

Hansa Medical

- PRESS RELEASE -
June 20, 2017

First patient treated in Phase II study with IdeS in anti-GBM antibody disease

Hansa Medical AB (publ) today announced that the first patient has been treated with the company lead drug candidate IdeS in an investigator initiated Phase II study in severe anti-GBM antibody disease.

Anti-GBM antibody disease, also known as Goodpasture's disease, is a rare autoimmune disease where autoantibodies directed against type IV collagen cause acute inflammation of the kidney and/or the lungs. In severe anti-GBM, the disease may progress to renal failure or death.

The study (ClinicalTrials.gov identifier NCT03157037) is an open label investigator initiated Phase II study in severe anti-GBM disease with Professor Mårten Segelmark at Linköping University Hospital as Sponsor/Coordinating principal investigator. Approximately 15 patients will be recruited to the study at up to 15 clinics in Europe.

The primary objective of this study is to evaluate the safety and tolerability of IdeS in patients with severe anti-GBM disease on background of standard care consisting of pulse-methylprednisolone, oral prednisolone and intravenous cyclophosphamide (CYC) combined with plasma exchange (PLEX). IdeS efficacy will be assessed by evaluating renal function at 6 months after IdeS treatment.

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 stated below on June 20, 2017 at 08.00 CEST.

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About anti-GBM antibody disease

Anti-GBM disease, also known as Goodpasture's disease, is a rare autoimmune disease in which autoantibodies against the glomerular basement membrane (GBM) can result in kidney inflammation and pulmonary hemorrhage. In severe anti-GBM disease the antibody attack results in rapidly progressive glomerulonephritis which usually results in renal failure in untreated patients. Anti-GBM antibodies are almost exclusively of IgG isotype. Standard of care consists of pulse-methylprednisolone, oral prednisolone and intravenous cyclophosphamide (CYC) combined with plasma exchange (PLEX). Still, the renal survival rate is less than 30 percent in anti-GBM disease. Anti-GBM disease is very rare, affecting 1/1 000 000 each year.

About IdeS

IdeS, IgG degrading enzyme of *Streptococcus pyogenes*, is an enzyme that depletes IgG antibodies fast and effectively. Hansa Medical is developing IdeS as a proprietary treatment to enable kidney transplantation in sensitized patients, previously unable to undergo transplantation surgery due to the presence of anti-HLA IgG antibodies. Efficacy data reported from three Phase II studies have demonstrated that IdeS rapidly and significantly reduced anti-HLA antibodies, enabling transplantation. IdeS is currently being evaluated in a multi-center study in the U.S. in highly sensitized patients that do not respond to

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available desensitization methods. Results from this study are expected in 2018. In addition to transplantation, IdeS has potential applications in a variety of 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 developing novel immunomodulatory enzymes for transplantation and acute autoimmune diseases. The lead project IdeS is a proprietary antibody-degrading enzyme currently in late- stage clinical development for kidney transplant patients, with significant potential for further development in other solid organ transplants and a wide range of acute autoimmune indications. The company also has a strong pipeline of preclinical assets that may provide a second wave of potential drugs. Under the project name NiceR, novel immunoglobulin cleaving enzymes are developed for repeat dosing translating the Hansa Medical technology into relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden, its shares (ticker: HMED) are listed on Nasdaq Stockholm.