

# Hansa Medical

- PRESS RELEASE -  
May 19, 2017

## IdeS selected for EMA Priority Medicines (PRIME) scheme

Hansa Medical AB (publ), a biopharmaceutical company developing novel immunomodulatory enzymes, announced today that European Medicines Agency (EMA) has granted access to its Priority Medicines (PRIME) scheme for IdeS; Hansa Medicals lead candidate intended for desensitization of highly sensitized kidney patients thus making them eligible for transplantation by inactivation of anti-HLA IgG antibodies.

Göran Arvidson, President and CEO of Hansa Medical, said: *"The granting of PRIME access by the EMA allows us to continue to accelerate the development of IdeS. We believe IdeS could be a potentially transformative treatment option for those patients in need of lifesaving kidney transplantation. We would like to thank the EMA for their support and we look forward to working with them to advance this important new drug towards submission of a Market Authorization Application (MAA) for EU marketing authorization."*

The PRIME designation for IdeS was granted on the basis of data from four independent Phase II studies in the U.S. and Sweden (ClinicalTrials.gov Identifiers NCT02224820, NCT02426684, NCT02475551 and NCT02790437), the request included data from 30 HLA-sensitized patients, who received IdeS immediately before kidney transplantation. IdeS was shown to be effective in reducing donor specific antibodies (DSAs) to levels allowing lifesaving kidney transplantation.

The clinical multicenter study Highdes (NCT02790437) is currently recruiting patients in the U.S. and Europe that have either failed on previous attempts of desensitization or are considered to be too difficult to desensitize with currently available methods. The aims are to complete recruitment of approximately 20 patients during 2017, submit a Biologics License Application (BLA) to the FDA in 2018 in order to get marketing authorization to commercialize IdeS in the U.S. and file Marketing Authorization Application (MAA) at the European Medicines Agency (EMA) for marketing authorization of IdeS in the European market.

*The information in this press release is disclosed pursuant to the EU Market Abuse Regulation. The information was released for public disclosure through the agency of the contact person stated below on May 19, 2017 at 14.00 CEST.*

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**About Priority Medicines (PRIME)**

PRIME is an initiative from the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. PRIME is intended to optimize development plans and speed up assessment of the medicine's application so these medicines may potentially reach patients earlier. PRIME focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by EMA. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical

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needs based on early clinical data.

## 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. 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. 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.

## 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.