

# Hansa Medical

- PRESS RELEASE -  
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## Hansa Medical's application for Orphan Drug Designation for IdeS in the EU receives positive opinion

LUND, Sweden, December 15, 2016, Hansa Medical AB (publ: HMED), a biopharmaceutical company focusing on novel immunomodulatory enzymes, announces that the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA) has issued a positive opinion on Hansa Medical's application for Orphan Drug Designation of recombinant IdeS for the prevention of graft rejection following solid organ transplantation. In September 2015, IdeS was granted Orphan Drug Designation for the prevention of antibody mediated organ rejection in solid organ transplant patients by the U.S. Food and Drug Administration (FDA).

Commenting on today's announcement, Göran Arvidson, CEO of Hansa Medical, said: "The positive opinion from the Committee for Orphan Medicinal Products on our Orphan Drug Designation application for IdeS is another important regulatory milestone, following the grant of Orphan Drug Designation from the FDA in 2015. Transplantation is a lifesaving procedure which can significantly improve the quality of life of these very sick patients. Sadly many patients are unable to receive the transplant they need because they are highly sensitized with significant levels of antibodies which can cause organ rejection. We believe IdeS has the potential to revolutionize the transplant process and to become the first therapy to enable these patients to be transplanted. The current preliminary clinical data generated with IdeS in kidney transplantation have been highly encouraging and we look forward to progressing it through the pivotal trial towards registration."

Based on positive opinion from the Committee for Orphan Medicinal Products (COMP), the European Commission grant Orphan Drug Designation to drugs intended for the treatment of life threatening or chronically debilitating rare diseases where no therapeutic options are either authorised or where the drugs will be of significant benefit to those affected by the condition. Rare diseases are those defined as having a prevalence of no more than five in 10,000 persons in Europe. The designation provides development and commercial incentives, including 10 years of market exclusivity, protocol assistance on the development of the drug, including clinical studies, and certain exemptions from or reductions in regulatory fees.

*This information is information that Hansa Medical AB (publ) is obliged to make public pursuant to the Financial Instruments Trading Act. The information was submitted for publication at 08:30am CET on December 15, 2016.*

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## 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. Preliminary efficacy data reported from three phase 2 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. 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 rare 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 30,000 patients in Europe, 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 antibody mediated organ rejection.

## About Hansa Medical AB

Hansa Medical is a biopharmaceutical company focusing on novel immunomodulatory enzymes. The lead project IdeS is a proprietary antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Additional projects focus on development of new antibody modulating enzymes, as well as HBP, a diagnostic biomarker for prediction of severe sepsis at emergency departments that is already introduced on the market. The company is based in Lund, Sweden. Hansa Medical's share (ticker: HMED) is listed on Nasdaq Stockholm.