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# Hansa Biopharma Receives Ethics and Regulatory Clearance to Start Phase 2 Study of imlifidase in Acute Antibody Mediated Rejection in Kidney Transplantation

**Lund, Sweden, March 26, 2019**– Hansa Biopharma AB (NASDAQ Stockholm: HNSA), the leader in immunomodulatory enzyme technology for rare IgG-mediated diseases, announced today that it received Clinical Trial Application and Ethics Committee approvals for the company's Phase 2 study of imlifidase in acute Antibody-Mediated Rejection (AMR) in Kidney Transplantation. The study will enroll approximately 30 patients at eight clinical trial centers in France, Sweden, Austria, Australia and the United States. Ethics and regulatory clearance is required to initiate the clinical study and to evaluate the effect of imlifidase in this patient group.

Acute AMR is one of the most challenging adverse events after kidney transplantation, occurring in 10-15% of patients, and is the main cause for graft dysfunction. In the U.S. and Europe, there are approximately 40,000 patients who receive kidney transplants annually and approximately 400,000 who currently live with a kidney transplant.

*"There is no approved treatment for acute AMR in heart, lung, kidney, liver and bone marrow transplants, and it remains a significant unmet medical need associated with loss of graft function. As we have demonstrated in our four Phase 2 studies of imlifidase to enable kidney transplantation for highly sensitized patients, our novel enzyme is effective in inactivating IgG. We believe imlifidase also has the potential to effectively treat acute AMR and prevent the devastating loss of a transplanted kidney,"* said Søren Tulstrup, Chief Executive Officer of Hansa Biopharma.

The Phase 2 study will recruit approximately 30 patients from eight sites in the U.S., France, Sweden, Austria and Australia over the next 12 months. The study is a randomized, open-label, multi-center, active control study designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in the treatment of active episodes of acute AMR in kidney transplant patients.

20 subjects will be randomized to receive imlifidase treatment, one intravenous dose of 0.25mg/kg. The 10 subjects in the active control arm will receive 5-10 sessions of plasma exchange (PE). Efficacy and safety will be monitored over a 6-month period post treatment.

More information about the study will be available at ClinicalTrials.gov under the study title “A Randomized, Open-Label, Multi-Centre, Active Control Study Investigating the Efficacy and Safety of Imlifidase in Eliminating Donor Specific Anti-HLA Antibodies in the Treatment of Active Antibody-Mediated Rejection in Kidney Transplant Patients”

Hansa has submitted a Marketing Authorisation Application to the European Medicines Agency (EMA) for IDEFIRIX™ (INN: imlifidase) for the treatment of highly sensitized patients to enable kidney transplantation. The submission was accepted for review by EMA on March 1, 2019. A dialogue is ongoing with FDA regarding a potential Biologic License Application (BLA).

*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 March 26, 2019.*

**About Antibody-Mediated Rejection**

Antibody-mediated rejection is a significant challenge to long term graft survival after kidney transplantation, occurring in 10-15% of new and existing cases. In the U.S. and Europe, there are approximately 40,000 patients who receive kidney transplants annually and approximately 400,000 who currently live with a kidney transplant. AMR can occur in patients with preexisting anti-Human Leukocyte Antigen (HLA) Donor-Specific Antibodies (DSAs) or in patients without DSAs at transplantation but who develop de novo DSAs. There are no approved drugs for AMR; today it is primarily treated with plasma exchange, intravenous gammaglobulin (IVIg) or rituximab. AMR patients not treated successfully risk graft failure, dialysis and return to transplantation waitlist.

**About imlifidase**

Imlifidase is an enzyme that specifically cleaves immunoglobulin G (IgG) antibodies, thereby inhibiting the IgG-mediated immune response. Hansa 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 Donor Specific Antibodies (DSAs). Efficacy data reported from four Phase 2 studies have demonstrated that imlifidase rapidly and significantly reduced these DSAs, enabling 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. Imlifidase is protected by a strong patent portfolio and results of studies with imlifidase have been published in multiple peer reviewed scientific journals.

**About Hansa Biopharma**

Hansa Biopharma AB (NASDAQ Stockholm: HNSA) is harnessing its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product, IDEFIRIX (imlifidase), is a unique antibody-degrading enzyme in late-stage clinical development to enable kidney transplantation in highly sensitized patients, with additional clinical studies in acute autoimmune indications. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden.

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