

Hansa Medical

Hansa Medical Receives Positive Opinion for Orphan Drug Designation in the EU for Imlifidase for Anti-GBM Disease

Lund, Sweden, October 24, 2018- Hansa Medical AB (NASDAQ Stockholm:HMED), the leading biopharma company focusing on inhibition of immunoglobulin G (IgG)-mediated immunopathologies, today announced that the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA) has issued a positive opinion on Orphan Drug Designation for imlifidase for the treatment of anti-glomerular basement membrane (anti-GBM) antibody disease. A positive opinion by the COMP precedes official designation by the European Commission.

"This positive opinion on Orphan Drug Designation for imlifidase in anti-GBM antibody disease underscores the high unmet medical need in this acute autoimmune disorder," said Søren Tulstrup, President and Chief Executive Officer of Hansa Medical. *"We are pleased the COMP has recognized the potential for imlifidase, with its rapid, effective and safe elimination of IgG, to help prevent acute kidney damage and avoid the need for chronic dialysis for patients with this devastating disease."*

Anti-GBM antibody disease, also known as Goodpasture's disease, 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, on the lungs as well. Severe anti-GBM antibody disease may progress to renal failure or death, and less than one third¹ of patients survive with preserved kidney function after six months follow-up.

Based on the positive opinion from the COMP, the European Commission grants Orphan Drug Designation to drugs intended for the treatment of life threatening or chronically debilitating rare diseases where either no therapeutic options are authorized 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.

An open-label, investigator-initiated Phase 2 study evaluating imlifidase for the treatment of severe anti-GBM antibody disease (ClinicalTrials.gov identifier NCT03157037) is ongoing. Target enrollment is approximately 15 patients in Sweden, Denmark, Austria, Czech Republic, France and the UK. 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. Efficacy will be assessed by evaluating renal function at six months following treatment with imlifidase.

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 CEST on October 24, 2018.

About anti-GBM antibody disease

Anti-GBM antibody disease, also known as Goodpasture's 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 annually².

About Imlifidase

Imlifidase (previously known as IdeS) is an enzyme that specifically cleaves IgG antibodies, thereby inhibiting the IgG-mediated immune response. Hansa Medical is developing imlifidase as a proprietary treatment to enable kidney transplantation in patients with an immunological barrier to transplant surgery due to the presence of donor specific antibodies (DSAs). Efficacy data reported from four Phase 2 studies have demonstrated that imlifidase rapidly and significantly reduced these DSAs, enabling kidney

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transplantation. In addition to transplantation, imlifidase is being evaluated in a Phase 2 clinical study in anti-GBM antibody disease, a rare autoimmune disorder, and imlifidase has potential applications in a variety of additional autoimmune diseases.

About Hansa Medical

Hansa Medical (NASDAQ Stockholm:HMED) is a biopharmaceutical company developing novel immunomodulatory enzymes for organ transplantation and acute autoimmune diseases. The Company's lead product, imlifidase, is a proprietary antibody-degrading enzyme in late-stage clinical development for kidney transplant patients and has significant potential for further development in other solid organ transplantation and in acute autoimmune indications. Hansa also has a strong pipeline of preclinical projects that may provide a second wave of potential drugs. Under the project name NiceR, the Company is developing novel immunoglobulin-cleaving enzymes for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden.

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"*

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