Hansa Medical

- PRESS RELEASE -

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Completed enrollment in Hansa Medical's international multi-center Phase II study Highdes

Hansa Medical AB (Nasdaq Stockholm: HMED), a biopharmaceutical company focusing on novel immunomodulatory enzymes, announced today the completion of enrollment for the international multi-center study Highdes.

The study aimed to recruit 15-20 patients. A total of 18 patients have been treated with the company's lead candidate IdeS and subsequently transplanted at five clinics in the US and Europe. All treated and transplanted patients will be followed up for six months. The primary objective of the study - to turn a positive cross-match test into a negative and thereby enable kidney transplantation - has been accomplished in all 18 treated patients.

"The presence of donor-specific antibodies can turn a patient with a readily available donor into a practically un-transplantable patient with the only option to remain in dialysis", said Christian Kjellman, Chief Scientific Officer at Hansa Medical AB.

"Long-term dialysis is associated with significant health risks and comparably poor quality of life. To the Highdes study, we have recruited patients who essentially have no prospect of receiving a transplant. For all those patients treated in the study, IdeS enabled kidney transplantation", he continued.

Safety and kidney function is followed for all patients during the six month follow-up study period. Final results are expected during the third quarter of 2018.

This is information that Hansa Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below at 08:00 CET on January 4, 2018.

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About the study (ClinicalTrials.gov Identifier: NCT02790437)
The primary objective of the study is to evaluate the efficacy of IdeS in 15-20 patients who are on the waiting list for kidney transplant and have previously undergone desensitization unsuccessfully or in whom effective desensitization will be highly unlikely. At study entry, the patients had an available deceased or live donor with a positive crossmatch test. The study assesses IdeS efficacy and safety in removing donor-specific antibodies (DSAs) and thereby converting a positive crossmatch test to negative. Patients have been enrolled at NYU Langone Medical Center in New York, Cedars-Sinai Medical Center in Los Angeles, The Johns Hopkins Hospital in Baltimore, Necker Hospital in Paris and Uppsala University Hospital in Uppsala, Sweden. The included patients have been transplanted with kidneys from both live and deceased donors.

About sensitized patients
Many patients on the waiting list for organ transplantation carry antibodies to HLA (i.e. being 'sensitized'). When these antibodies are targeted towards the HLA of a potential donor (i.e. 'donor specific antibodies' or DSA) the transplanted organ can be significantly compromised. Patients who are highly sensitized (i.e. with high levels of antibodies) will have a very low likelihood to find a donor, towards which they will not

have DSA. Therefore, they may not be able to receive a transplantation at all and remain in a severe and debilitating disease state.

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 highly sensitized patients that do not respond to available desensitization methods. Results from two ongoing studies are expected in 2018. In addition to transplantation, IdeS is being evaluated in a clinical Phase II study in the rare autoimmune disease anti-GBM antibody disease and IdeS has potential applications in a variety of additional 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

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for transplantation and acute autoimmune diseases. The lead product, 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 in acute autoimmune indications. The company also has a strong pipeline of preclinical projects that may provide a second wave of potential drugs. Under the project name NiceR, novel immunoglobulin-cleaving enzymes are developed for repeat dosing with the objective of applying the Hansa Medical technology in relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden, and its shares are listed on Nasdaq Stockholm (ticker: HMED).