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PRESS RELEASE

Hansa Biopharma and partner Sarepta Therapeutics plan to initiate a clinical study with imlifidase as a pre-treatment to Sarepta's SRP-9001 gene therapy in DMD in 2023

- The clinical study will evaluate imlifidase as pre-treatment in patients with pre-existing IgG antibodies to Sarepta's SRP-9001, an investigational AAV-based gene therapy for the treatment of DMD
- DMD is an irreversible, progressive disease affecting one in 3,500 to 5,000 males born worldwide[1]

Lund, Sweden November 2, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, today announced that its partner Sarepta Therapeutics plans to initiate a clinical study in 2023 to evaluate imlifidase as pre-treatment in patients with Duchenne muscular dystrophy (DMD) and pre-existing IgG antibodies to the adeno-associated viral (AAV) vector rh74 to enable safe and effective dosing with SRP-9001. SRP-9001 is Sarepta's investigational gene therapy for the treatment of DMD. On September 29, 2022, Sarepta announced that it had submitted a Biologics License Application (BLA) to the U.S. FDA for the accelerated approval of SRP-9001 to treat ambulant patients with DMD.

DMD is a rare and fatal genetic disease caused by a mutation in the *DMD* gene encoding for the protein dystrophin. It is an irreversible, progressive disease that causes the muscles in the body to become weak and damaged over time, leaving most patients in a wheelchair by the age of 12. It is currently estimated that DMD affects one in 3,500 to 5,000 males born worldwide. Approximately 14% of DMD patients have pre-existing IgG antibodies to the rh74 vector.[2]

Preclinical work conducted by Hansa and Sarepta demonstrated the ability of imlifidase to reduce pre-existing IgG antibodies to rAAVrh74, allowing for safe and successful administration of SRP-9001. This data supports clinical development of imlifidase as a pre-treatment to the administration of SRP-9001 in patients with pre-existing rAAVrh74 antibodies, when appropriate.

In 2020, Hansa granted Sarepta, a leader in precision genetic medicine for rare diseases, an exclusive, worldwide license to develop and promote imlifidase as a pre-treatment for Sarepta's gene therapy treatments for DMD and Limb-girdle muscular dystrophy (LGMD). Under the terms of the agreement, Hansa is eligible for a total of up to USD 397.5 million in development, regulatory and sales milestone payments. Hansa will book all sales of imlifidase and earn tiered royalties up to the mid-teens on Sarepta's incremental gene therapy sales when treating patients with pre-existing antibodies enabled through pre-treatment with imlifidase.

"Pre-existing antibodies against AAV vectors used in a broad range of gene therapies can be a barrier to treatment and we see significant potential for our antibody-cleaving enzyme technology to help overcome this barrier", said Søren Tulstrup, President & CEO of Hansa. "We are very excited about the results we have seen in the preclinical phase of our collaboration

[1] National Institutes of Health. Genetics Home Reference. Duchenne and Becker muscular dystrophy; https://ghr.nlm.nih.gov/condition/duchenne-and-becker-muscular- dystrophy

[2] https://investorrelations.sarepta.com/static-files/e1fd0d6f-7819-45da-a233-5e516700d036

with Sarepta. These results strengthen our hope that the unique features of imlifidase may potentially enable gene therapy treatment in patients who today are not eligible for these breakthrough therapies due to pre-existing antibodies".

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 21:30 CET on November 2 2022.

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.

About gene therapy and pre-existing antibodies

Gene therapy is a growing and revolutionizing treatment technology in which healthy gene sequences are inserted into cells of a patient. The treatments are potentially curative in monogenic diseases like hemophilia and muscular dystrophy through a single dose. Recombinant viruses are used to carry the healthy genes into the cell. Due to the partial viral origin of the gene therapy constructs, a certain subset of patients carry anti-AAV antibodies towards gene therapy products, depending on what AAV serotype being used, forming a barrier for treatment eligibility.

Antibodies prevent effective transfer of the healthy gene sequence and can be a safety concern. Imlifidase as a pre-treatment may have the potential to eliminate pre-existing antibodies prior to gene therapy. Similarly, imlifidase may have the potential to enable any potentially necessary re-dosing of gene therapy for all patients.

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 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.

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