

Hansa Medical

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Successful Phase 2 Study of IdeS in Highly Sensitized Dialysis Patients awaiting Kidney Transplantation

Hansa Medical AB today announced preliminary data showing that IdeS has very good efficacy in a phase 2 study with 8 highly sensitized patients on the waiting-list for kidney transplantation. The study shows that IdeS has the capacity to make sensitized patients eligible for transplantation by decreasing HLA antibodies to acceptable levels. IdeS increased the probability of compatible transplantation by reducing the percentage panel reactivity to low levels in all patients.

Hansa Medical AB today announced preliminary data showing that IdeS has very good efficacy in a phase 2 study with 8 highly sensitized patients on the waiting-list for kidney transplantation. Data analysis shows that IdeS rapidly decreases anti-HLA antibodies to levels acceptable for transplantation, thereby increasing the probability of finding a compatible donor. This is demonstrated by a significant reduction of percentage panel reactivity after treatment. In addition, essentially all IgG was cleaved within 24 hours after dosing in all patients. IdeS was considered safe and well tolerated in HLA sensitized dialysis patients awaiting kidney transplantation.

"IdeS can be directly life-saving for patients waiting for transplantation who have antibodies to transplantation antigens, The worst affected patients represent about 15 % of the wait-listed patients. In addition, a further 25 % of the patients waiting for a transplant may benefit from IdeS treatment." says Gunnar Tufveson, Professor in Transplantation Surgery, Uppsala University Hospital.

"The data show that IdeS swiftly and efficiently degrades the antibodies which prevent kidney transplantation of these patients. We are highly encouraged to pursue further investigation of IdeS for sensitized transplantation patients as well as patients suffering from having other obstructive and pathogenic IgG." says Christian Kjellman, Chief Scientific Officer of Hansa Medical AB.

About the Study

The phase 2 IdeS study was a single arm, single centre, ascending dose study at Uppsala University Hospital, Sweden. Eight sensitized dialysis patients were included and they received 0.12 or 0.25 mg/kg body weight of intravenous IdeS once or twice within 2 days. IgG was rapidly and efficiently cleaved within minutes after IdeS treatment. Antibodies to HLA, measured with single-antigen bead analysis and T- and B-cell panel reactive antibody analysis, reached levels acceptable for transplantation within hours of treatment. IdeS had an acceptable safety and tolerability profile in the intended category of patients; myalgia and increased susceptibility to infection were identified as potential side effects. Susceptibility to infection is expected in connection with immunosuppressive treatments. Hansa Medical has previously reported about one patient in the study who was made eligible for kidney transplantation by treatment with IdeS and successfully transplanted with a deceased donor. IdeS treatment converted the positive cross-match tests (both FACS-CXM and CDC-CXM) negative, thereby making the transplantation possible. Today, the patient is well, with a fully functional graft without any signs of rejection.

About sensitized patients

Approximately one third of the several hundred thousands of patients waiting for organ transplantation are sensitized to human leukocyte antigen (HLA). These patients have developed antibodies to HLA primarily as the result of allo-immunisation from previous transplantations, blood transfusions or pregnancies. Antibodies to HLA hamper the identification of a suitable donor and HLA-antibodies that react to a potential donor (i.e. a positive cross-match test) are a direct contraindication to transplantation because of the risk of antibody-mediated rejection. Consequently, sensitized patients have extended waiting times on dialysis and risk never being transplanted, despite highest priority. End-stage renal

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disease patients can be maintained on dialysis. However, kidney transplantation is the treatment-of-choice since the patient's life expectancy and quality of life is dramatically increased and there are substantial cost-savings associated with transplantation compared to dialysis.

About IdeS

IdeS, a unique molecule with a novel mechanism, is a bacterial enzyme that cleaves human IgG antibodies. IdeS degrades all IgG specifically, swiftly and efficiently. IdeS has been tested for safety and efficacy in numerous in vitro and in vivo models. During 2013, a phase I clinical trial on 29 healthy subjects was conducted, demonstrating IdeS as efficacious and well tolerated with a favourable safety profile. During 2014, a phase II clinical trial in sensitized patients awaiting kidney transplantation was initiated, to be reported during 2015. IdeS has potential indications within transplantation and a broad variety of rare autoimmune diseases, where it addresses unmet medical needs. IdeS is protected by several patents and has been published in numerous peer review journals.

About Hansa Medical AB

Hansa Medical is a biopharmaceutical company focused on novel immunomodulatory enzymes. Lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Other projects include HBP (a market introduced diagnostic marker for severe sepsis) and EndoS (an antibody-modulating bacterial enzyme in pre-clinical development). The company is based in Lund, Sweden. Hansa Medical's share (HMED) is listed on NASDAQ First North in Stockholm with Remium Nordic AB as Certified Adviser. Major shareholders are Farstorps Gård AB and Nexttobe AB.

For further information, please contact:

Hansa Medical AB
Fredrik Lindgren, President and CEO
Mobile: +46 705 61 61 77
E-mail: fredrik.lindgren@hansamedical.com

Emanuel Björne, Corporate Development Director
Mobile: +46 707 17 54 77
E-mail: emanuel.bjorne@hansamedical.com

www.hansamedical.com