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

www.hansabiopharma.com

PRESS RELEASE

Key data demonstrating the potential of Hansa Biopharma's imlifidase to significantly alter course of anti-GBM disease published in JASN

- Results of an investigator-initiated open-label Phase 2 study of imlifidase in patients with anti-glomerular basement membrane (anti-GBM) disease published in leading nephrology publication *Journal of the American Society of Nephrology (JASN).*[1]
- Imlifidase rapidly and completely reduced pathogenic anti-GBM antibody levels to below reference range.
- At six months 67% of the included patients had functioning kidneys versus 18% in a historical control cohort.
- The publication recognises the study's significance in autoimmune diseases as it suggests that deactivation of autoantibodies could alter the course of an autoimmune disease, allowing restoration of kidney function. These results highlight the potential of imlifidase beyond kidney transplantation, paving the way for a Phase 3 study in anti-GBM, planned to begin this year.

Lund, Sweden March 8, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), the pioneer in immunomodulatory enzyme technology for rare IgG-mediated diseases, today announces the publication of important data from an investigator-initiated study in anti-GBM in leading nephrology journal *Journal of the American Society of Nephrology* (*JASN*). The publication of the results in JASN is a recognition of the considerable potential for imlifidase in autoimmune diseases involving pathogenic IgG. The investigator-initiated Phase 2 open-label study explored the efficacy of imlifidase for the treatment of anti-GBM disease as add-on to standard of care with pulse methylprednisolone, oral corticosteroids, cyclophosphamide (CYC) and plasma exchange (PLEX).[2]

The results show that kidney function at 6 months was significantly better than in previously published cohorts, without any safety concerns. Of the 15 patients included, 10 were dependent on dialysis at enrollment. At 6 months, a total of 67% (N=10) of the included patients were dialysis independent, which is significantly better than in the historical control cohort, where only 18% had functioning kidneys. All patients that were dialysis-independent at baseline remained so during the study.

"These are really exciting results, as this is the first time we have seen a study suggesting that the course of an acute autoimmune disease like anti-GBM disease can be changed by targetting the antibodies underpinning the immune response. The effects were such that half of patients that were on dialysis before the treatment had regained kidney function by the end of the trial, compared to less than 20% in the historical control group." says Coordinating Principle Investigator, Mårten Segelmark, Professor of Nephrology at Lund University, previously Linköping Universtity. "I am pleased to see these results being recognized in one of the leading nephrology journals, but I am even more excited for the many patients suffering from anti-GBM disease, as these data give hope. Today, most anti-GBM patients suffer terminal damage to their kidneys during the course of the disease. With standard of care, the disase leads to dialysis in most cases and even death in some cases. Dialysis dependance takes a huge toll on a person's life, and is associated with chronic pain and depression, among other debilitating symptoms. Therefore, the opportunity to greatly reduce the risk of dialysis dependance represents a significant step forward for a patient group who currently have very few treatment options."

Anti-GBM disease is a rare and acute autoimmune condition which can lead to permanent kidney failure and even death. It is caused when the immune system mistakenly attacks a specific part of the kidneys called the glomerular basement membrane (GBM), damaging the kidneys and in some cases the lungs also. Prognosis for the condition is poor, particularly because its rarity can lead to delayed diagnosis in a situation where, given the disease's acute nature, prompt treatment is very important.

"The JASN publication not only brings hope to patients suffering from anti-GBM disease, but illustrates the potential of imlifidase beyond transplantation," says Christian Kjellman, Chief Scientific Officer at Hansa Biopharma. "The results of this study highlight the potential for imlifidase to dramatically alter the course of a rare IgG-mediated autoimmune condition such as anti-GBM, for which there is a significant unmet medical need, and underscore the versatility of our IgG-cleaving enzyme technology platform to generate drug candidates for a broad spectrum of conditions involving pathogenic IgG."

The recently completed investigator-initiated Phase 2 study was sponsored by Professor Mårten Segelmark and Linköping University.

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For more information:

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

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

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. It has a rapid onset of action, cleaving IgG-antibodies and inhibiting their activity within hours of 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.[3]

Due to the pressing unmet needs in patients with this condition, imlifidase was granted orphan drug designation in anti-GBM disease by both the US Food and Drug Administration and European Commission. Following the success of this investigator-initiated Phase 2 trial with imlifidase to treat anti-GBM disease, Hansa has announced that it is progressing with its trial program.

About anti-glomerular basement membrane (anti-GBM) disease

Anti-GBM disease, also known as Goodpasture's disease, is a rare acute autoimmune disease affecting around one in one million people.[4] The condition causes the immune system to mistakenly attack a specific part of the kidneys called the glomerular basement membrane (GBM), damaging the kidneys and in some cases the lungs also. Severe anti-GBM can be fatal, sometimes causing kidney failure and bleeding in the lungs.

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.

References

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