

# Hansa Medical

- PRESS RELEASE -  
August 11, 2015

First patient in IdeS study at Cedars-Sinai Medical Center in Los Angeles receives kidney transplantation

**Hansa Medical AB (publ) today announced that the first patient in an investigator-sponsored Phase II clinical study at Cedars-Sinai Medical Center in Los Angeles, California, has been treated with IdeS and subsequently transplanted.**

The study is an open-label study to assess the safety and efficacy of IdeS in eliminating donor specific antibodies and thus prevent antibody-mediated rejection in highly sensitized patients. The study will include up to 20 highly sensitized patients on the UNOS (United Network for Organ Sharing) waiting list.

The principal investigator, Professor Stanley Jordan, is a leading expert in transplant immunology. Hansa Medical has previously announced that Dr. Jordan received a Letter to Proceed from the US food and Drug Administration (FDA) in response to an IND submitted in collaboration with the company.

IdeS will be added to Dr. Jordan's standard protocols for sensitized patients, and all patients will undergo kidney transplantation. Patients will be followed for 6 months post transplantation.

"We are very pleased that the first patient in the study has been treated. IdeS has the potential to revolutionize the whole area of transplantation, especially in sensitized patients" said Dr. Jordan.

"This collaboration with Dr. Jordan is an important component of the development of IdeS in kidney transplantation. In parallel, we run other clinical studies for IdeS in Europe and plan for further studies in the US", commented Christian Kjellman, CSO of Hansa Medical.

*The information in this press release is disclosed pursuant to the Securities Markets Act or the Financial Instruments Trading Act. The information was released for public disclosure on August 11, 2015, at 08.00 CET.*

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## About IdeS

IdeS, a unique molecule with a novel mechanism, is a bacterial enzyme that cleaves human IgG antibodies. IdeS aims to degrade immunoglobulin G (IgG) and has been tested for safety and efficacy in numerous *in vitro* and *in vivo* models. During 2013, a Phase I clinical trial on 29 healthy subjects was conducted, demonstrating IdeS as efficacious and well tolerated with a favourable safety profile. During 2014 and 2015, a Phase II clinical trial in sensitized patients awaiting kidney transplantation has been conducted. Data show that IdeS is effective in reducing anti-HLA antibody levels in highly sensitized patients on the kidney transplant waitlist. The study shows that IdeS has the capacity to make sensitized patients eligible for transplantation by decreasing HLA antibodies to levels acceptable for transplantation. In addition to transplantation, IdeS has potential applications in a variety of rare autoimmune diseases. IdeS is protected by several patents and results of studies with IdeS have been published in a number of peer reviewed medical and scientific journals.

## About Dr. Stanley Jordan

Dr. Stanley Jordan is a Director of Kidney Transplantation and Transplant Immunology, Kidney and Pancreas Transplant Center and Director of Division of Pediatric and Adult Nephrology at Cedars Sinai Medical Center, Los Angeles, USA. Dr. Jordan's focus is on immunology and transplantation. He has performed extensive research funded by dozens of research grants and awards, including National Institutes of Health controlled clinical trials in kidney transplantation.

Dr. Jordan has written hundreds of articles in scientific journals and authored about two dozen book chapters. He was appointed by the National Institutes of Health's National Institute of Allergy and Infectious Diseases to advise Congress on the safety and efficacy of intravenous gamma globulin products. Dr. Jordan has been principal investigator on 3 NIH Controlled Clinical Trials in Kidney Transplantation.

He has received the Medical Sciences Award from the UCLA Alumni Association, Gift of Life Award from the National Kidney Foundation, Established Investigator Award from the American Society of Transplantation, Distinguished Alumni Award from the University of North Carolina-Chapel Hill School of Medicine and the inaugural PRISM Award from Cedars-Sinai for excellences in clinical research. Dr. Jordan is a member of national and international professional societies and has served on the editorial boards of numerous professional journals.

## About Hansa Medical AB

Hansa Medical is a biopharmaceutical company focused on novel immunomodulatory enzymes. Lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Other projects include HBP (a market introduced diagnostic marker for severe sepsis) and EndoS (an antibody-modulating bacterial enzyme in pre-clinical development). The company is based in Lund, Sweden. Hansa Medical's share (HMED) is listed on Nasdaq First North in Stockholm with Remium Nordic AB as Certified Adviser.