Hansa Biopharma receives positive CHMP opinion for Idefirix™ (imlifidase) for kidney transplant in EU

The positive opinion marks an important milestone as the Company prepares its transformation into a commercial stage biopharmaceutical company.

Lund, Sweden June 25, 2020. Hansa Biopharma, the leader in immunomodulatory enzyme technology for rare IgG mediated diseases, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending conditional approval of Idefirix™ (imlifidase) for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020.

"We are very excited to receive a positive opinion from the CHMP. This brings hope to the thousands of highly sensitized patients across Europe waiting for a life-saving kidney transplant and takes Hansa Biopharma one important step closer to becoming a commercial stage biopharmaceutical company" says **Søren Tulstrup, President and CEO of Hansa Biopharma.**

"Today's decision by the CHMP further serves to validate the potential of Hansa Biopharma's proprietary drug development engine to develop approvable immunomodulatory drug candidates for rare and serious diseases and comes at a time when we are significantly expanding our activities into autoimmune diseases, gene therapy and oncology".

The Marketing Authorization Application for imlifidase in kidney transplant was accepted for review by the European Medicines Agency on Feb. 28, 2019 based on data from four completed phase 2 studies across Sweden, France and the United States. Imlifidase met all primary and secondary endpoints in each study.

Imlifidase was supported through EMA's PRIority MEdicines (PRIME) scheme, which provides early and enhanced scientific and regulatory support to medicines that have a particular potential to address patients' unmet medical needs. Imlifidase was granted eligibility to PRIME in May 2017.

In the US, following overall agreement with the FDA, Hansa Biopharma submitted a study protocol to the FDA on June 17, 2020. The randomized, controlled clinical study is planned to be initiated in Q4 this year and could support a future BLA submission in the US by 2023, as communicated earlier. The Company aims to recruit 45 highly sensitized patients at 10-15 centers in the US for this study.

Clinical pipeline

Enrollment in the investigator initiated Anti-GBM study was completed at the end of January 2020 and the first data read-out is expected in the third quarter of 2020 as previously guided.

In the AMR and GBS phase 2 studies, 4 of the targeted 30 patients have been treated with imlifidase in the respective studies. Enrollment in the AMR and GBS studies is expected to be completed in H1 2021 and H2 2021, respectively, as communicated previously.

Contact information

Klaus Sindahl
Head of Investor Relations
Hansa Biopharma
M: +46 (0) 709–298 269
E: klaus.sindahl@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, transplant rejection and cancer.

The Company's lead product candidate, imlifidase, is an antibodycleaving 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.

CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020.

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 and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

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

Nasdaq OMX Stockholm
Ticker: HNSA
ISIN: SE 0002148817

About imlifidase

Imlifidase is a unique antibody-cleaving enzyme originating from *Streptococcus pyogenes* that specifically targets IgG and inhibits IgG-mediated immune response. It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration.

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Hansa has also reached an agreement with the FDA on a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients in the U.S. and has three ongoing phase 2 trials in autoimmune diseases and post-transplant indications.