Hansa Biopharma confirms follow-up meeting with FDA

In line with previous guidance, Hansa Biopharma has scheduled a follow-up meeting with the U.S. Food and Drug Administration. The meeting will take place on November 20th, 2019.

Lund, Sweden September 25, 2019. Hansa Biopharma, the leader in immunomodulatory enzyme technology for rare IgG-mediated diseases, today announced that a date for a follow- up meeting with the U.S. Food and Drug Administration (FDA) has now been confirmed. The meeting will take place on November 20th, 2019.

At the upcoming meeting with the FDA, Hansa Biopharma intends to continue the discussion from December 2018 regarding the path forward for a regulatory filing of imlifidase in kidney transplantation of highly sensitized patients in the U.S.

During the initial FDA meeting in December 2018, the agency provided positive feedback on the phase 2 data generated on imlifidase and acknowledged the high unmet medical need of highly sensitized patients for whom it is extremely difficult to access kidney transplantation.

Following the 2018 meeting, Hansa Biopharma has conducted complementary analyses to further illustrate the value that imlifidase brings to highly sensitized patients, also in the context of the US Kidney Allocation System (KAS).

Hansa Biopharma expects to receive minutes from the FDA meeting before end-of-December 2019.

Contact information

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

Rolf Gulliksen
Head of Corporate Communications
Hansa Biopharma
M: +46 (0) 733-328 634
E: rolf.gulliksen@hansabiopharma.com

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, imlifidase, is a unique antibody-degrading enzyme to 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 potential 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 the UK and US.

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

Nasdaq OMX Stockholm
Ticker: HNSA