Hansa Medical

- PRESS RELEASE -

July 9, 2018

Hansa Medical lead candidate imlifidase (IdeS) granted orphan drug designation by the FDA for anti-GBM antibody disease

Hansa Medical today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to imlifidase (IdeS) for the treatment of anti-GBM antibody disease (anti-GBM), also known as Goodpastures disease. More information about the orphan drug designation has been posted on www.fda.gov

Anti-GBM is a severe kidney disease where the immune system mistakenly develops IgG-antibodies, resulting in an acute immune attack on the kidneys and in some patients also on the lungs. In severe anti-GBM, the disease may progress to renal failure or death. There is no approved treatment of anti-GBM and less than one third[1] of the patients survive with a preserved kidney function after six months follow-up.

"We believe that imlifidase's fast, effective and well tolerated IgG eliminating property has the potential to make a significant difference for patients with anti-GBM", said Søren Tulstrup, CEO at Hansa Medical AB. "*We are very pleased to receive orphan designation for imlifidase in the US for the treatment of anti-GBM. This both confirms the high unmet medical need and further encourages us to continue our clinical investigations with imlifidase in this devastating disease."*

The FDA Orphan Drug Act (ODA) provides for granting special status to a drug or biological product to treat a rare disease that affect fewer than 200,000 people in the US. Orphan drug designation qualifies the sponsor of the drug for various development incentives of the ODA, including tax credits, protocol assistance and up to seven years of US marketing exclusivity from time of approval of BLA.

In June 2017, an open label investigator-initiated Phase II study in severe anti-GBM antibody disease (ClinicalTrials.gov identifier NCT03157037) was initiated with Hansa Medical lead candidate imlifidase with Professor Mårten Segelmark at Linköping University Hospital, Sweden, as coordinating principal investigator and sponsor. The aim is to enrol approximately 15 patients in Sweden, Denmark, Austria, Czech Republic, France and the UK by the end of 2018. The primary objective of the study is to evaluate the safety and tolerability of imlifidase in patients with severe anti-GBM antibody disease in addition to standard-of-care. Imlifidase efficacy will be assessed by evaluating renal function at six months after imlifidase treatment.

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 08:00am CET on July 9, 2018.

For further information, please contact:
Hansa Medical AB (Publ)
Emanuel Björne, Vice President Business Development and Investor Relations
Mobile: +46707175477
E-mail: emanuel.bjorne@hansamedical.com
www.hansamedical.com

About anti-GBM antibody disease

Anti-GBM antibody disease, also known as Goodpasture disease, is an acute autoimmune disease where autoantibodies directed against type IV collagen cause acute inflammation of the kidney and/or the lungs. Anti-GBM antibody disease is a rare disease affecting one in a million annually[2].

About imlifidase

Imlididase (INN), also known as IdeS, is an enzyme that depletes IgG antibodies fast and effectively. Hansa Medical is developing imlifidase 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 imlifidase rapidly and significantly reduced anti-HLA antibodies, enabling transplantation. Imlifidase 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, imlifidase is being evaluated in a clinical Phase II study in the rare autoimmune disease anti-GBM antibody disease and imlifidase has potential applications in a variety of additional autoimmune diseases. Imlifidase is protected by several patents and results of studies with imlifidase 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, imlifidase (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).

References

1. Hellmark et al., Journal of Autoimmunity 48-49 (2014) 108e112. *“Diagnosis and classification of Goodpasture’s disease (anti-GBM)”*
2. R Kluth et al., J Am Soc Nephrol. 1999 Nov;10(11):2446-53, *“Anti-Glomerular Basement Membrane Disease”*