Hansa Biopharma submits responses to outstanding questions from EMA on May 26. Review is on track; an opinion from CHMP is expected by end of June.

Lund May 25, 2020. Hansa Biopharma, the leader in immunomodulatory enzyme technology for rare IgG mediated diseases, today announced that the ongoing EMA review of imlifidase for a potential marketing authorization in Europe is on track. A CHMP opinion is expected at the June 22-25 meeting, followed by a decision by the European Commission in Q3 2020.

At the CHMP meeting on April 28-30 a list of outstanding issues was adopted, including definition of patient population and design of the post approval study. A one-month clock-stop was initiated to enable Hansa Biopharma to address the outstanding issues. The Company will submit a comprehensive response on May 26 and expect an opinion from CHMP following the June 22-25 meeting.

"The EMA review process is progressing in line with our previous guidance. Throughout the process, we have had a positive and constructive dialouge with EMA and we look forward to an opinion from the CHMP in June", says **Søren Tulstrup, President and CEO of Hansa Biopharma.** *"If approved, imlifidase has the potential to enable lifesaving kidney transplants in highly sensitized patients, who currently cannot receive this standard of care treatment."*

The Marketing Authorization Application for imlifidase in kidney transplantation was accepted for review by the European Medicines Agency on Feb. 28, 2019.

The information was submitted for publication, through the contact person set out below, at 08:00amx (CET) on May 25, 2020.

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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 Companys 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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