The EU Commission grants conditional approval for Idefirix™ (imlifidase) in highly sensitized kidney transplant patients in the European Union

The conditional approval by the European Commission serves as a landmark milestone for Hansa Biopharma, as Idefirix™ (imlifidase) will be the Company's first approved drug and will transform Hansa Biopharma into a commercial stage biopharmaceutical company

Lund, Sweden August 26, 2020. Hansa Biopharma ("Hansa"), the leader in immunomodulatory enzyme technology for rare IgG mediated diseases, today announced that the European Commission has granted conditional approval for Idefirix™ in highly sensitized kidney transplants patients.

The formal approval by the European Commission was received two months after the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion, recommending conditional approval of Idefirix for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

"We are very excited about today's decision from the European Commision to approve Idefirix in highly sensitized kidney transplant patients. This is the first approved drug for Hansa Biopharma and will bring hope to the thousands of highly sensitized patients across Europe waiting for a life-saving kidney transplant" says **Søren Tulstrup, President & CEO of Hansa Biopharma.**

"Today's approval further serves as a validation of the potential of Hansa Biopharma's proprietary drug development engine and will transform the company into a commercial stage biopharmaceutical company that brings lifesaving and life altering therapies to patients with rare diseases who need them and generate value to society at large."

Idefirix has been reviewed as part of the European Medicines Agency's (EMA) PRIority MEdicines (PRIME) programs, which support medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options.

The first treatments with Idefirix is expected to be available to patients in select European countries during the fourth quarter 2020, as communicated earlier.

A post-approval study will be initiated in parallel with the launch following the market authorization.

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About Hansa Biopharma

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.

The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications.

Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth quarter of 2020.

Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

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