Hansa Biopharma provides business update ahead of the JP Morgan Global Healthcare Conference

- Responses to Day 120 questions submitted for EMA MAA of imlifidase
- First patients dosed in GBS trial; Enrollment in anti-GBM trial near completion
- Solid year-end cash position

Lund, Sweden January 12, 2020. Hansa Biopharma, the leader in immunomodulatory enzyme technology for rare IgG mediated diseases, today announced a business update for the fourth quarter 2019 and preliminary, unaudited key financials for its financial year 2019.

The company will be participating in the JP Morgan Global Healthcare Conference in San Francisco from January 13 to 16, 2020.

2019 Fourth Quarter Business Highlights

The European Medicines Agency (EMA) is reviewing a Marketing Authorization Application for imlifidase in Europe. Hansa Biopharma submitted responses to the Day 120 questions on December 22, 2019 and the review process is on track. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected in the second quarter of 2020, followed by a potential decision by the European Commission during the summer 2020.

Hansa Biopharma met with the FDA on November 20th and agreed on a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients in the United States. Hansa will conduct a randomized, controlled clinical study in a well-defined population of approximately 50 patients with the highest unmet medical need to demonstrate the clinical benefit of imlifidase in the context of the U.S. Kidney Allocation System. It is expected that the outcome of this study will support submission of a Biologic License Application (BLA) by 2023.

“Our primary focus in 2020 is to obtain conditional approval of imlifidase in the EU, ensure a successful launch in Europe, and initiate a randomized, controlled clinical study in the US to support a future filing of a BLA in the United States”, says Søren Tulstrup, President and CEO, Hansa Biopharma.

Hansa Biopharma has submitted an abstract with long term outcomes of desensitization with imlifidase to the Cutting Edge of Transplantation, CEOT, an annual congress arranged by the American Society of Transplantation on March 5-7, 2020. The long term data indicate that the graft survival for this study population of highly sensitized and cross match positive population was overall comparable to data reported in the literature with other desensitization methods and the general transplantation patient population. Desensitization with imlifidase may provide highly sensitized patients, who are unlikely to find an HLA compatible donor, access to deceased donor organs, potentially reducing mortality and time on the waiting list.

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About Hansa Biopharma

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

The Company’s lead product candidate, imlifidase, is a unique antibody-cleaving enzyme that potentially may enable kidney transplantation in highly sensitized patients with potential for further development in other solid organ transplantation and acute autoimmune indications. Imlifidase is currently under review for marketing authorization by EMA. Hansa’s research and development program is advancing the next generation of the Company’s technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology.

Hansa Biopharma is based in Lund, Sweden and also has operations in Europe and US.

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Clinical pipeline update

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

- Hansa Biopharma has enrolled 14 of targeted 15 patients to date in a phase 2 study to evaluate the safety and efficacy of imlifidase in patients with severe Anti-GBM.
- Anti-GBM is an ultra-rare disease affecting one in a million annually with the majority of the patients losing their kidneys, requiring chronic dialysis and kidney transplantation.
- Six patients were recruited during the last six months and the Company expects to complete enrollment during the first quarter of 2020 and data read out in the second half of the year.

GBS (Guillain Barré Syndrome)

- The first two patients (out of 30) with Guillain Barré Syndrome, GBS, were treated in a phase 2 study with imlifidase.
- GBS is an acute autoimmune attack on the peripheral nervous system, which affects 1 in 100,000. GBS is a severe disease where up to 22 % of the patients end up in ICU needing respiratory support.
- Six clinics across France and the UK are open for recruitment and the Company expects to complete enrollment during the first half of 2021.

AMR (Antibody Mediated Rejection)

- 2 out of targeted 30 patients enrolled in a phase 2 study in Antibody Mediated Rejection, AMR, a challenge to long term graft survival after kidney transplantation.
- Six clinics are recruiting across the US, Europe and Australia. The Company expects to complete enrollment towards the end of 2020.

Key Financials (preliminary, unaudited)

For the financial year 2019, total Operating loss is expected at approx. SEK 360 million. As of December 31, 2019 the company had a cash position (incl. short-term investments) of SEK 601 million, which is expected to finance Hansa's operations at least through 2020.

SEK million	Q4 2019	FY 2019
SG&A expenses	-53	-167
R&D expenses	-58	-193
Operating profit/loss	**-110**	**-360**
Cash and short-term investments Dec 31, 2019	**601**	**601**

The Q4-2019 interim report including audited financials will be published on February 6, 2020.