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PRESS RELEASE

Hansa announces first patient dosed with imlifidase in a global pivotal phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease

Lund, Sweden May 30, 2023. Hansa Biopharma ("Hansa"), a pioneer in enzyme technology for rare immunological conditions, today announced the first patient has been dosed with imlifidase in the GOOD-IDES-02 trial, a global pivotal phase 3 trial in anti-glomerular basement membrane (anti-GBM) disease.

Søren Tulstrup, President and CEO, Hansa Biopharma said, "This is an exciting next step in the development of imlifidase and for patients with anti-GBM disease. GOOD-IDES-02 is the first and currently only pivotal randomized trial in anti-GBM disease, a condition with significant unmet medical need. This trial underscores our ongoing commitment and focus in advancing the science of and applications for imlifidase in conditions involving pathogenic IgG antibodies."

GOOD-IDES-02 is an open label, multi-center, phase 3 trial of 50 patients. A total of 30-40 centers are expected to be included in the study across the US, UK, and EU. The primary objective of the study is to assess the superior effect of imlifidase in combination with standard of care (SoC) versus SoC alone (consisting of a combination of immunosuppressives, glucocorticoids, and plasma exchange) in the treatment of patients affected by severe anti-GBM disease. The performance of the treatment is assessed through the evaluation of renal function at 6 months as measured by filtration rate and need of dialysis. In addition, the safety profile and efficacy on pulmonary symptoms and health related quality of life aspects will be explored.

The study follows a completed investigator-initiated phase 2 trial, which concluded that imlifidase therapy leads to rapid clearance of anti-GBM antibodies, with two-thirds of patients achieving dialysis independence six months after treatment compared to 18% in a historical control cohort.[1]

Mårten Segelmark, International Coordinating Investigator and Professor of Nephrology at Lund University and Skåne University Hospital said, "In anti-GBM disease, timely treatment is key to minimizing its potential damage to the kidneys. However, the ultra-rare nature of this condition can delay its identification and diagnosis. Imlifidase, not only reduces antibody levels in the bloodstream more rapidly compared to plasma exchange PLEX, but it also interferes with antibodies already bound to the kidney and lung tissues. This in turn may halt further disease progression in a faster and more efficient way as compared to standard of care. By promptly counteracting the immune reaction, we can aim to reduce the mortality of this disease and the risk of dialysis dependance. This could represent a significant step forward for a patient group who currently have very few treatment options."

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 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).

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

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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

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