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PRESS RELEASE

Hansa Biopharma announces positive full results from 15-HMedIdeS-09 Phase 2 study and comparative analysis of imlifidase in patients with Guillain-Barré Syndrome

Lund, Sweden, 17 December 2024. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), today announced positive full results from the 15-HMedIdeS-09 single arm Phase 2 study of imlifidase, a first in class IgG cleaving enzyme, in Guillain-Barré Syndrome (GBS) and an indirect treatment comparison of the 15-HMedIdeS-09 study data to the International Guillain-Barré Syndrome Outcome Study (IGOS), a worldwide prospective study by the Inflammatory Neuropathy Consortium on prognosis and biomarkers of GBS.

Data from the 15-HMedIdeS-09 study demonstrated that severe GBS patients treated with a single dose of imlifidase (0.25 mg/kg) plus intravenous immunoglobulin (IVIg) had rapid overall improvement in functional status including expedited recovery of muscle strength, fast return to independently walking, and a median time to independently walk (e.g., reaching Guillain-Barré Syndrome Disability Scale (GBS DS) 2 or less) by 16 days.

The indirect treatment comparison concluded that patients in the 15-HMedIdeS-09 study treated with imlifidase plus IVIg returned to independently walking 6 weeks sooner when compared to severe GBS patients in the IGOS real-world comparator group treated with IVIg. Additionally, patients in the 15-HMedIdeS-09 study experienced statistically significant improvement across several clinically meaningful measures at multiple time points as compared to the IGOS real-world comparator group including 6.4 times more likely at week 1, and 4.2 times more likely at week 4 to walk independently.

Hitto Kaufmann, Chief R&D Officer, Hansa Biopharma said, "Our Phase 2 study results and the indirect treatment comparison with IGOS are critically important. Together they demonstrate the significant role imlifidase may play in future treatment options for GBS patients. Unlike other molecules, imlifidase can effectively and very rapidly remove IgG through enzymatic cleavage - halting the progression of nerve damage associated with GBS and stopping disease progression. The main goal of improved GBS treatments is to stop nerve damage early, reducing the time of hospitalization and support patients in regaining independence sooner. These findings underscore the role pathogenic IgG plays in severity and progression of GBS, and the clear potential of imlifidase to address unmet need in IgG-driven autoimmune diseases where faster acting treatment options are needed."

In GBS, IgG is a key driver of inflammatory attacks on peripheral nerves and has been clinically linked to the severity and progression of the disease. Rapid reduction of IgG levels has the potential to benefit GBS patients by depleting pathological IgG antibodies, thereby halting disease

progression resulting in faster recovery and less severe disease.[1] Improvement in GBS DS is important because it directly affects the clinical outcomes, recovery, and quality of life for patients. Better management of disease severity can help reduce the risk of life-threatening complications, shorten recovery time, prevent long-term disability, lower healthcare costs, and improve overall patient well-being.

Professor Shahram Attarian, Head of Department of Neuromuscular Diseases and ALS, Hopitaux Universitaires de Marseille (APHM), and International Coordinating Principal Investigator in the 15-HMedIdeS-09 Phase 2 study, said, “In the treatment of GBS and subsequent recovery process, early improvement and the ability to walk independently are important clinical milestones as they indicate a return to basic mobility and independence, and to an improved quality of life for patients. This analysis supports the potential role of imlifidase followed by standard of care IVIg as a potentially new treatment option in GBS. These are important results for patients and clinicians in the GBS community.”

Key Results: 15-HMedIdeS-09 Study
The 15-HMedIdeS-09 study included 30 adult patients who were treated with imlifidase plus IVIg. During the study, three patients were re-diagnosed, and the remaining 27 patients received a confirmatory diagnosis of severe GBS and were included in the efficacy analysis.

By the first week, 37% of patients in the 15-HMedIdeS-09 study were able to independently walk and the mean improvement in muscle strength was 10.7 points as assessed by Medical Research Council (MRC) sum score.

The median time to improve by at least one grade in the GBS DS was six days. By eight weeks, 67% of patients were able to walk independently, 40.7% of patients had regained the ability to run, and 37% of the patients had improved by at least three points in the GBS DS. Six months after imlifidase treatment, 63% of patients were able to run or had no functional disability (GBS DS ≤1). Administration of imlifidase was well tolerated in the study.

Key Results: Indirect Treatment Comparison of 15-HMedIdeS-09 Study with Real-World Comparator Group
When compared to the IGOS real-world comparator group (severe GBS patients treated with IVIg, n=754), patients in the 15-HMedIdeS-09 study (severe GBS patients treated with imlifidase in combination with IVIg, n=27) experienced significantly faster improvement in disability as measured by the GBS DS.

Patients in the 15-HMedIdeS-09 study improved by at least one step on the GBS DS, 3 weeks sooner (p=0.002) and returned to independently walking (GBS DS≤2) 6 weeks sooner versus patients in the IGOS real-world comparator group treated with IVIg (p=0.03).

Moreover, patients in the 15-HMedIdeS-09 study were more likely to quickly regain the ability to independently walk than the IGOS real-world comparator group treated with IVIg. At one week, patients in the 15-HMedIdeS-09 study were 6.4 times more likely (odds ratio 95% confidence interval: 2.3-17.5, p<0.001), and at four weeks, 4.2 times more likely (odds ratio 95% confidence interval: 1.6-11.5, p=0.005) to walk independently than those patients in the IGOS real-world comparator group treated with IVIg. Results were matched and weighted for various prognostic

factors including time from weakness onset to treatment initiation and baseline value for age, autonomic disfunction, cranial nerve involvement, GBS DS, and MRC sum score.

Hansa is developing novel immunomodulating biologic therapies based on its proprietary, first in class IgG cleaving platform and is focused on IgG driven immune mediated disease where there is high unmet medical need and little to no treatment options. The company has two IgG cleaving compounds. Imlifidase is a first generation, first in class, single dose therapy with proven efficacy and safety. It's conditionally approved in the EU for desensitization in kidney transplantation. HNSA-5487 is a second-generation molecule with redosing potential with a clinical development path focused on acute exacerbations in neuro-autoimmune disease including myasthenia gravis (MG).

The company plans to publish data from the study and indirect comparison. More information about the study is available at ClinicalTrials.gov under NCT03943589.

Hansa Biopharma will host a telephone conference on 18 December at 14:00 CET / 8:00 AM ET.

Slides used in the presentation will be available online following the call.

To participate in the telephone conference, please use the dial-in details provided below:

Participant Dial In (Toll Free): 1-877-270-2148
Participant International Dial In: 1-412-902-6510
*Please ask to be joined into the Hansa Biopharma call

Join the webcast here:
https://event.choruscall.com/mediaframe/webcast.html?webcastid=b3UzB3xg

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 21:40 CET on 17 December 2024.

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Notes to editors

About Guillain-Barré Syndrome

Guillain-Barré Syndrome (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.[2] In GBS, rapid onset and progression of muscle weakness occurs and can lead to severe paralysis of the arms and legs. Approximately 25 percent of patients require

mechanical ventilation for days to months and 20 percent are unable to walk after six months.[3,4] Even with current standard of care - either plasma exchange or IVIg therapy - GBS is fatal in 3-7% of cases.[3,5] Most GBS patients also have sensory disturbance (tingling or numbness or ataxia) and pain, and some patients have double vision or problems with swallowing. GBS may also involve the respiratory muscles, leading to intensive care unit (ICU) admission and mechanical ventilation.[6]

About Guillain-Barré Syndrome Disability Scale

The Guillain-Barré Syndrome Disability Scale (GBS DS) is a tool used to evaluate a patient's functional outcome and motor function. A disability score of 0 represents a normal condition; 1 indicates the patient has mild symptoms and is capable of running; 2 indicates the patient is able to walk 10 meters independently but is unable to run; 3 indicates the patient is able to walk only with assistance; 4 indicates the patient is bedridden or chair-bound; 5 indicates the patient is mechanically ventilated, and a score of 6 indicates the patient is deceased.

About GBS Medical Research Council Score

The Medical Research Council (MRC) Scale for Muscle Strength is a commonly used scale for assessing muscle strength from Grade 5 (normal) to Grade 0 (no visible contraction). The MRC sum score was first described by Kleyweg et al (1988) for use in the Dutch Guillain-Barré trial. This score was defined as the sum of MRC scores from six muscles in the upper and lower limbs on both sides so that the score ranged from 60 (normal) to 0 (quadriplegic).[7] The MRC sum score is used to monitor changes in muscle strength over time, assess the severity of GBS at diagnosis, and determine the need for further treatment interventions.[8]

About imlifidase

Imlifidase is a unique antibody-cleaving enzyme originating from *Streptococcus pyogenes* that specifically targets IgG and inhibits IgG-mediated immune response.[9] 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.[9]

About 15-HMedIdes-09 study

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 a single dose of imlifidase (0.25 mg/kg) in 30 adult 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 Hansa 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.[10-12] Pathogenic IgG can contribute to a broad spectrum of autoimmune diseases.

Hansa Biopharma is exploring how imlifidase and HNSA-5487 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 and Guillain-Barré Syndrome (GBS). HNSA-5487 is moving quickly into the clinical phase focusing on patients with myasthenia gravis (MG) and potentially other neuro-autoimmune diseases.

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. The company has a rich and expanding research and development program based on its proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in autoimmune diseases, gene therapy and transplantation. The company's portfolio includes imlifidase, a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients and HNSA-5487, a second-generation IgG cleaving molecule with redosing potential. 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 and follow us on LinkedIn.

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