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PRESS RELEASE

Imlifidase met primary endpoint in 16-HMedIdes-12 phase 2 trial in patients with AMR following kidney transplantation

Statistically significant reduction in donor-specific antibodies (DSAs) observed among imlifidase patients within five days of treatment as compared to standard of care

Lund, Sweden, 14 December 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), today announced full results from the 16-HMedIdeS-12 phase 2 trial in patients with antibody mediated rejection (AMR) episodes following a kidney transplant demonstrating that imlifidase significantly reduced donor-specific antibodies (DSAs) within the first five days of treatment.

In the trial, the primary endpoint was the maximum reduction in DSA level at any time point during the 5 days following the start of treatment. Patients treated with imlifidase demonstrated a statistically significant reduction of DSAs by 94.4% compared to a 35.6% (p-value: <0.001) reduction in patients who received standard of care (plasma exchange, or PE). DSA levels subsequently returned to approximately 70% of the initial level in both treatment arms.

The secondary endpoint investigated overall kidney function following treatment. The imlifidase arm demonstrated a 74% six-month graft survival and eGFR of 30mL/min/1.73m2. A 100% six-month graft survival and eGFR of 33mL/min/1.73m2 was observed in the PE arm. Given the heterogeneity of the patient population, the trial was not designed nor sufficiently powered to be able show a statistically significant difference in the secondary outcome measures. Imlifidase demonstrated a safety profile consistent with previous clinical trials.

Dr. Achim Kaufhold, Chief Medical Officer, Hansa Biopharma said, "This is the first clinical trial with a head-to-head comparison of imlifidase and a frequently used standard of care treatment (plasmapheresis, or plasma exchange). Plasmapheresis can be challenging for both the patient and the physician, often requiring multiple treatment sessions over several weeks with slow reduction in donor specific antibody (DSA) levels. We are very encouraged by these results which underscore imlifidase's ability to rapidly reduce DSA levels, which is good news for patients who require safe and efficient reduction of DSA levels."

Prof. Stanley Jordan MD, Principal Investigator, Director of Division of Pediatric and Adult Nephrology at Cedars Sinai Medical Center, Los Angeles said, "AMR is a heterogeneous and complex disease that remains difficult to diagnose and treat. As clinicians we focus on reduction of DSAs levels quickly and effectively to limit the irreversible damage to the organ that can occur. This is an important step in understanding how imlifidase may benefit patients with AMR. The findings of this trial may inform a path forward to potentially address the issues of chronic inflammation and antibody rebound which will allow clinically meaningful results for this very difficult to treat patient population."

The AMR patient population is heterogeneous, consisting of both chronic patients – those who experience slow rejection after a transplant, and which often results in irreversible damage to the organ – and acute patients who experience AMR early post-transplant. Additionally, AMR can be driven by a combination of antibodies and T-cells-mediated action (CMR – cell mediated rejection), creating additional complexity when it comes to treatment strategy. Treatment guidance indicate reduction of DSA levels as one of the main goals of any AMR treatment.[1] To date, there are no approved therapies for the treatment of AMR, and all current treatments including standard of care are used off-label.[1]

More information about the trial is available at ClinicalTrials.gov: NCT03897205.

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 20:00 CET on 14 December 2023.

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Notes to editors

About imlifidase

Imlifidase is a unique antibody-cleaving enzyme originating from Streptococcus pyogenes that specifically targets IgG and inhibits IgG-mediated immune response.[2] It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours after administration. Imlifidase has conditional marketing approval in Europe and is marketed under the trade name Idefirix® for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor.

About 16-HMedIdes-12

16-HMedIdes-12 is randomized, open-label, multi-center, controlled phase 2 trial designed to evaluate safety, tolerability, and efficacy of imlifidase compared to plasma exchange (PE) in removal of DSAs in patients experiencing active and chronic active AMR episodes. The trial included 30 patients with AMR randomized to receive either imlifidase or PE in a 2:1 ratio.

About imlifidase and autoimmune diseases

Autoimmune diseases occur when the immune system mistakenly recognizes the body's own proteins, as foreign and mounts an immune response, creating antibodies against the body's own cells and tissues. Many autoimmune diseases are driven by pathological IgGs.

Hansa is exploring how imlifidase may be able to prevent or slow disease progression including debilitating, life-threatening symptoms. Imlifidase is currently being studied in the following autoimmune diseases: anti-glomerular basement membrane (anti-GBM) disease, Guillain-Barré Syndrome, and ANCA-associated vasculitis.

About Hansa Biopharma

Hansa Biopharma is a commercial-stage biopharmaceutical company and pioneer in immunoglobulin G (IgG)-cleaving enzyme technology 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 IgG antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients. 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.

References

1. Schinstock CA, et al. *Transplantation. 2020* May;104(5):911-922.
2. EDQM. (2020). International figures on donation and Transplantation 2019