Hansa Medical

- PRESS RELEASE -

January 3, 2018

Finalized enrollment in US Phase II study with IdeS in highly sensitized patients

Hansa Medical AB (Nasdaq Stockholm: HMED), a biopharmaceutical company focusing on novel immunomodulatory enzymes, announced today that enrollment has been finalized in the US investigator-initiated Phase II study with lead candidate IdeS in highly sensitized patients.

A total of 17 patients have been enrolled in the study (ClinicalTrials.gov Identifier: NCT02426684) at Cedars-Sinai Medical Center with Professor Stanley Jordan as principal investigator. The study aimed at enrolling 10 to 20 patients. Patients had donor specific antibodies (DSAs) and a positive cross-match test prior to IdeS treatment. IdeS effectively reduced the level of DSAs in all patients and turned the cross-match tests from positive to negative, thereby enabling transplantation for all patients. All patients will be followed for six months with respect to safety, kidney function and DSA levels. Professor Jordan commented on the problem of sensitization and how IdeS has improved transplant rates for these patients:

"HLA sensitization is a major barrier to kidney transplantation. Despite advancements in desensitization, effective methods to remove incompatible HLA antibodies remains a significant challenge in transplantation. There are currently no approved treatments for desensitization and there is a significant unmet medical need for new therapies to address this issue", he continued,

"Our study shows that IdeS cleaves IgG antibodies remarkably fast and effectively, with a favorable safety profile. This unique and completely novel mechanism of action has enabled kidney transplantation for patients where previous attempts at desensitization have failed. We have managed to transplant patients that have been on dialysis for more than 25 years."

The results from 14 of these 17 patients were published in *The New England Journal of Medicine* on August 3, 2017 (Vol. 377 No. 5, pages 442-53). In the article, titled *IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation*, researchers demonstrated that treatment with IdeS is effective in reducing donor-specific antibodies (DSAs) to levels allowing lifesaving kidney transplantation of highly sensitized patients. The publication in *The New England Journal of Medicine* covered three separate studies, performed in Sweden and the US, and included 25 HLA-sensitized patients who received IdeS immediately before kidney transplantation.

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 above at 08:00 CET on January 3, 2018.

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About the study (ClinicalTrials.gov Identifier: NCT02426684)
This investigator initiated study has the official name *A Phase I/II Trial to Evaluate the Safety and Tolerability of IdeS (IgG Endopeptidase) to Eliminate Donor Specific HLA Antibodies (DSAs) and Prevent Antibody-Mediated Rejection Post-Transplant in Highly-HLA Sensitized Patients*. The study investigates IdeS safety and efficacy in removing DSAs in patients where previous attempts of desensitization have failed.

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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 IdeS

IdeS, IgG-degrading enzyme of *Streptococcus pyogenes*, is an enzyme that depletes IgG antibodies fast and effectively. Hansa Medical is developing IdeS 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 IdeS rapidly and significantly reduced anti-HLA antibodies, enabling transplantation. IdeS 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, IdeS is being evaluated in a clinical Phase II study in the rare autoimmune disease anti-GBM antibody disease and IdeS has potential applications in a variety of additional autoimmune diseases. IdeS is protected by several patents and results of studies with IdeS 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, IdeS, 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).