

Hansa Medical

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Presentation at the *2018 American Transplant Congress* highlights the long-term risk-benefit profile of imlifidase (IdeS) in kidney transplantation

Hansa Medical AB (Nasdaq Stockholm: HMED), a biopharmaceutical company developing novel immunomodulatory enzymes, today announced additional data and conclusions from the investigator-initiated Phase II study with imlifidase (IdeS), presented by Professor Stanley Jordan at the *2018 American Transplant Congress (ATC)*, June 5, 2018.

As announced on May 30, 2018, ahead of the ATC-presentation, the results from the study demonstrate that patients desensitized with imlifidase and transplanted with an HLA-incompatible kidney show good renal function and minimal evidence of antibody mediated rejection (AMR) at a mean 18.76 months post kidney transplantation, with graft and patient survival at 94%. Overall, the levels of donor specific antibodies (DSA) stay low over time, and only four of 16 patients have low but significant levels of DSAs. Biopsies were performed on 15 patients. All but three showed no findings of suspected AMR (according to Banff 2017 criteria) and none of the patients had a positive C4d staining.

In addition, Professor Jordan highlighted that the two-year follow-up data demonstrate good patient and graft survival without increased infection risk and that no serious adverse events related to imlifidase have been reported in his study. Also, Professor Jordan estimated the seven-year allograft survival probability to be 77 to 100 percent for 14 out of 15 patients and 47 percent for one patient. The estimate is based on a so called iBox Risk Prediction Score.

"In our study, imlifidase consistently reduced or eliminated DSAs to allow transplantation from HLA-incompatible donor without risk of early antibody mediated rejection (AMR). All patients exhibited extensive sensitization with a median cPRA of 95 percent prior to imlifidase treatment. Imlifidase is superior to other DSA-removal strategies like plasma exchange which still leaves 35 percent of the antibodies remaining", commented Professor Stanley Jordan.

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

In this study, imlifidase is investigated in combination with high-dose intravenous gamma globulin 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 transplantation. Imlifidase effectively reduced the level of DSAs in all patients thereby enabling transplantation for all patients.

An abstract with a summary of the presentation of the long-term data and conclusions is available through the ATC website (<http://atcmeetingabstracts.com>) and 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).

Also at the ATC, a presentation with the title *Effects of IdeS on HLA-SAB, C1q-SAB and CDC-X* was made by Dr Sofia Järnum, Director R&D at Hansa Medical. Dr Järnum gave a detailed description on the role of imlifidase in conjugation with assays important for decision making in transplantation. In addition, a poster with the title *Anti-IdeS Antibodies in IVIg and Its Effect on IdeS Activity* was presented by Anna Runström, Scientist at Hansa Medical and was awarded "Poster of distinction" by the ATC.

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 June 6, 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).