Hansa Biopharma
Scheelevägen 22
SE- 223 63 Lund, Sweden
Phone: +46 46 16 56 70

www.hansabiopharma.com

PRESS RELEASE

Hansa Biopharma announces positive topline data from the imlifidase phase 2 study in antibody mediated rejection (AMR) episodes post kidney transplantation

- Data readout demonstrates a significantly superior capacity of imlifidase to rapidly reduce levels of donor-specific antibodies (DSAs) compared to plasma exchange (standard of care) in the five days following the start of the treatment.
- A total of 30 patients have been randomized 2:1 to either imlifidase or plasma exchange with a six-month follow up period.[1]
- These first results are an important milestone in executing on Hansa's strategy to expand the reach of its IgG antibody cleaving technology platform to address significant unmet medical needs in a wide spectrum of disease areas and indications.

Lund, Sweden November 28, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announces positive topline data from its phase 2 study evaluating safety, tolerability, and efficacy of imlifidase in reducing donor specific antibodies (DSAs) in patients with active and chronic active antibody mediated rejection (AMR) episodes. This data readout follows the completion of randomization and subsequent treatment of all enrolled patients and is in line with previously indicated timelines.

The topline data associated with the primary endpoint shows that imlifidase has significantly superior efficacy compared to plasma exchange in reducing DSAs during the five days following the start of treatment. Imlifidase effectively reduced the majority of DSAs in the patient population, achieving these results more rapidly and with significantly higher reduction levels compared to plasma exchange, which required multiple sessions to obtain adequate DSAs reduction. With regard to safety, imlifidase was well tolerated, and no safety signals were encountered during the study. Hansa plans to publish the full dataset from the study in 2023.

AMR is one of the most challenging adverse events after kidney transplantation and it constitutes a main cause for graft dysfunction and loss, with acute AMR episodes occurring in 5-7% of kidney transplants.[2] There are currently no approved therapies for the treatment of AMR, with the most commonly used treatments being intravenous immune globulin (IVIg) and therapeutic plasma exchange (PLEX).

"Acute AMR episodes post-transplantation and chronic AMR remain significant problems which can cause damage and loss of the organ, and force patients to revert to dialysis. The performance and rapidity of imlifidase which we have observed in this study is very promising and could open up new opportunities for improving the therapies for post-transplant AMR" says Prof. Stanley Jordan MD, Principal Investigator, Director of Division of Pediatric and Adult Nephrology at Cedars Sinai Medical Center, Los Angeles.

"What we are seeing from the first readout of our AMR phase 2 trial is very encouraging and provides further evidence of the potential imlifidase may have for management of transplant rejection", says Christian Kjellman, Chief Scientific Officer, Hansa Biopharma. "Current protocols can take up to several weeks to reach the desired effect, and in some cases the

outcome remains incomplete or ineffective. There is a clear need to provide patients experiencing post-transplant AMR with a more rapid and effective therapy that can quickly diminish DSAs, thereby minimizing the risk of damage to the kidney. Every organ successfully transplanted with longer graft-survival is a life-changing opportunity for patients and a benefit to society at large".

Hansa's AMR phase 2 program is a randomized, open-label, multi-center, controlled study, with a total of 30 randomized AMR patients across centers in France, Germany, Austria, Australia, and the United States. The primary objective of the study is to investigate the efficacy and safety of imlifidase compared to plasma exchange (PE) in removal of DSAs in patients who are experiencing an active or chronic active AMR episode after kidney transplantation. A total of 20 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 are monitored over a six- month period post treatment.

More information about the trial is available at ClinicalTrials.gov under NCT03897205 (2019).

This is information that Hansa Biopharma AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the contact person set out below, at 18:00 CET on November 28 2022.

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For more information:

Klaus Sindahl, *Head of Investor Relations*
M: +46 (0) 709-298 269
E: klaus.sindahl@hansabiopharma.com

Notes to Editors

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 https://hansabiopharma.com

References

1. ClinicalTrials.gov. NCT03897205 (2019). Available at: https://clinicaltrials.gov/ct2/show/NCT03897205
2. Puttarajappa C, et al. *J. Transplant.* 2012; 2012:193724