

# Hansa Medical

- NEWS -  
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## Lead candidate IdeS discussed in FDA workshop

Hansa Medical AB (publ), a biopharmaceutical company developing novel immunomodulatory enzymes, announced today that its lead candidate IdeS was discussed at a 2-day workshop titled “*Antibody Mediated Rejection in Kidney Transplantation*”, arranged by the U.S. Food and Drug Administration (FDA). Transcripts from the workshop have been released and are available on the FDA website.

In the workshop, novel opportunities for the treatment and prevention of Antibody Mediated Rejection (ABMR or AMR) were discussed. Initial data from studies using IdeS was presented by Professor Robert Montgomery, MD, Director of NYU Transplant Institute in New York, New York, and Professor Steve Woodle, MD, Director of the Division of Transplantation at University of Cincinnati, Cincinnati, Ohio. No new data was disclosed.

Dr Lena Winstedt, Vice President Project Management at Hansa Medical, says: “*The discussions covered the potential risk-benefit profile of IdeS as a desensitization treatment and the treatment of severe AMR in kidney transplantation. The presenters and the audience at the well-attended workshop were generally very optimistic about the potential of IdeS in kidney transplantation.*”

The presentations by Professor Montgomery and Professor Woodle, as well as the transcripts from the workshop are available on the FDA website:  
<https://www.fda.gov/Drugs/NewsEvents/ucm532070.htm>

In the transcripts, IdeS is discussed on pages 285-289, 300-306 and 311 from Day 1 of the workshop and on pages 66-68 and 98-100 from Day 2 of the workshop.

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 and Europe 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.

*The information was submitted for publication, through the agency of the contact person set out below, at 8 am CEST on May 12, 2017.*

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## **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 a wide range of 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.