Hansa Biopharma announces exclusive agreement with Sarepta Therapeutics to develop and promote imlifidase as pre-treatment ahead of gene therapy in select indications

Hansa grants Sarepta exclusive license to develop and promote imlifidase as a potential pre-treatment prior to the administration of gene therapy in Duchenne muscular dystrophy and Limb-girdle muscular dystrophy, for patients with neutralizing antibodies (NAbs) to adeno-associated virus (AAV).

Under the terms of the license:

- Hansa will receive a USD 10 million upfront payment and is eligible for up to USD 397.5 million in development, regulatory and sales milestone payments.
- Hansa will book all sales of imlifidase and would be eligible for royalties in the high single-digits to mid-teens on any gene therapy sales enabled through pre-treatment with imlifidase in NAb-positive patients.

Lund, Sweden July 2, 2020. Hansa Biopharma ("Hansa"), the leader in immunomodulatory enzyme technology for rare IgG mediated diseases, announced today that it has entered into an agreement with Sarepta Therapeutics Inc. ("Sarepta"), the leader in precision genetic medicine for rare diseases, through which Sarepta is granted an exclusive, worldwide license to develop and promote imlifidase as a pre-treatment to enable Sarepta gene therapy treatment in Duchenne muscular dystrophy (DMD) and Limb-girdle muscular dystrophy (LGMD). The pre-treatment is intended for patients with pre-existing neutralizing antibodies (NAb-positive patients) to adeno-associated virus (AAV), the technology that is the basis for Sarepta's gene therapy products.

Sarepta will be responsible for conducting pre-clinical and clinical studies with imlifidase and any subsequent regulatory approvals. Sarepta will also be responsible for the promotion of imlifidase as a pre-treatment to Sarepta's gene therapies following potential approval.

Under the terms of the agreement, Hansa will receive a USD 10 million upfront payment, and 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 high single-digit to mid-teens royalties on Sarepta's incremental gene therapy sales when treating NAb-positive patients enabled through pre-treatment with imlifidase.

Søren Tulstrup, President & CEO of Hansa Biopharma comments,
"We see significant potential for our enzyme technology in the gene therapy space overall, and we are excited to partner with Sarepta, a leading player in the field, to use the unique features of imlifidase to potentially enable gene therapy treatment in patients who today aren't eligible for these breakthrough therapies due to pre-existing neutralizing antibodies in two conditions indications with a very high unmet medical need."

Doug Ingram, President & CEO, Sarepta Therapeutics said,
"As we expand our leadership position in genetic medicine and build out our gene therapy engine, one of Sarepta's central ambitions is to find scientific solutions that bring our potentially life-saving therapies to the greatest number of the rare disease patients we serve. One of the

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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, transplant rejection and cancer.

The Company's lead product candidate, imlifidase, is an antibodycleaving 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.

CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third 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 and oncology. Hansa Biopharma is based in Lund, Sweden and also has operations in other European countries and in the U.S.

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current limitations of gene therapy is the inability to treat patients who have pre-existing neutralizing antibodies to the AAV vector. While our AAVrh74 vector has been associated with a low screen out rate for neutralizing antibodies, even that low rate is inconsistent with our mission. In pre-clinical and clinical models, Hansa's technology has shown the ability to clear the IgG antibodies that prevent dosing AAV-based gene therapies. If successful, this could offer the potential of extending our gene therapy treatments to DMD and LGMD patients who would otherwise have been denied access due to pre-existing antibodies."

Hansa Biopharma will be hosting a conference call with President & CEO Søren Tulstrup, CSO & COO Christian Kjellman and CFO Donato Spota.

Conference Call "Partnership agreement with Sarepta Therapeutics"
A conference call will take place July 2nd, 2020 at 10:00am CET. The audio cast will be recorded and subsequently be available on the Hansa website https://hansa.eventcdn.net/202007

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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.

CHMP/EMA has adopted a positive opinion, recommending conditional approval of imlifidase for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch against an available deceased donor. Endorsement of the positive opinion by the European Commission is expected in the third quarter of 2020.

Hansa has also reached an agreement with the FDA on a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients in the U.S. and has three ongoing phase 2 trials in autoimmune diseases and post-transplant indications.

About gene therapy and neutralizing 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. Harmless 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 neutralizing 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 healthy gene sequence and can be a safety concern. Imlifidase as a pre-treatment may have the potential to eliminate neutralizing 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 Duchenne Muscular Dystrophy (DMD)

Duchenne muscular dystrophy is a rare genetic disease caused by mutation in the DMD gene, encoding for the protein dystrophin. Duchenne is an irreversible, progressive disease that causes the muscles in the body to become weak and damaged over time. It is eventually fatal and there is no cure. DMD affects one in 3,500 to 5,000 males born worldwide (approximately 400-500 annual cases in the US) and causes muscles in the body to become weak and most patients use wheelchair by the age of 12.

About Limb-Girdle Muscular Dystrophy (LGMD)

Limb-girdle muscular dystrophy or (LGMD) is a genetically and clinically heterogeneous group of rare muscular dystrophies. It is characterised by progressive muscle wasting which affects predominantly hip and shoulder muscles. LGMD has an autosomal pattern of inheritance and currently has no known cure or treatment. It can be caused by a single gene defect that affects specific proteins within the muscle cell, including those responsible for keeping the muscle membrane intact. LGMD has a global prevalence of approximately 1.63 per 100,000 individuals worldwide.