Hansa Medical

- PRESS RELEASE -

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Intermediate evaluation of a sub-population in the Highdes study demonstrates good kidney function 5.5 months (median) post transplantation

Hansa Medical AB (Nasdaq Stockholm: HMED), a biopharmaceutical company developing novel immunomodulatory enzymes, today announced that intermediate clinical results from Hansa Medical's ongoing multi-center study in highly sensitized patients has been accepted for presentation at the 138th Annual Meeting of the American Surgical Association (ASA) in Phoenix, Arizona, April 19-21. An abstract has been published ahead of the meeting, summarizing the intermediate outcomes in seven patients from the Highdes study enrolled at NYU Langone Medical Center in New York.

Enrollment to the Highdes study has been completed and a total of 18 patients have been treated and transplanted. All 18 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. Final results, including six months follow up data from all 18 patients are expected mid/Q3 2018.

The abstract summarizes that all seven patients were highly sensitized, with PRA 99-100%, (PRA=Panel Reactive Antibody) and positive crossmatches prior to IdeS treatment and thus prohibited for transplantation. IdeS treatment resulted in negative crossmatch tests for all patients, who thereafter could be successfully transplanted.

Three of the seven patients experienced antibody mediated rejection which responded to standard of care. Three of the seven patients had delayed graft function which ultimately resolved. No serious adverse events were associated with IdeS, and all seven patients had functioning kidneys at a median follow up of 171 days (5.5 months).

"IdeS may represent a ground-breaking new method of desensitization for patients who otherwise have no hope for a lifesaving transplant" said Professor Robert Montgomery, principal investigator at the NYU Langone Medical Center, one of the Highdes study sites.

To date, desensitization has mainly been feasible when there is a living donor available, which allows for significant planning and pre-treatment with e.g. plasmapheresis, IVIG and/or rituximab. IdeS, with its rapid cleavage of all IgG antibodies, seems to be capable of effectively and safely enable kidney transplantation also for sensitized patients relying only on kidneys from deceased donors. Two thirds of kidney transplantations in the US and Europe are from deceased donors.

The abstract is available at the ASA website through the following link:
http://www.americansurgical.org/meeting/abstracts/2018/10.cgi

The information was submitted for publication, through the agency of the contact person set out below, at 8:40 am CEST on February 14, 2018.

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About the Highdes study (ClinicalTrials.gov Identifier: NCT02790437)

The primary objective of the study is to evaluate the efficacy of IdeS in 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).