

# Hansa Medical

- PRESS RELEASE -  
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## Hansa Medical receives FDA Orphan Drug Designation for IdeS

**Hansa Medical today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to IdeS for the prevention of antibody mediated organ rejection in solid organ transplant patients. More information about the ODD has been posted on [www.fda.com](http://www.fda.com)**

Approximately 30 percent of the patients on the waiting lists for kidney, heart, lung and pancreas, equivalent to approximately 35 000 patients in the US, are sensitized to Human Leukocyte Antigen (HLA). HLA sensitization is a risk factor in transplantation and a significant part of the sensitized patients are rarely considered for transplantation due to the increased risk of antibody mediated organ rejection. Hansa Medical currently conducts Phase II trials with candidate drug IdeS for the prevention of antibody mediated organ rejection in kidney transplant patients.

*"We are pleased to receive orphan designation for IdeS in the US as HLA sensitization constitutes a significant barrier for transplantation for thousands of patients annually. We believe that IdeS has the potential to enable transplantation for these patients "* states Göran Arvidson, CEO at Hansa Medical AB.

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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. Currently, Phase II trials with IdeS are ongoing in Sweden and the US. 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 Hansa Medical AB**

Hansa Medical is a biopharmaceutical company focused on novel immunomodulatory enzymes and diagnosis of severe inflammatory conditions. Its 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-launched 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.

*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 September 14, 2015 at 14.30 CET.*