Hansa Medical

- PRESS RELEASE -
July 19, 2016

Hansa Medical initiates pivotal multicenter study in the US with IdeS for treatment of refractory highly sensitized kidney patients

Hansa Medical AB (publ) today announced that the company sponsored pivotal multicenter study in the US with IdeS in refractory highly sensitized patients is open for recruitment.

The single arm Phase II study will include approximately 20 highly sensitized patients awaiting kidney transplantation, who are refractory to currently available desensitization strategies. The patients in this new study have either failed on previous attempts of desensitization or the currently available methods are considered insufficiently effective.

The study is entitled "A Phase II Study to Evaluate the Efficacy of IdeS (IgG endopeptidase) to Desensitize Transplant Patients with a Positive Crossmatch Test" with the short name Highdes. The primary objective of the study is to assess the efficacy of IdeS in creating a negative crossmatch test. The trial will also evaluate safety, kidney function and immunogenicity during the 6-month follow-up period. The aim is to complete recruitment of approximately 20 patients over a 12-month period. The recruitment of patients has been initiated at Cedars-Sinai Medical Center in Los Angeles.

"The initial evaluation of the results in the ongoing Phase II studies with IdeS in Sweden and the U.S. verifies our strong belief in the potential of IdeS as a safe, fast and highly effective desensitization treatment. We are excited that we have initiated a fully Hansa Medical sponsored US study with the ambition to recruit patients in immediate need of desensitization", commented Göran Arvidson, President and CEO of Hansa Medical AB.

Study results could potentially form the basis for filing a Biologics License Application, i.e. an application to the US Food and Drug Administration (FDA) for authorization to commercialize IdeS in the US.

Hansa Medical is currently evaluating the possibility to add European sites to this now initiated study in order to support the regulatory process at the European Medicines Agency, EMA, for marketing authorization of IdeS in the European market.

This study was cleared by the FDA in April 2016. More information about this trial in refractory highly sensitized patients is available at www.clinicaltrials.gov under the identifier NCT02790437.

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 below on July 19, 2016 at 08.30 CET

About refractory highly sensitized patients

Approximately one third of the kidney patients that require dialysis are sensitized to human leukocyte antigens (HLA). The presence of antibodies that react with a potential donor organ is a significant barrier to transplantation due to the risk of acute antibody mediated rejection. Sensitized patients in general have an increased waiting time for transplantation. Depending on level of HLA-immunization, some sensitized patients can be transplanted with treatment procedures using plasmapheresis or intravenous gamma globulin at some specialized clinics. Refractory highly sensitized patients are highly sensitized patients that have either failed on previous attempts of desensitization or in whom effective desensitization using currently available methods is highly unlikely.

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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 two on-going clinical trials in sensitized kidney patients in Sweden and in the U.S. 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 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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