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August 2, 2017

The New England Journal of Medicine publishes results from Phase II studies of Hansa Medical's lead candidate IdeS in highly sensitized patients

Hansa Medical AB (Nasdaq Stockholm: HMED), a biopharmaceutical company developing novel immunomodulatory enzymes, today announced that combined data from three independent clinical Phase II studies with Hansa Medical's lead candidate IdeS will appear in The New England Journal of Medicine 2017;377:442-53, August 3, 2017 issue.

In the article *"IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation"*, researchers demonstrated that treatment with IdeS is effective in reducing donor specific antibodies (DSAs) to levels allowing lifesaving kidney transplantation of highly sensitized patients.

"The results from these studies provide further evidence of the potential of IdeS as a novel treatment to enable lifesaving kidney transplantation," said Professor Stanley Jordan, Cedars-Sinai Medical Center, Los Angeles, joint lead author of the paper. "*HLA sensitization is a major barrier to kidney transplantation. Despite advancements in desensitization, effective methods to remove incompatible HLA antibodies remains a significant challenge in transplantation. There are currently no approved treatments for desensitization and there is a significant unmet medical need for new therapies to address this issue. IdeS could represent a novel approach to eliminate DSAs and enable transplantation for highly sensitized patients."*

"End-stage renal disease (ESRD) is a life-threatening condition. Sensitized patients are likely to spend extended time on the transplant waiting list in dialysis, which is expensive, causes serious health problems and significantly decreases quality of life," said Dr Tomas Lorant, Uppsala University, Uppsala, Sweden, joint lead author of the paper. *"Data from these studies show that IdeS effectively reduces HLA antibodies and enables patients with very poor prospects, who are unlikely to find a donor, to be transplanted. Importantly, patients are doing well with good kidney function at the end of the study, six months post transplantation."*

Kidney transplantation is the preferred treatment for patients with ESRD. About 30 percent[1] of these patients are HLA-sensitized which makes it difficult to find a matching donor and results in longer waiting time on transplant waitlists due to the presence of anti-HLA IgG antibodies. For highly sensitized patients it is even more difficult to find a suitable donor and for nine percent (www.unos.org) of patients on the kidney transplant waitlist it is almost impossible, with dialysis as the only treatment. Current therapies to eliminate DSAs are limited and not effective in patients with high titers of DSAs. IdeS eliminates IgG antibodies fast and effectively.

The studies, performed in Sweden and the U.S., included 25 HLA-sensitized patients who received IdeS immediately before kidney transplantation. All HLA-antibodies were eliminated in all patients after IdeS treatment prior to surgery. Of the 25 treated and transplanted patients, 24 patients had good kidney function at study completion, six months following transplantation. One graft loss occurred in the U.S. study due to non-HLA IgM and IgA antibodies. Five biopsy confirmed episodes of acute antibody-mediated rejection (ABMR) occurred in the 24 patients but all responded well to treatment. The article concludes that IdeS is generally well tolerated and effective in eliminating HLA antibodies including DSAs, thus enabling successful transplantation in highly sensitized patients.

IdeS is currently being evaluated in a multi-center study ("Highdes") in the U.S., France and Sweden in highly sensitized patients that do not respond to currently available desensitization methods. Results from this study are expected in 2018.

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The New England Journal of Medicine publication may be found online at www.nejm.org, DOI: 10.1056/NEJMoa1612567

The Company will be hosting a call on August 3, 2017 at 2pm CEST (5am PDT, 8am EDT, 1pm BST) to present the study results in further detail. The presentation will be followed by a Q&A session and the following representatives will participate in the conference call:

- Professor Stanley Jordan, Cedars-Sinai Medical Center, Los Angeles
- Dr Christian Kjellman, Senior Vice President Research & Development, Hansa Medical AB
- Göran Arvidson, President and CEO, Hansa Medical AB
- Emanuel Björne, Vice President Business Development & Investor Relations, Hansa Medical AB

Slides used in the presentation will be live on the company's website during the call under Events & Webcast. To participate in the telephone conference, please call:

SE: +46856642665
US: +18558315948
UK: +442030089801

A link to audio cast can be found on the Hansa Medical website under Events & Webcasts or here: https://tv.streamfabriken.com/2017-08-03-hansa-medical-press-conference

About the studies (NCT02224820), (NCT02426684), (NCT02475551)
The open label single arm Phase II clinical studies were performed independently at Cedars-Sinai Medical Center, Los Angeles, Uppsala University Hospital, Sweden and Karolinska University Hospital, Huddinge, Sweden. The initial Swedish study examined the efficacy of IdeS to remove HLA antibodies in HLA-sensitized patients without subsequent transplantation (NCT02224820). The following U.S. (NCT02426684) and Swedish (NCT02475551) studies examined the safety and tolerability of IdeS given prior to kidney transplantation in sensitized patients to eliminate DSAs and allow HLA incompatible transplantation. Eligible patients were 18 to 70 years, with end-stage renal disease (ESRD) on dialysis, awaiting kidney transplantation on the United Network for Organ Sharing (UNOS) (U.S.) wait list, or the Scandiatransplant wait list (SE).

1.Jordan et al. British Medical Bulletin, 2015, 114:113-125

This information is information that Hansa Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation and the Securities Markets Act. The information was submitted for publication, through the agency of the contact person set out below, at 11:00PM CEST on August 2 2017.

For further information, please contact:

Hansa Medical AB (Publ)
Emanuel Björne, Vice President Business Development and Investor Relations
Mobile: +46707175477
E-mail: emanuel.bjorne@hansamedical.com

Göran Arvidson, President and CEO
Mobile: +4670633 3042
E-mail: goran.arvidson@hansamedical.com
www.hansamedical.com

Cord Communications, Stockholm
Lars Wahlström
Mobile: +46 73 434 0771

FTI Consulting, London
Julia Phillips / Stephanie Cuthbert / Hanna Skeppner: +44 203 727 1000

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Article reference

The New England Journal of Medicine 2017;377:442-53, August 3, 2017, *"IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation"*.

Authors

Stanley C. Jordan, MD (1,2,5†), Tomas Lorant, MD (6†), Jua Choi, Pharm.D. (1,2), Christian Kjellman, PhD (12), Lena Winstedt, PhD (12), Mats Bengtsson, MD (9), Xiaohai Zhang, PhD (3), Torsten Eich, MD (7), Mieko Toyoda, PhD (1,5), Britt-Marie Eriksson, MD (8), Shili Ge, PhD (1,5), Alice Peng, MD (1,2) Sofia Jarnum, PhD (12), Kathryn J Wood, DPhil (10), Torbjorn Lundgren, MD (11), Lars Wennberg, MD (11), Lars Backman, MD (6), Erik Larsson, MD(9), Rafael Villicana, MD (1,2), Joe Kahwaji, MD (1,2), Sabrina Louie, MPH (1,2), Alexis Kang, BS (1,2), Mark Haas, MD (4), PhD, Cynthia Nast, MD(4), Ashley Vo, Pharm.D (£,1,2) and Gunnar Tufveson, MD (£,6).

Comprehensive Transplant Center (1), Transplant Immunotherapy Program (2), HLA Laboratory (3), Department of Pathology (4), Transplant Immunology Laboratory (5), Cedars-Sinai Medical Center, Los Angeles CA. 90048.

Department of Surgical Sciences, Section of Transplantation Surgery (6), Department of Immunology, Genetics and Pathology, Section of Clinical Immunology (7), Department of Medical Sciences, Section of Infectious Diseases (8), Department of Immunology, Genetics and Pathology, Section of Molecular and Morphological Pathology (9), Uppsala University, Uppsala, Sweden.

Nuffield Department of Surgical Sciences, Oxford University, Oxford UK (10).

Division of Transplantation Surgery, CLINTEC, Karolinska Institutet, and Department of Transplantation Surgery, Karolinska University Hospital, Stockholm, Sweden (11).

Hansa Medical AB (12), Lund, Sweden.

† Both investigators share first authorship.
£ Both investigators share senior authorship.

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., France and Sweden in highly sensitized patients that do not respond to 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 sensitized patients

Approximately 30 percent of the patients on the waiting lists for kidney, liver, heart, lung and pancreas transplants, equivalent to more than 80,000 patients in Europe and the US, are sensitized to HLAs. HLA sensitization is a risk factor in transplantation meaning that a significant number of sensitized patients are rarely considered for transplantation due to the increased risk of early ABMR.

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 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.