Hansa Medical

Hansa Medical Receives FDA Fast Track Designation for Imlifidase for Transplantation

Lund, Sweden, October 17, 2018- Hansa Medical AB (NASDAQ Stockholm: HMED), the leading biopharma company focusing on inhibition of immunoglobulin G (IgG)-mediated immunopathologies, today announced that the U.S. Food and Drug Administration (FDA) has granted imlifidase Fast Track Designation for the investigation of imlifidase for transplantation.

Imlifidase (IdeS) is an enzyme in late-stage clinical development that specifically cleaves IgG antibodies, thereby inhibiting the IgG-mediated immune response. Hansa Medical is initially developing imlifidase as a proprietary treatment to enable kidney transplantation in sensitized patients previously unable to undergo transplant surgery due to the presence of donor-specific antibodies (DSAs). In addition, imlifidase is being evaluated in a Phase 2 study in anti-GBM antibody disease, a rare and acute autoimmune disorder, and imlifidase has potential applications in other solid organ transplants and in a variety of additional acute autoimmune indications.

"This Fast Track Designation is validation of imlifidase's potential to address the significant unmet medical need for highly sensitized patients, a patient population for which transplantation is extremely difficult or impossible," said Søren Tulstrup, President and Chief Executive Officer of Hansa.

"Our two recently reported Phase 2 studies demonstrate imlifidase's ability to enable kidney transplantation for these patients, who otherwise face high mortality rates associated with long-term dialysis. We continue to actively engage with the regulatory agencies and anticipate submitting a Biologic License Application (BLA), as well as a Marketing Authorisation Application (MAA), in either the fourth quarter of this year or the first quarter of 2019."

The imlifidase Fast Track Designation is supported by efficacy data reported from four successfully completed Phase 2 studies that demonstrate imlifidase's ability to rapidly and significantly reduce Donor Specific Antibodies (DSAs), thereby enabling kidney transplantation. The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs to treat serious or life-threatening conditions that demonstrate the potential to address an unmet medical need. Fast Track designation provides a company more frequent communication with the FDA regarding the investigational drug's development plan and also provides eligibility for priority review if certain criteria are met.

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 17, 2018.

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 sensitized patients previously unable to undergo transplant surgery due to the presence of DSAs. Efficacy data reported from four Phase 2 studies have demonstrated that imlifidase rapidly and significantly reduced these DSAs, enabling kidney 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 Sensitized Patients

Many patients on the waiting list for organ transplantation carry antibodies to HLA, which is known as being 'sensitized'. When these antibodies are targeted towards the HLA of a potential donor, called DSAs, the transplanted organ can be significantly compromised. Patients who are highly sensitized, with high levels

of DSAs, will have a very low likelihood of finding a donor towards which they will not have DSA, potentially eliminating the ability to receive a transplant and requiring them to remain on dialysis in a debilitating disease state. Current desensitization methods are not feasible for most highly sensitized patients. Imlifidase's rapid cleavage of all IgG antibodies desensitizes sensitized patients, enabling deceased donor kidney transplantation. Two thirds of kidney transplantations in the U.S. and Europe are from deceased donors.

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.

For further information, please contact:

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

Swedish Investor and Media Relations:
Cord Communications
Mikael Widell
+46 70-311 99 60

U.K. Investor and Media Relations
FTI Consulting
Simon Conway/ Stephanie Cuthbert
+44 (0)20 3727 1000

U.S. Investor and Media Relations:
Argot Partners
Stephanie Marks / David Rosen (media)
+1 212 600 1902