

PRESS RELEASE

Hansa Biopharma completes enrollment in imlifidase phase 2 study in antibody mediated rejection (AMR) episodes post kidney transplantation

- 30 patients with active or chronic active antibody mediated rejection (AMR) episodes post kidney transplantation have been enrolled and randomized 2:1 to imlifidase v.s. standard-of-care
- Completion of enrollment marks an important milestone for Hansa, as the company explores the potential of imlifidase in the post transplantation setting.
- Acute AMR episodes post kidney transplantation occur in 5-7% of patients, with significant risk of patients losing graft function. There is no approved treatment for preventing and treating AMR.

Lund, Sweden May 23, 2022. Hansa Biopharma AB, "Hansa", (Nasdaq Stockholm: HNSA), pioneer in enzyme technology for rare immunological conditions, today announces the completion of enrollment in its phase 2 study evaluating safety, tolerability and efficacy of imlifidase in patients with active and chronic active antibody mediated rejection ("AMR") episodes. A first data read out is expected in the second half of 2022, as previously guided.

"The on-time completion of enrollment in the AMR phase 2 study is an important milestone in the clinical development of imlifidase for this patient population and is a testimony to our commitment to develop potentially life-saving and life-altering therapies for patients with rare immunological diseases with significant unmet medical need", says Christian Kjellman, Chief Science Officer, Hansa Biopharma. "Long-term graft survival is challenged by AMR post kidney transplantation, and imlifidase has the potential to have a meaningful positive impact for these patients and the healthcare system at large."

Acute AMR post kidney transplantation is a serious condition that occurs in 5-7%¹ of kidney transplants and is a significant challenge to long-term graft survival. AMR, is the main cause of graft dysfunction and loss after kidney transplantation. In the U.S. and Europe, approximately 45,000 patients receive kidney transplants annually, and approximately 400,000, currently live with a kidney transplant².

The AMR phase 2 program is a randomized, open-label, multi-center, controlled study, that has enrolled a total of 30 AMR patients across centers in France, Germany, Austria, Australia, and the U.S. This study is designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies ("DSAs") in acute AMR patients, post transplantation. Twenty individuals have been randomized to receive imlifidase treatment comprised of one intravenous dose of 0.25mg/kg, while 10 individuals in the active control arm received 5-10 sessions of plasma exchange. Efficacy and safety is monitored over a six-month period post treatment.

More information about the trial is available at ClinicalTrials.gov under [NCT03897205 \(2019\)](https://clinicaltrials.gov/ct2/show/study/NCT03897205).

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About imlifidase

Imlifidase is a unique antibody-cleaving enzyme originating from *Streptococcus pyogenes* that specifically targets IgG and inhibits IgG-mediated immune response. It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their

¹ Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724

² Global Observatory on donation & transplant

activity within hours after administration. Imlifidase has conditional marketing approval in Europe and is marketed under the trade name Idefix® for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

About Hansa Biopharma

Hansa Biopharma is a pioneering commercial-stage biopharmaceutical company on a mission to develop and commercialize innovative, lifesaving and life altering treatments for patients with rare immunological conditions. Hansa has developed a first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. Hansa has a rich and expanding research and development program, based on the Company's proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in transplantation, autoimmune diseases, gene therapy and cancer. Hansa Biopharma is based in Lund, Sweden and has operations in Europe and the U.S. The Company is listed on Nasdaq Stockholm under the ticker HNSA. Find out more at www.hansabiopharma.com.