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PRESS RELEASE

Imlifidase demonstrated positive safety, tolerability, and early efficacy outcomes in 15-HMedIdeS-09 phase 2 trial in Guillain-Barré Syndrome (GBS)

Lund, Sweden, 7 December 2023. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), today announced positive high-level data from the 15-HMedIdeS-09 phase 2 trial that demonstrated imlifidase was safe and well tolerated when administered prior to standard of care, including rapid improvement in disease-related efficacy measures. Further analysis of efficacy data will be conducted in 2024. 15-HMedIdeS-09 is an open-label, single arm, trial evaluating the safety, tolerability and efficacy of imlifidase in GBS patients in combination with standard of care (SoC) intravenous immunoglobulin (IVIg).

GBS is a rare, acute, paralyzing, inflammatory disease of the peripheral nervous system caused by the immune system damaging nerve cells and structures. It affects 1-2 in 100,000 people annually.[1] In GBS, rapid onset and progression of muscle weakness occurs and can lead to severe paralysis of the arms and legs. Approximately 25% of patients require mechanical ventilation for days to months and 20% are unable to walk after six months.[2,3] Even with current standard of care - either plasma exchange or immunoglobin therapy - GBS is fatal in 3-7% of cases.[2,4]

Dr. Achim Kaufhold, Chief Medical Officer, Hansa Biopharma said, "The results of 15-HMedIdeS-09 are very encouraging. Imlifidase was safe and well tolerated, and when compared to previously published data, a rapid improvement across several efficacy outcome measures was observed in patients treated with imlifidase in combination with standard of care. Immunoglobulin G (IgG) antibodies are thought to play an important role in GBS disease. With its ability to rapidly cleave IgGs, imlifidase could be a promising new option for halting this progressive and oftentimes debilitating disease."

Professor Shahram Attarian, Head of Department of Neuromuscular Diseases and ALS, Hopitaux Universitaires de Marseille (APHM), and International Coordinating Principal Investigator in the Phase 2 trial, said, "In the treatment of GBS, reducing the long-term damage caused to the peripheral nervous system is key. In severe patients, this damage can lead to long recovery times or even permanent muscle weakness, pain, and fatigue. The immediate reduction of autoantibodies could help stop the progression of the disease. I look forward to seeing the full results of this trial to better understand how imlifidase may be able to help more rapidly stop and revert the progression of GBS."

Further analysis will contextualize efficacy data from the single arm 15-HMedIdeS-09 study through a comparison to data from patients receiving standard of care treatment in the International Guillain-Barré Syndrome Outcome Study (IGOS) database. This analysis is expected to be completed and communicated in 2024.

More information about the trial is available at ClinicalTrials.gov under NCT03943589.

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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.[5] 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 15-HMedIdes-09 Trial

15-HMedIdes-09 is an open-label, single arm, multi-center study across the UK, France, and the Netherlands evaluating the safety, tolerability, and efficacy of imlifidase in GBS patients in combination with standard of care (SoC) intravenous immunoglobulin (IVIg). The administration of imlifidase prior to standard of care in patients experiencing GBS proved to be safe, well tolerated, and did not give rise to any safety concern. All subjects received a full dose of imlifidase, and no serious adverse events caused by imlifidase infusion related reactions were recorded.

About imlifidase and autoimmune diseases

Autoimmune diseases form a group of serious diseases caused by the immune system attacking the body. In many autoimmune diseases the immune system mistakenly recognizes the body's own proteins as foreign and mounts an immune response, creating antibodies to attack the body's own cells and tissues. Pathogenic IgG can contribute to a broad spectrum of autoimmune diseases.

Hansa is exploring how imlifidase may be able to prevent or slow the progression of these diseases and their 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.

In 2018, the U.S. Food and Drug Administration granted Orphan Drug Designation to imlifidase for the treatment of GBS. Despite treatment with current standard of care, GBS has a serious long-term impact on the patients' work and private life, even 3–6 years after the onset of illness. Recovery can be slow and take years. Persistent disability is seen in 20%–30% of adult patients and severe fatigue is a sequel of GBS in two thirds of adult patients.

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.

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