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The *American Journal of Transplantation* publishes results from Hansa Medical's first Phase II study with IdeS

Hansa Medical AB (Nasdaq Stockholm: HMED), a biopharmaceutical company developing novel immunomodulatory enzymes, today announced that clinical results from Hansa Medical's first Phase II study (ClinicalTrials.gov Identifier: NCT02224820) with lead candidate IdeS (INN: Imlifidase) will be published today by the *American Journal of Transplantation (AJT)*, the monthly peer reviewed medical journal published by the *American Society of Transplant Surgeons* and the *American Society of Transplantation*.

"The publication in the AJT describes the design and results from our very first clinical study in sensitized patients, which highlighted the potential of IdeS as a novel treatment to enable lifesaving kidney transplantation." said Dr Christian Kjellman, Chief Scientific Officer at Hansa Medical. *"This was a ground-breaking study, during which we made crucial observations on dosing, safety, tolerability, pharmacokinetics and efficacy of IdeS in the sensitized patients and the findings have formed the foundation for all of our consecutive clinical studies in sensitized patients."*

The study, which was completed in 2015, was a single center, open label ascending dose study in sensitized chronic kidney disease patients assessing the safety, immunogenicity, pharmacokinetics and efficacy of IdeS. The study was conducted at Uppsala University Hospital in Sweden and eight sensitized patients (median Panel Reactive Antibodies, PRA: 64%) received 1 or 2 intravenous infusions of IdeS.

In the study, IdeS eliminated IgG in sensitized patients with unprecedented efficacy and no intact IgG could be detected less than one hour following IdeS treatment. Anti-HLA IgG antibody reactivity was substantially reduced in all patients and C1q binding to anti-HLA IgG was abolished. IdeS also cleaved the IgG-type B cell receptor on CD19+ memory B cells. Three cases of infection and one case of myalgia were reported as SAEs (Serious Adverse Events) potentially related to IdeS. These events were effectively treated or resolved.

The study was a dose finding study but transplantation was allowed within the study if a kidney was offered during the study period. An HLA-incompatible kidney from a deceased donor was offered to one of the patients. This sensitized patient had 13 different anti-HLA IgG antibodies, a PRA of 69 % as well as a positive CDC crossmatch to the offered kidney at enrolment. The IdeS treatment effectively reduced donor-specific antibodies and shifted the crossmatch test from positive to negative, thereby enabling the first kidney transplantation through IdeS-based desensitization. Stable kidney function has been maintained in this patient for more than 3 years.

"To date, there is no standard protocol for desensitization that is effective in patients with anti-HLA IgG antibodies." said Dr Tomas Lorant, lead author of the AJT-publication and Consultant Transplant Surgeon at Uppsala University Hospital. *"Some patients with an available live donor and low levels of donor-specific antibodies may be desensitized with plasma exchange but patients with moderate to high levels of donor specific antibodies are very difficult to desensitize. Extensive plasma exchange is a burden for the patient and only applicable if a potential organ is available from a living donor. IdeS' novel mode-of-action to safely and effectively eliminate donor-specific antibodies in a few hours stands out as a potential breakthrough to enable transplantation for sensitized patients."*

The scientific article will be available through the AJT website:

<http://asts.org/news-and-publications/american-journal-of-transplantation>

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 March 21, 2018.

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About completed and ongoing clinical studies with IdeS

IdeS has been evaluated in a Phase I study in healthy subjects and in two finalized Phase II studies in sensitized patients awaiting kidney transplantation. The results from these studies demonstrate that IdeS is highly effective in reducing anti-HLA IgG antibodies to levels acceptable for transplantation and is well tolerated. The efficacy and safety of IdeS is currently being investigated in two ongoing Phase II studies in highly sensitized kidney transplantation patients. Patient recruitment was completed in early January 2018 to these two Phase II studies and the patients will be monitored for six months with respect to safety, kidney function and DSA levels. An investigator-initiated Phase II study with IdeS in the rare and acute autoimmune kidney disease anti-GBM antibody disease is ongoing in collaboration with several European nephrology clinics.

Table 1. Overview of completed and ongoing clinical studies with IdeS

Type of study	Clinical trials.gov identifier	Subjects	Status	Publication
Phase I in healthy subjects	NCT01802697	29	Completed	<i>PLOS ONE</i> (2015)
Phase II in sensitized patients	NCT02224820	8	Completed	<i>American Journal of Transplantation</i> (2018)
Phase II in sensitized patients	NCT02475551	10	Completed	<i>The New England Journal of Medicine</i> (2017)
Phase II in highly sensitized patients	NCT02426684	17	Fully enrolled. Final results by mid/Q3 2018	<i>The New England Journal of Medicine</i> (2017)
Multicenter Phase II in highly sensitized patients (Highdes)	NCT02790437	18	Fully enrolled. Final results by mid/Q3 2018	
Phase II in Anti-GBM disease (GOODIDES)	NCT03157037	Approx. 15	Enrolling	

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-

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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).