Hansa Medical

- PRESS RELEASE -
August 23, 2016

Top line results from the Swedish ongoing Phase II study with IdeS in sensitized patients presented today at the 26th International Congress of the Transplantation Society

Hansa Medical AB (publ) today announced that preliminary results of the Sweden based ongoing Phase II study of IdeS were presented today by Professor Gunnar Tufveson at the 26th International Congress of the Transplantation Society in Hong Kong on August 23, 2016. The results show that IdeS has enabled kidney transplantation in all 10 out of 10 included sensitized patients. The Phase II study also shows that IdeS treatment resulted in negative cross match test in all patients, none of the transplanted patients experienced delayed graft function and all 10 transplantations resulted in very good creatinine levels.

The ongoing and fully recruited Phase II study at Uppsala University Hospital and Karolinska University Hospital in Huddinge, Sweden, includes 10 patients who received a single dose of IdeS (0.25 or 0.5 mg/kg) before kidney transplantation. The study's primary focus is to evaluate safety and tolerability of Hansa Medical's 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. Patients in the study are followed for six months after transplantation to continue to evaluate drug safety and kidney function. The study is expected to be finalized in Q4 2016.

Professor Tufveson concludes in his presentation that IdeS treatment is a suitable way to achieve rapid and effective desensitization allowing transplantation in immunized patients and that a dose level of 0.25 mg/kg body weight is a suitable dose.

Two additional clinical studies with IdeS in sensitized patients are ongoing: an investigator initiated Phase II study at Cedars-Sinai Medical Center in Los Angeles and a pivotal multicenter study in the US with IdeS in refractory highly sensitized patients. Results from the multicenter study hold the potential to form the basis for filing a Biologics License Application, which is an application to the US Food and Drug Administration (FDA) for authorization to commercialize IdeS in the US. In addition, Hansa Medical is evaluating the possibility of adding various European sites to this multicenter study to better support the regulatory process at the European Medicines Agency, EMA, to gain marketing authorization of IdeS in the European market.

The information in this press release is disclosed pursuant to the EU Market Abuse Regulation. The information was released for public disclosure through the agency of the contact person stated below on August 23, 2016 at 08.30 CET.

About IdeS

IdeS, a unique molecule with a novel mechanism, is an enzyme that specifically cleaves human IgG antibodies. During 2013, a Phase I clinical trial including 29 healthy subjects was conducted, demonstrating IdeS as efficacious and well tolerated with a favorable safety profile. During 2014, a Phase II study in 8 sensitized patients awaiting kidney transplantation was conducted. Data from the study show that IdeS is effective in reducing anti-HLA antibody levels in highly sensitized patients to levels acceptable for transplantation. The efficacy and safety of IdeS in transplantation are currently investigated in three on-going clinical trials in sensitized kidney patients in Sweden and in the US. 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.

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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, rare autoimmune diseases and oncology. 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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