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

www.hansabiopharma.com

PRESS RELEASE

Hansa Biopharma Completes Enrolment in Global Pivotal Phase 3 Trial of imlifidase in Anti-Glomerular Basement Membrane Disease

Data from the trial is expected to be shared in 2025

Lund, Sweden, 5 December 2024. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA) today announced it has completed the enrolment of patients in the GOOD-IDES-02 trial, a global pivotal Phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease. Anti-GBM is a rare, severe autoimmune condition affecting around 1.6 people per million annually.[1] Imlifidase has been granted orphan drug designation for the treatment of anti-GBM disease by both the U.S. FDA and the European Medicines Agency (EMA). Enrolment completion was originally planned for 2025.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "We are very pleased with the fast enrolment of all 50 patients in the GOOD-IDES-02 trial. The completion of patient enrolment in this pivotal Phase 3 trial is an important milestone in our efforts to investigate the potential role for imlifidase to address the high unmet need in anti-GBM. The majority of patients with anti-GBM today lose kidney function and two-thirds experience kidney failure requiring long-term dialysis. We look forward to sharing further updates on the outcome of the study and potential path forward in 2025."

Anti-GBM is Hansa Biopharma's most advanced program in the autoimmune space. GOOD-IDES-02 is an open label, multi-center Phase 3 trial involving over 40 centers across the US, UK, and EU. A total of 50 patients have been enrolled in the trial. In the trial, 25 patients were randomized to receive imlifidase in combination with standard of care (SoC), consisting of a combination of immunosuppressives, glucocorticoids, and plasma exchange, and 25 patients received only SoC. The primary objective of the study is to assess the superior effect on kidney function of imlifidase in combination with SoC versus SoC alone in the treatment of patients affected by severe anti-GBM disease. The performance of the treatment is assessed at 6 months through the evaluation of renal function as measured by estimated glomerular filtration rate (eGFR) and need of dialysis. In addition, the safety profile and efficacy on pulmonary symptoms and health related quality of life aspects are evaluated.

More information about the trial is available at ClinicalTrials.gov under NCT05679401.

--- ENDS ---

Contacts for more information:

Evan Ballantyne, Chief Financial Officer
IR@hansabiopharma.com

Stephanie Kenney, VP Global Corporate Affairs
media@hansabiopharma.com

Notes to editors

About anti-GBM disease

Anti-glomerular basement membrane (anti-GBM) disease, also known as Goodpasture disease, is a rare, severe autoimmune condition affecting around 1.6 people per million annually[1] with majority of patients losing their kidney function.[2,3] In anti-GBM disease, the immune system mistakenly develops antibodies against an antigen intrinsic to the glomerular basement membrane, resulting in an acute immune attack of the kidneys and, in around half of the patients, also the lungs. Approximately two thirds of anti-GBM patients will experience kidney failure and require long-term dialysis while awaiting potential kidney transplantation.[4] Some patients may also experience bleeding from the lungs. In one out of six patients, anti-GBM disease can become fatal during the acute phase.

Imlifidase has been granted orphan drug designation for the treatment of anti-GBM disease by both the U.S. FDA and the European Medicinal Agency (EMA).

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.[5]

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.6-8 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).

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 Biopharma 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 Biopharma 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 and follow us on LinkedIn.

References

1. Canney M, et al. Spatial and Temporal Clustering of Anti-Glomerular Basement Membrane Disease. Clin J Am Soc Nephrol. 2016 Aug 8;11(8):1392-1399. doi: 10.2215/CJN.13591215.
2. McAdoo SP, Pusey CD. Anti-Glomerular Basement Membrane Disease. Clin J Am Soc Nephrol. 2017 Jul 7;12(7):1162-1172. doi: 10.2215/CJN.01380217
3. Kluth DC, Rees AJ. Anti-glomerular basement membrane disease. J Am Soc Nephrol. 1999 Nov;10(11):2446-53. doi: 10.1681/ASN.V10112446.
4. Hellmark T, Segelmark M. Diagnosis and classification of Goodpasture's disease (anti-GBM). J Autoimmun. 2014 Feb-Mar;48-49:108-12. doi: 10.1016/j.jaut.2014.01.024.
5. European Medicines Agency. Idefirix® summary of product characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/idefirix-epar-product-information_en.pdf.
6. Angum F, et al. The Prevalence of Autoimmune Disorders in Women: A Narrative Review. Cureus. 2020 May 13;12(5):e8094. doi: 10.7759/cureus.8094.

7. Wang L, et al. Human autoimmune diseases: a comprehensive update. J Intern Med. 2015 Oct;278(4):369-95. doi: 10.1111/joim.12395.
8. Ma H, Murphy C, Loscher CE and O'Kennedy R (2022) Autoantibodies – enemies, and/or potential allies? Front. Immunol. 13:953726. doi: 10.3389/fimmu.2022.953726