

Hansa Medical

- PRESS RELEASE -
April 30, 2015

Professor Stanley Jordan, a leading expert in transplant immunology, initiates a US study with IdeS in transplantation of highly sensitized kidney patients

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As previously announced, Dr. Jordan, the principal investigator, has submitted an IND for IdeS in collaboration with Hansa Medical, and a Letter to Proceed has been received from the US Food and Drug Administration (FDA). The institutional review board of Cedars-Sinai Medical Center has now approved the study.

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. 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.

"This important collaboration with Dr. Jordan is an acknowledgement that IdeS is an exciting project that has the potential to revolutionize the whole area of transplantation, especially in sensitized patients. In parallel, we are pursuing other clinical studies for IdeS in Europe and the US", commented Christian Kjellman, CSO of Hansa Medical.

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 and Distinguished Alumni Award from the University of North Carolina-Chapel Hill School of Medicine. Dr. Jordan is a member of national and international professional societies and has served on the editorial boards of numerous professional journals.

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About IdeS

IdeS, a unique molecule with a novel mechanism, is a bacterial enzyme that cleaves human IgG antibodies. IdeS degrades all IgG specifically, swiftly and efficiently. IdeS 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 favorable safety profile. During 2014 and 2015, a Phase II clinical trial in sensitized patients awaiting kidney transplantation has been conducted. Preliminary data shows that IdeS has very good efficacy 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 indications within a variety of rare autoimmune diseases. IdeS is protected by several patents and has been published in numerous peer review 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.

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