Hansa Medical

- PRESS RELEASE -
June 15, 2016

Successful desensitization with IdeS in all recruited patients in ongoing US Phase II study

Hansa Medical AB (publ) today announced that additional data from the ongoing US Phase II study with IdeS in kidney transplantation was presented at the 2016 American Transplant Congress (ATC) in Boston on June 14 at 6:00 pm (EDT).

The ongoing Phase II study at Cedars Sinai Medical Center is an investigator-initiated study that is looking at the effects of IdeS in enabling kidney transplantation in highly sensitized kidney transplant patients. Recruitment for the study will be up to 20 patients.

The data presented by the study's principal investigator Professor Stanley Jordan, shows that all ten included patients have been successfully desensitized and subsequently transplanted. The ten patients, recruited in the study between July 18, 2015 and May 2, 2016, will be followed for 6 months post transplantation for safety and graft function. At ATC, Professor Jordan confirmed that all the transplanted kidneys are performing well and that creatinine levels were normalized in all patients following transplantation.

This initial evaluation presented at ATC showed that the level of donor specific antibodies (DSA) was reduced to zero in all patients within six hours of IdeS treatment. One of the ten patients developed DSA and antibody mediated rejection (ABMR) six months post-transplant and responded well to treatment. Post treatment all DSAs were eliminated.

Professor Jordan concluded that the use of IdeS pre-transplant in highly sensitized patients represents a robust and highly efficient technique to eliminate DSAs. A single pre-operative dose administered to DSA positive patients eliminated circulating DSAs, allowed transplantation without early ABMR and, in conjunction with desensitization therapy based on intravenous gammaglobulin and rituximab, resulted in long term DSA suppression.

"We are encouraged by the latest results that Dr. Jordan, from Cedars Sinai Medical Center, presented at ATC," stated Göran Arvidson, CEO of Hansa Medical." He continued, "Reducing the pre-transplantation anti-HLA antibody levels in ten highly sensitized patients allowing transplantation is a significant step forward for the development of IdeS."

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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. IdeS is currently investigated in two on-going clinical trials in sensitized kidney patients in Sweden and in the US. The trials will involve 20-30 patients in total and the objective is to investigate the efficacy and safety of IdeS. 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.

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 June 15, 2016 at 08.30 CET.