press release

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Hansa Medical files application for phase II-study with IdeS

Hansa Medical has filed a clinical trial application to the Swedish Medical Products Agency for the performance of a phase II study with drug candidate IdeS in dialysis patients awaiting kidney transplantation. IdeS is being developed as an intravenous therapy for enabling kidney transplantation in patients with donor specific antibodies (DSA).

High levels of DSA makes it very difficult to identify suitable donors and these patients are therefore rarely transplanted. IdeS is expected to lower the level of DSA and make these patients transplantable. The primary objective with the phase II-study is to study IdeS efficacy and safety in patients with DSA. The study will be performed in Sweden and is planned for start in May 2014 and will proceed during fall 2014.

Successful Phase I-study

During 2013 a successful phase I-study was performed with IdeS demonstrating IdeS as safe, fast and efficient in inactivating antibodies. Within minutes after dosing no intact IgG is detectable in healthy subjects. These characteristics are much anticipated by transplantation surgeons around the world as this has the potential to enable transplantation of thousands of patients with donor specific antibodies.

IdeS (Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes*)

IdeS is an enzyme specifically inactivating IgG-antibodies. Donor-specific antibodies are of the IgG-type and Hansa Medical envisions a single dose intravenous injection of IdeS being dispensed prior to kidney transplantation in patients with donor specific antibodies. IdeS has the potential to remove the antibody barrier within minutes after dosage, hence enabling transplantation of patients today referred to long-term dialysis treatment. Long-term dialysis is costly and is associated with a significantly increased risk of death caused by stroke and/or heart disease. Approximately one third of dialysis patients decease while waiting for a transplant.

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