Hansa Medical

Hansa Medical AB Provides Regulatory Update for Imlifidase in Kidney Transplantation

Lund, Sweden, January 15, 2019 - Hansa Medical AB (Nasdaq Stockholm:HNSA) ("Hansa Medical" or the "Company"), a biopharmaceutical company focused on inhibition of immunoglobulin G (IgG)-mediated immunopathologies, today provided an update following the Company's regulatory interactions with the European Medical Agency (EMA) and the U.S. Food and Drug Administration (FDA) for imlifidase in kidney transplantation.

"We have had very productive meetings with the EMA and FDA, during which both agencies provided positive feedback on the data generated on imlifidase to date and acknowledged the high unmet medical need of highly sensitized patients who currently can't access kidney transplantation," said Søren Tulstrup, President and CEO of Hansa Medical AB.

"In Europe, we continue to expect to file a Marketing Authorization Application with the EMA this quarter. The dialogue with the FDA to determine the path forward for regulatory approval in the U.S. will continue in a subsequent meeting in the coming months per the agency's request for additional information regarding imlifidase treatment in the context of the new U.S. Kidney Allocation System (KAS). We will provide updated guidance regarding expected timeline for a potential BLA filing after this meeting has taken place. Our highest priority is getting imlifidase to market to enable lifesaving kidney transplants for highly sensitized patients, who currently can't receive this standard of care treatment," continued Mr. Tulstrup.

The U.S. Kidney Allocation System was updated in 2014 in order to increase equity in allocation, reduce kidney discard rates and reduce organ/recipient longevity mismatches. While the KAS has improved the possibility for highly sensitized patients to receive a kidney transplant, thousands of highly sensitized patients remain unable to be successfully matched.

In September 2018, Hansa successfully completed two Phase 2 clinical studies evaluating imlifidase for kidney transplantation in highly sensitized patients, with imlifidase enabling transplantation in all 35 patients. Imlifidase met all primary and secondary endpoints in each study. Imlifidase has received Fast Track designation from the FDA and has been selected for Priority Medicines (PRIME) by the EMA. Imlifidase has received Orphan Drug Designation from the EMA and FDA.

This is information that Hansa Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below at 08:00am CET on January 15, 2019.

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About Imlifidase

Imlifidase is an enzyme that specifically cleaves IgG antibodies, thereby inhibiting the IgG-mediated immune response. Hansa is developing imlifidase as a proprietary treatment to enable kidney transplantation in sensitized patients, previously unable to undergo transplant surgery due to the presence of Donor Specific Antibodies (DSAs). Efficacy data reported from four Phase 2 studies have demonstrated that imlifidase rapidly and significantly reduced these DSAs, enabling transplantation. In addition to transplantation, imlifidase is being evaluated in a clinical Phase 2 study in anti-GBM antibody disease, a rare autoimmune disorder, and imlifidase has potential applications in a variety of additional autoimmune diseases. Imlifidase is protected by a strong patent portfolio and results of studies with imlifidase have been published in multiple peer reviewed scientific journals.

About Sensitized Patients

Many patients on the waiting list for organ transplantation carry antibodies to human leukocyte antigen (HLA), which is known as being 'sensitized'. When these antibodies are targeted towards the HLA of a potential donor, called DSAs, the transplanted organ can be significantly compromised. Patients who are highly sensitized, with high levels of DSAs, will have a very low likelihood of finding a donor towards which they will not have DSA. Therefore, they may not be able to receive a transplant at all and remain on dialysis in a debilitating disease state. Current desensitization methods are not feasible for most highly sensitized patients. Imlifidase's rapid cleavage of all IgG antibodies, desensitizes sensitized patients, enabling deceased donors kidney transplantation. Two thirds of kidney transplantations in the U.S. and Europe are from deceased donors.

About Hansa Medical

Hansa Medical (NASDAQ Stockholm:HNSA) is a biopharmaceutical company developing novel immunomodulatory enzymes for organ transplantation and acute autoimmune diseases. The Company's lead product, imlifidase, is a proprietary antibody-degrading enzyme in late-stage clinical development for kidney transplant patients and has significant potential for further development in other solid organ transplantation and in acute autoimmune indications. Hansa also has a strong pipeline of preclinical projects that may provide a second wave of potential drugs. Under the project name NiceR, the Company is developing novel immunoglobulin-cleaving enzymes for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden.