

Hansa Medical

- PRESS RELEASE -
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First patient treated with IdeS in Phase II study in acquired Thrombotic Thrombocytopenic Purpura (TTP)

Hansa Medical AB (publ) today announced that the first patient has been recruited and treated in a Phase II clinical study with IdeS in the acute autoimmune disease acquired *Thrombotic Thrombocytopenic Purpura (TTP)* at University College Hospital in London.

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 organs. 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.

The patients in the study will have low ADAMTS13 activity. ADAMTS13 is a significant component in the coagulation system. An important goal of the study is to investigate if one dose of IdeS results in increased ADAMTS13 activity by cleaving ADAMTS13 autoantibodies. The Clinical Investigator, Dr. Marie Scully, consultant haematologist at UCLH, is a leading expert in patient care and clinical research in TTP.

The study will include up to six patients with acquired TTP and low ADAMTS13 activity who are asymptomatic at the time of enrolment into this study. The study is expected to be completed during 2017.

“This novel therapy, initially investigated to determine safety and efficacy, could provide an innovative treatment for acute TTP, clearing the antibodies against ADAMTS 13, aiding response to remission and reducing morbidity and mortality”, says Dr. Scully, who is supported by the National Institute for Health Research University College London Hospitals Biomedical Research Centre.

“We are happy to now announce our progress into the autoimmune space through the initiation of this explorative Phase II trial with IdeS in acquired TTP. The effective and fast IgG-cleaving mode-of-action of IdeS makes it highly relevant to evaluate the efficacy and safety of IdeS in this potentially devastating acute condition”, says Göran Arvidson, CEO of Hansa Medical AB.

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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 Göran Arvidson as stated below on October 11, 2016 at 08.30 CET.

About acquired TTP

Acquired TTP is an ultra-rare, acute, auto-immune blood clotting disorder, affecting 1/100,000

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inhabitants. It has a sudden onset caused by impaired activity of the ADAMTS13 enzyme (typically <10% of that in plasma of healthy individuals), leaving ultra-large Von Willebrand Factor (vWF) molecules uncleaved (vWF is an essential protein involved in the blood clotting process). These ultra-large vWF molecules bind to blood platelets, resulting in severe thrombocytopenia (very low platelet counts) and formation of micro-clots in small blood vessels throughout the body. Acquired TTP is associated with severe morbidities of the brain, heart and kidney and affects life expectancy and quality of life. Mortality is high at 10-15% within 2 weeks after initial diagnosis. Moreover, the risk of recurrences is high in patients with persistently low levels of ADAMTS13 after treatment with the current standard of care, which consists of daily plasma exchange and immune-suppressants.

About IdeS

IdeS, a unique molecule with a novel mechanism, is an enzyme that specifically cleaves human IgG antibodies. IdeS has been evaluated in a Phase I study in healthy subjects and in a Phase II study in sensitized patients awaiting kidney transplantation demonstrating that IdeS is highly effective in reducing anti-HLA antibodies to levels acceptable for transplantation with a favorable safety profile. The efficacy and safety of IdeS in transplantation are currently investigated in three on-going Phase II studies in sensitized kidney patients in Sweden and the US. In addition to transplantation, IdeS has potential applications in a variety of rare autoimmune diseases and currently, the efficacy and safety of IdeS are investigated in a Phase II study in acquired Thrombotic Thrombocytopenic Purpura.

About Hansa Medical AB (publ)

Hansa Medical is a biopharmaceutical company focusing on novel immunomodulatory enzymes. The lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation, rare autoimmune diseases and oncology. 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.

About UCLH

UCLH (University College London Hospitals NHS Foundation Trust), situated in the West End of London, is one of the largest NHS trusts in the United Kingdom and provides first-class acute and specialist services. The state-of-the-art University College Hospital which opened in 2005, is the focal point of UCLH alongside four cutting-edge specialist hospitals. UCLH is committed to research and development and forms part of UCL Partners which in March 2009 was officially designated as one of the UK's first academic health science centres by the Department of Health. UCLH works closely with UCL, translating research into treatments for patients. For more information, visit: www.uclh.nhs.uk, Facebook (UCLHNHS), Twitter (@UCLH) or Youtube (UCLHvideo).