Hansa Medical

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Hansa Medical announces successful completion of a Phase II clinical trial of IdeS in sensitized kidney patients

Hansa Medical AB (Nasdaq Stockholm: HMED), a biopharmaceutical company focusing on novel immunomodulatory enzymes, announces The second Swedish open label Phase II IdeS-study conducted at Uppsala University Hospital and Karolinska University Hospital in Huddinge is now complete with all IdeS treated patients transplanted.

Hansa Medical AB today announced completion of a Phase II study entitled "A Phase II Study to Evaluate the Safety, Tolerability, Efficacy and Pharmacokinetics of Intravenous Ascending Doses of IdeS in Kidney Transplantation" in which 10 sensitized kidney patients were given IdeS prior to transplantation. The primary and secondary objectives were met with IdeS in the study.

Dr. Steven Glazer, Chief Medical Officer at Hansa Medical said, "We are encouraged by these results. These data further support our belief that our novel immunomodulatory enzyme holds significant therapeutic value for sensitized patients in need of lifesaving transplantation. We plan to move forward with continued recruitment of patients to our ongoing multi-center study with IdeS in highly sensitized kidney transplantation patients, allowing us to accumulate additional data and further evidence of the value of IdeS and our clinical program."

Data generated from this trial have been submitted for peer review in a scientific journal.

This information is information that Hansa Medical AB (publ) is obliged to make public pursuant to the Financial Instruments Trading Act. The information was submitted for publication at 09:45am CET on December 21, 2016.

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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

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transplantation in sensitized patients, previously unable to undergo transplantation surgery due to the presence of anti-HLA IgG antibodies. Top-line efficacy data reported from three phase 2 studies have demonstrated that IdeS rapidly and significantly reduced anti-HLA antibodies, enabling transplantation. IdeS is currently being evaluated in a multi-center study in the U.S. in highly sensitized patients that do not respond to available desensitization methods. Results from this study are expected in 2018. In addition to transplantation, IdeS has potential applications in a variety of rare 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 sensitized patients

Approximately 30 percent of the patients on the waiting lists for kidney, liver, heart, lung and pancreas transplants, equivalent to more than 30,000 patients in Europe, are sensitized to HLAs. HLA sensitization is a risk factor in transplantation meaning that a significant number of sensitized patients are rarely considered for transplantation due to the increased risk of antibody mediated organ rejection.

About Hansa Medical AB

Hansa Medical is a biopharmaceutical company focusing on novel immunomodulatory enzymes. The lead project IdeS is a proprietary 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.