Hansa Biopharma announces positive high-level data from investigator-initiated phase 2 trial with imlifidase to treat anti-GBM disease

Study concludes that imlifidase leads to rapid clearance of anti-GBM antibodies, with two-thirds of patients achieving dialysis independence six months after treatment

Positive data demonstrates potential to increase renal survival in anti-GBM antibody disease and marks an important milestone for expansion of imlifidase outside transplantation

Lund, Sweden September 24, 2020. Hansa Biopharma ("Hansa"), the leader in immunomodulatory enzyme technology for rare IgG mediated diseases, today announces positive high-level data from an investigator-initiated phase 2 trial that evaluated safety, tolerability and efficacy of imlifidase in 15 patients with severe anti-GBM antibody disease.

Anti-GBM antibody disease, also known as Goodpasture's disease, is a severe autoimmune disease where the immune system mistakenly develops IgG-antibodies directed against the glomerular basement membrane (GBM), resulting in an acute immune attack causing severe kidney injury and, in some patients, also injuring the lungs.

Anti-GBM is a rare and acute immunological disease with a significant unmet medical need that affects approximately 1.5 in a million people annually, with a majority of patients losing their kidney function and requiring chronic dialysis and kidney transplantation. In severe cases, anti-GBM antibody disease may lead to death.

The first high-level data read out has been completed and the encouraging results indicate that imlifidase treatment may lead to increased renal survival in patients with anti-GBM antibody disease due to rapid clearance of IgG antibodies. The phase 2 anti-GBM study enrolled 15 subjects, six females and nine males with a median age of 61 years of age (range 19-79 years) recruited across centers from five European countries, including Sweden, Denmark, Czech Republic, France and Austria.

At inclusion, ten of the patients were dialysis dependent, including five that were oliguric/anuric, while five patients were dialysis independent but had eGFR levels below 15 ml/min. Six hours after imflidase no patient had anti-GBM antibody levels above the normal range.

At six months, ten patients were dialysis independent (median eGFR 27 ml/min). Four patients were dialysis dependent, while one patient had died (unrelated to imlifidase treatment). The safety profile of imlifidase in the population was concluded as being favourable.

"The positive results from the phase 2 trial suggest the potential for treatment and thereby the opportunity to increase the chances of renal survival in difficult to treat patients with anti-GBM disease", says Sponsor and Coordinating Principle Investigator, Mårten Segelmark, Professor of Nephrology at Lund University and Linköping University.

"We are very encouraged by the positive outcome from the phase 2 trial in anti-GBM antibody disease. Anti-GBM is the first IgG-mediated disease outside transplantation, where imlifidase has been shown to stop an immunologic attack. This marks an important milestone in Hansa Biopharma's efforts to develop potentially lifesaving and life altering therapies for patients with

Contact information

Klaus Sindahl
Head of Investor Relations
Hansa Biopharma
M: +46 (0) 709–298 269
E: klaus.sindahl@hansabiopharma.com

Katja Margell
Head of Corporate Communications
Hansa Biopharma
M: +46 (0) 768-198 326
E: katja.margell@hansabiopharma.com

About Hansa Biopharma

Hansa Biopharma is leveraging its proprietary enzyme technology platform to develop immunomodulatory treatments for enabling transplantations and rare immunoglobulin G (IgG)-mediated autoimmune conditions, gene therapy and cancer.

The Company's lead product candidate, imlifidase, is an antibody cleaving enzyme being developed to enable kidney transplantation in highly sensitized patients and may be further developed for use in other organ and tissue transplantation as well as acute autoimmune indications.

Imlifidase has been granted conditional approval in the European Union for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Commercial launch in select European countries is expected in the fourth quarter of 2020.

Hansa's research and development program is advancing the Company's enzyme technology to develop the next generation of IgG-cleaving enzymes with potentially lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases, gene therapy and oncology. Hansa Biopharma is based in Lund, Sweden and has operations in both Europe and the U.S.

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

Nasdaq OMX Stockholm

rare immunological diseases within a range of therapeutic areas where there is a significant unmet medical need", says Søren Tulstrup, President and CEO, Hansa Biopharma.

Hansa Biopharma was granted orphan drug designation for imlifidase as a treatment for anti-GBM antibody disease in both the EU and the US in 2018.

Hansa Biopharma is hosting a Capital Markets Day planned for October 29, 2020 in Copenhagen, where more information from the anti-GBM phase 2 trial will be presented. For more information and registration for this event, click here

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 th the contact person set out above at 20:15 CET on September 24, 2020.