Hansa Medical

- PRESS RELEASE -

February 16, 2018

Hansa Medical receives FDA Orphan Drug Designation for IdeS and the treatment of Guillain-Barré syndrome

Hansa Medical today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to IdeS (INN: Imlifidase) for the treatment of Guillain-Barré syndrome (GBS). More information about the ODD has been posted on www.fda.com

"We are pleased to receive orphan designation for IdeS in the US for the treatment of Guillain-Barré syndrome. IdeS' fast and effective ability to cleave IgG antibodies has significant treatment potential in Guillain-Barré syndrome and we are planning a Phase II study with IdeS in this acute neurological disease", states Ulf Wiinberg, Acting CEO at Hansa Medical AB.

Guillain Barré syndrome (GBS) is an acute autoimmune disease in which the peripheral nervous system is attacked by the immune system and IgG-antibodies. It affects 1-2 in 100,000 people annually[1]. In February 2017, preclinical data demonstrating the treatment potential of IdeS in GBS were published[2]. In a model of GBS, inactivation of IgG by IdeS treatment significantly promoted the recovery and reduced the degeneration of peripheral nerves. The data show that treatment with IdeS could potentially become a novel therapeutic strategy for the treatment of GBS.

1. McGrogan et al., *"The Epidemiology of Guillain-Barré Syndrome Worldwide",* Neuroepidemiology;2009, 32(2):150-63
2. Wang et al. *"IgG-degrading enzyme of Streptococcus pyogenes (IdeS) prevents disease progression and facilitates improvement in a rabbit model of Guillain-Barré syndrome",* Exp Neurol. 2017 May;291:134-140

This is information that Hansa Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below at 9:45am CET on February 16, 2018.

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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. 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 highly sensitized patients that do not respond to available desensitization methods. Results from two ongoing studies are expected in 2018. In addition to transplantation, IdeS is being evaluated in a clinical Phase II study in the rare autoimmune disease anti-GBM antibody disease and IdeS has potential applications in a variety of additional 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

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for transplantation and acute autoimmune diseases. The lead product, 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 in acute autoimmune indications. The company also has a strong pipeline of preclinical projects that may provide a second wave of potential drugs. Under the project name NiceR, novel immunoglobulin-cleaving enzymes are developed for repeat dosing with the objective of applying the Hansa Medical technology in relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden, and its shares are listed on Nasdaq Stockholm (ticker: HMED).