.

Clinical pipeline update

GBS (Guillain Barré Syndrome)

- Five out of 30 targeted patients with Guillain Barré Syndrome, GBS, have been enrolled in a phase 2 study with imlifidase. The recruitment process to the phase 2 study was temporarily paused due to the COVID-19 pandemic and reinitiated in the fourth quarter 2020 as previously guided.

Antibody Mediated Rejection (AMR)

- Four of 30 targeted patients with active AMR episodes have been enrolled in a phase 2 study with imlifidase. The recruitment process to the phase 2 study was temporarily paused due to the COVID-19 pandemic and was reinitiated in the fourth quarter 2020 as previously guided.

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

- On September 24, 2020, positive high-level data was presented from the investigator-initiated phase 2 trial with imlifidase to treat anti-GBM disease with two-thirds of patients achieving dialysis independence six months after treatment. The positive data marked an important milestone for Hansa Biopharma's expansion of imlifidase outside transplantation.
- Regulatory discussions with the European Medicines Agency (EMA) and FDA will be initiated to determine the regulatory path forward for imlifidase in anti-GBM.

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 and initiation of IND-enabling toxocology studies is expected to commence in the first half of 2021.

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

- On July 2, 2020, Hansa announced an exclusive agreement with Sarepta Therapeutics 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).
- The partnership has progressed as planned and during the second half of 2020, Sarepta initiated ongoing pre-clinical investigations with imlifidase as a potential pre-treatment in the gene therapy setting. On January 7, Sarepta announced top-line results for part 1 of Study 102 evaluating SRP-9001, one of its investigational gene therapy candidates for the treatment of Duchenne Muscular Dystrophy. Imlifidase was not given to any patients in this study. For further information, please refer to www.sarepta.com.

Key Financials (preliminary, unaudited)

For the financial year 2020, total Operating loss is expected to be approximately SEK 425 million. As of December 31, 2020, the company had a cash position (including short-term investments) of approx. SEK 1.4 billion, which is expected to finance Hansa's operations into 2023.

SEK million	Q4 2020	FY 2020
SG&A expenses	63	202
R&D expenses	53	230
Operating profit/loss	-108	-425
Cash and short-term investments Dec 31, 2020	1,378	1,378

The fourth quarter 2020 interim report including condensed financial statements will be published on February 4, 2021.