

Hansa Medical

Hansa Medical Announces Appointment of Vincenza Nigro as Vice President, Global Medical Affairs

Lund, Sweden, September 17, 2018 -- Hansa Medical AB (NASDAQ Stockholm: HMED), a biopharmaceutical company focused on immunomodulatory enzymes for organ transplantation and acute autoimmune conditions, today announced the appointment of Vincenza Nigro as Vice President, Global Medical Affairs.

Ms. Nigro brings more than two decades of international, life sciences industry expertise in medical affairs, clinical development and commercial leadership roles, including deep experience in transplantation and orphan diseases. She will report to Søren Tulstrup, President & CEO of Hansa Medical and will be based in the US. Ms. Nigro will assume overall responsibility for Hansa Medical's global medical affairs strategy for its lead candidate imlifidase (INN), also known as IdeS, including pre-launch medical affairs activities for imlifidase in kidney transplantation. She will also be responsible for expanding and leading Hansa Medical's global medical affairs team, with her primary focus on the US and Europe.

Imlifidase is an enzyme with a novel and proprietary mechanism to rapidly and specifically cleave immunoglobulin G (IgG), enabling kidney transplantation in sensitized patients. Follow-up data from two Phase 2 studies of imlifidase in kidney transplantation are expected later this month; these results have the potential to serve as the basis of a Biologics License Application (BLA) submission to the US Food and Drug Administration.

"We are delighted to welcome Vincenza to Hansa at this exciting time as we await follow-up data from our Phase 2 trials for imlifidase in kidney transplantation. With her extensive experience building and leading high-performance medical affairs teams and life cycle management of innovative transplant related and immunology products, she will be a strong and valuable addition to our team as we transform Hansa Medical into a full-fledged, global commercial-stage biotech company," said Søren Tulstrup, President & CEO of Hansa Medical.

Most recently, Ms. Nigro built and led the global medical affairs function at Veloxis, a specialty pharmaceutical company focused on transplantation. Previously, she spent over a decade at Hoffmann-La Roche in the US in drug discovery, clinical development and commercial roles within immunology and transplantation. She has also held a commercial leadership role at US specialty pharma company Enzon Pharmaceuticals, which was focused on oncology. Ms. Nigro holds a Bachelor of Science degree in Biology from Fairleigh Dickinson University and an MBA degree from Massachusetts Institute of Technology (MIT).

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 September 17, 2018.

About imlifidase

Imlifidase (IdeS) is an enzyme that depletes Immunoglobulin G (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 transplant surgery due to the presence of anti-human leukocyte antigen (HLA) IgG antibodies. Efficacy data reported from three Phase 2 studies have demonstrated that imlifidase rapidly and significantly reduced anti-HLA antibodies, enabling transplantation. In addition to transplantation, imlifidase is being evaluated in a clinical Phase 2 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.

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About sensitized patients

Many patients on the waiting list for organ transplantation are 'sensitized,' meaning they carry antibodies to HLA. When these antibodies are targeted towards the HLA of a potential donor, they are known as donor specific antibodies (DSA) and can significantly compromise a transplanted organ. Patients with high levels of antibodies are highly sensitized and have a very low likelihood of finding a donor towards which they will not have DSA. Therefore, they may not be able to receive a transplantation at all and remain in a severe and debilitating disease state.

About Hansa Medical

Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for organ 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).

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