Hansa Medical

- PRESS RELEASE -
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Long-term follow up data from investigator-initiated Phase II study with imlifidase (IdeS) to be presented at *2018 American Transplant Congress (ATC)*

Hansa Medical AB (Nasdaq Stockholm: HMED), a biopharmaceutical company developing novel immunomodulatory enzymes, today announced that long-term follow up results from the ongoing investigator-initiated US study with imlifidase (IdeS) in highly sensitized patients will be presented in an oral session at the *2018 American Transplant Congress (ATC)* in Seattle, U.S. on June 5.

The long-term follow up results from the study, demonstrate that patients desensitized with imlifidase (IdeS) and transplanted with HLA-incompatible kidney show good renal function and minimal evidence of antibody mediated rejection (AMR) at a mean 18.76 months post kidney transplantation. An abstract with a summary of the coming presentation of the long-term data and conclusions is available through the ATC website, http://atcmeetingabstracts.com

The study (ClinicalTrials.gov Identifier: NCT02426684) is an investigator-initiated study conducted at Cedars-Sinai Medical Center in Los Angeles, USA with Professor Stanley Jordan as principal investigator. The study investigates the safety and efficacy of imlifidase in removing donor specific antibodies (DSAs) in patients where previous attempts of desensitization have failed.

In the study, imlifidase is investigated in combination with high dose intravenous gammaglobulin and anti-CD20 treatment and in January 2018, patient enrollment was closed with a total of 17 patients treated with imlifidase and subsequently transplanted. Patients had DSAs and a positive cross-match test prior to imlifidase treatment and kidney transplantation. Imlifidase effectively reduced the level of DSAs in all patients thereby enabling transplantation for all patients.

The abstract with the long-term results demonstrate that all patients exhibited extensive sensitization with a median cPRA of 95%. Graft and patient survival at a mean 18.76±5.6 M post-imlifidase enabled transplantation were 94%. Rebound DSA responses were rare and of low MFI values with only four patients demonstrating DSAs, all with MFIs ≤3000. Biopsies were performed in 15 patients. All but three showed no findings or findings "suspicious" for AMR (according to Banff 2017 criteria). No patient had positive C4d staining.

Results from 14 of the 17 patients were published in *The New England Journal of Medicine* in August 2017 (N Engl J Med 2017;377:442-53).

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 8:00 CEST on May 30, 2018.

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About sensitized patients

Many patients on the waiting list for organ transplantation carry antibodies to HLA (i.e. being ‘sensitized’). When these antibodies are targeted towards the HLA of a potential donor (i.e. ‘donor specific antibodies’

or DSA) the transplanted organ can be significantly compromised. Patients who are highly sensitized (i.e. with high levels of antibodies) will have a very low likelihood to find a donor, towards which they will not have DSA. Therefore, they may not be able to receive a transplantation at all and remain in a severe and debilitating disease state.

About imlifidase (IdeS)

Imlifidase is an enzyme that depletes IgG antibodies fast and effectively. Hansa Medical is developing imlifidase as a proprietary treatment to enable kidney transplantation in sensitized patients, previously unable to undergo transplantation surgery due to the presence of anti-HLA IgG antibodies. Efficacy data reported from three Phase II studies have demonstrated that imlifidase rapidly and significantly reduced anti-HLA antibodies, enabling transplantation. Imlifidase is currently being evaluated in highly sensitized patients that do not respond to available desensitization methods. Results from two ongoing studies are expected in 2018. In addition to transplantation, imlifidase is being evaluated in a clinical Phase II study in the rare autoimmune disease anti-GBM antibody disease and imlifidase has potential applications in a variety of additional autoimmune diseases. Imlifidase is protected by several patents and results of studies with imlifidase have been published in a number of peer reviewed scientific journals.

About Hansa Medical

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for transplantation and acute autoimmune diseases. The lead product, imlifidase, is a proprietary antibody-degrading enzyme currently in late-stage clinical development for kidney transplant patients, with significant potential for further development in other solid organ transplants and in acute autoimmune indications. The company also has a strong pipeline of preclinical projects that may provide a second wave of potential drugs. Under the project name NiceR, novel immunoglobulin-cleaving enzymes are developed for repeat dosing with the objective of applying the Hansa Medical technology in relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden, and its shares are listed on Nasdaq Stockholm (ticker: HMED).