Hansa Medical

- PRESS RELEASE -
April 4, 2016

FDA clears Hansa Medical's IND application for IdeS in kidney transplantation

Hansa Medical AB (publ) today announced that the US Food and Drug Administration (FDA) has completed the safety review of the company's Investigational New Drug application (IND) and has concluded that the proposed clinical investigation can proceed. This enables Hansa Medical to start a clinical study to primarily evaluate IdeS' efficacy in making highly sensitized kidney patients with positive crossmatches eligible for transplantation by removing donor specific antibodies. The clinical trial is scheduled to begin soon.

The single arm study will include up to 20 kidney transplantation patients that have either failed on previous attempts of desensitization or in whom effective desensitization using currently available methods is highly unlikely. The trial is scheduled to begin soon at reputable medical institutions in the US, with the aim to complete recruitment during the first half of 2017.

"Following the encouraging results in the on-going trials conducted by Professor Gunnar Tufveson at Uppsala University Hospital and Professor Stanley Jordan at Cedars-Sinai Medical Center, respectively, we are excited to begin this US trial with Hansa Medical as sponsor, investigating IdeS in highly sensitized patients", said Göran Arvidson, President and CEO of Hansa Medical AB.

"FDA clearance of the IdeS IND is a milestone for the company defining a potential path toward product approval."

The first trial to be conducted under this IND is titled "A Phase II Study to Evaluate the Efficacy of IdeS (IgG endopeptidase) to Desensitize Transplant Patients with a Positive Crossmatch Test". The primary objective is to assess IdeS' efficacy in creating a negative crossmatch test. The trial will also evaluate the safety, kidney function and immunogenicity during the 6-month follow-up period.

The information in this press release is disclosed pursuant to the Swedish Securities Markets Act and/or the Swedish Financial Instruments Trading Act. The information was released for public disclosure on April 4, 2016 at 08.00 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. IdeS' efficacy and safety in transplantation are currently investigated in two 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 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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