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Hansa Biopharma Announces European Medicines Agency Accepts Marketing Authorization Application for IDEFIRIX™ (imlifidase) as a Treatment for Enabling Kidney Transplantation in Highly Sensitized Patients

Lund, Sweden, March 1, 2019 – Hansa Biopharma AB (NASDAQ Stockholm: HNSA), the leader in immunomodulatory enzyme technology for rare IgG-mediated diseases, announced today that the European Medicines Agency (EMA) has accepted the Company's Marketing Authorization Application (MAA) for review of IDEFIRIX™ (INN: imlifidase). Hansa is seeking approval of IDEFIRIX as a treatment to enable kidney transplantation in highly sensitized patients. IDEFIRIX is a novel antibody-degrading enzyme that eliminates immunological barriers. It is administered as a single intravenous infusion immediately prior to transplantation and rapidly inactivates donor specific antibodies (DSAs).

This acceptance follows Hansa's submission of the MAA on 5 February 2019 and marks the beginning of the regulatory review process for IDEFIRIX in the European Union (EU). IDEFIRIX has both EU Orphan Drug Designation and Priority Medicines (PRIME) designation, an EMA program to enhance support for the development of medicines that target an unmet medical need. An opinion of the Committee for Medicinal Products for Human Use (CHMP) is expected within 210 days (plus any clock-stops for the applicant to provide answers to questions which may arise during the review). After the adoption of a CHMP opinion, a final decision regarding the MAA for IDEFIRIX is made by the European Commission.

"The MAA filing represents a significant milestone for Hansa as it is our first regulatory application for marketing authorization and a major step toward making IDEFIRIX available for highly sensitized patients waiting for a kidney transplant. These patients have a significant unmet medical need, often remaining in a debilitating disease state on long-term dialysis treatment. We have demonstrated that our unique enzyme's rapid and specific cleavage of IgG antibodies successfully enables lifesaving kidney transplantation, for these patients. IDEFIRIX has the potential to significantly improve highly sensitized patients' access to kidney transplantation," said Søren Tulstrup, Chief Executive Officer of Hansa.

The MAA for IDEFIRIX is based upon the successful outcomes from five clinical studies demonstrating the efficacy and safety of IDEFIRIX to successfully enable kidney transplantation. In addition, the file includes evidence of the significant medical need for highly sensitized patients who today have extremely limited opportunity for transplantation.

The dialogue with the U.S. Food and Drug Administration (FDA) to determine the path forward for U.S. regulatory approval is ongoing and Hansa will provide updated guidance regarding expected timeline for a Biologic License Application filing in the upcoming months. The FDA has granted IDEFIRIX Orphan Drug Designation and Fast Track Designation in kidney transplantation.

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 1, 2019.

About IDEFIRIX (imlifidase)

IDEFIRIX™ (imlifidase) is an enzyme that specifically cleaves immunoglobulin G (IgG) antibodies, thereby inhibiting the IgG-mediated immune response. Hansa is developing IDEFIRIX 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 IDEFIRIX rapidly and significantly reduced all DSAs, enabling transplantation. In addition to transplantation, IDEFIRIX is being evaluated in a Phase 2 clinical study in anti-GBM antibody disease, a rare autoimmune disorder, and IDEFIRIX has potential applications in a variety of additional autoimmune diseases. IDEFIRIX is protected by a strong patent portfolio and results of studies with IDEFIRIX have been published in multiple peer reviewed scientific journals.

About Highly Sensitized Patients

Many patients on the waiting list for organ transplantation carry antibodies to human leukocyte antigen (HLA), which is known as being 'sensitized.' Antibodies targeted towards HLA of a potential donor, called Donor Specific Antibodies (DSAs), can significantly compromise the transplanted organ. 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. Therefore, they may not be able to receive a transplant at all and remain on dialysis in a debilitating disease state indefinitely. Current desensitization methods are not feasible for most highly sensitized patients. IDEFIRIX's rapid cleavage



of all IgG antibodies, eliminates DSAs, enabling deceased donor kidney transplantation. Two thirds of kidney transplantations in the U.S. and Europe are from deceased donors.

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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