

# Hansa Medical

- PRESS RELEASE -  
December 21, 2016

## Hansa Medical discontinues its Phase II study in acquired Thrombotic Thrombocytopenic Purpura (TTP)

**Hansa Medical AB (Nasdaq Stockholm: HMED) today announced that it will not continue its clinical Phase II study with IdeS in acquired TTP. The decision follows Hansa Medical's review of initial results from the study demonstrating a non-favourable risk benefit profile. This decision to discontinue the study has no impact on Hansa Medical's ongoing studies with IdeS in renal transplantation or planned studies in other autoimmune indications.**

The initial data from treatment of two patients with asymptomatic TTP clearly demonstrated that IdeS effectively cleaves IgG antibodies, including all pathogenic anti-ADAMTS13 autoantibodies. However, the efficient cleaving of the anti-ADAMTS13 autoantibodies did not result in a convincing positive effect on the activity of the ADAMTS13 enzyme in relation to the level of adverse events observed. Both patients treated in the study experienced symptoms including fever, rash and joint pain approximately one week after treatment, possibly related to treatment with IdeS in asymptomatic TTP-patients. The symptoms were clinically manageable and unexpected based on observations from completed and ongoing studies.

Commenting on today's announcement, Dr. Steven Glazer, Chief Medical Officer of Hansa Medical, said, "Hansa Medical has a deep commitment to the development of antibody-degrading and antibody-modulating enzymes for use in transplantation and autoimmune diseases. While we are disappointed that we were not able to demonstrate a convincing risk benefit profile in asymptomatic patients with acquired TTP, we are optimistic about the clinical development of IdeS in our lead programs, including transplant patients. These findings in asymptomatic TTP patients have no implications for ongoing studies with IdeS in transplantation or other planned studies in autoimmune indications. We are evaluating the possibility to investigate the safety and efficacy of IdeS in symptomatic acute patients with TTP in a separate Phase II study in the future."

Acquired TTP is a severe and acute autoimmune blood disorder in which the presence of autoantibodies can result in systemic life threatening micro-clotting in vital organ. The Hansa Medical-sponsored study with IdeS in TTP is an open-label study to evaluate the safety, tolerability, efficacy, pharmacodynamics and pharmacokinetics of IdeS in asymptomatic patients with acquired TTP.

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 09:40am CET on December 21, 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. Top-line 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 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.