Hansa Medical

- PRESS RELEASE -
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Initial results from the ongoing Swedish Phase II study with IdeS in sensitized kidney transplant patients will be presented at TTS 2016

Dr. Tomas Lorant, principal investigator, will present data from the ongoing Swedish Phase II study with IdeS in sensitized kidney transplant patients at the 26th International Congress of the Transplantation Society in Hong Kong in August 2016. The meeting abstract published ahead of the presentation includes preliminary data from 6 transplanted patients with HLA antibodies in the on-going Phase II study.

The ongoing and now fully recruited Phase II study includes 10 patients that received a single dose of IdeS (0.25 or 0.5 mg/kg) before kidney transplantation. The study primarily evaluates safety and tolerability of the candidate drug IdeS in sensitized kidney transplantation patients. The study is also aimed at identifying an IdeS dose that results in anti-HLA antibody levels acceptable for transplantation within 24 hours from dosing. These patients are followed for six months after transplantation for safety and kidney function and final results from the study are expected in Q4 2016.

In the published abstract, Dr. Lorant and co-authors conclude that IdeS treatment significantly reduced the level of HLA antibodies and eliminated complement (C1q) binding antibodies. The complement binding antibodies were inactivated within 1 hour after IdeS treatment. Positive cytotoxic and flow cytometry crossmatches against the donors were converted to negative by IdeS treatment and the treatment allowed transplantation in all patients treated with IdeS.

In addition, the abstract presents data from Hansa Medicals first Phase II study with IdeS in sensitized patients, which was finalized in January 2015. The study included 8 highly sensitized patients that received either 1 or 2 doses (0.12 or 0.25 mg/kg) of IdeS. The study aimed at making patients eligible for transplantation by lowering HLA antibodies and the primary endpoint of the study was achieved. Meeting abstract available at the TTS website: https://confman.tts2016.org/mobis/lecture/942

By May 31, 2016 in total 21 sensitized patients have been treated with IdeS and subsequently transplanted in three separate Phase II studies with IdeS; two ongoing studies at Uppsala University Hospital, Karolinska University Hospital in Huddinge and at Cedars Sinai Medical Center, Los Angeles, and one finalized Phase II study at Uppsala University Hospital.

About Hansa Medical AB
Hansa Medical is a biopharmaceutical company focusing on novel immunomodulatory enzymes. The lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Additional projects focus on development of new antibody modulating enzymes, as well as HBP, a diagnostic biomarker for prediction of severe sepsis at emergency departments that is already introduced on the market. The company is based in Lund, Sweden. Hansa Medical's share (ticker: HMED) is listed on Nasdaq Stockholm.

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