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PRESS RELEASE

Hansa Biopharma announces supportive data from treatment with imlifidase prior to the administration of gene therapy for Duchenne muscular dystrophy

Lund, Sweden, 1 August 2025. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), today announced topline results from three patients with Duchenne muscular dystrophy (DMD) treated with Hansa's imlifidase prior to receiving Sarepta's ELEVIDYS (delandistrogene moxeparvovec-rokl) in the SRP-9001-104 trial.

After one dose of imlifidase, three patients experienced a rapid reduction of IgG antibodies, to levels ≥95% less than baseline. In addition, in these three patients pre-existing anti-AAV antibodies were reduced below a titre of 1:400, which enabled treatment with ELEVIDYS. The safety profile of imlifidase was in keeping with prior experience and the trial did not generate any new safety signals. Twelve weeks after administration of the gene therapy, patients in the trial demonstrated evidence of AAV-mediated transduction and expression of micro-dystrophin, however with levels lower than seen in other trials with ELEVIDYS. Based on these outcomes, Hansa and Sarepta will discuss appropriate next steps for the program.

Renée Aguiar-Lucander, CEO, Hansa Biopharma said, "These are the first results from a clinical trial, assessing imlifidase's potential for patients with high levels of anti-AAV antibodies to access approved gene therapies. We are encouraged that imlifidase was able to substantially reduce both IgG antibodies and pre-existing anti-AAV-antibodies, to enable patients to be treated with gene therapy. We also look forward to reporting data from another ongoing gene therapy collaboration later this year, to continue to collect evidence of the potential benefits of imlifidase in gene therapy."

This is information that Hansa Biopharma AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, at 21:15 CEST on 2025-08-01.

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Notes to editors

About Duchenne Muscular Dystrophy (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.[1,2] Approximately 14% of DMD patients have pre-existing IgG antibodies to the rh74 vector.[3] Many gene therapies are based on the use of Adeno Associated Viruses (AAV) vectors. In some patients the immune system carries antibodies called anti-AAV antibodies that counteract the gene therapy treatment preventing its success.

About SRP-9001-104

SRP-9001-104 is an open-label trial of ambulatory male patients with DMD between four and nine years of age, and with pre-existing antibodies to ELEVIDYS. Up to six patients will be treated with imlifidase followed by ELEVIDYS. All patients included in the trial are currently ineligible to receive ELEVIDYS due to the presence of antibodies targeting AAVrh74, the vector used to deliver Sarepta's gene therapy treatment.

About imlifidase and gene therapy

Imlifidase is currently being evaluated as a pre-treatment to gene therapy in areas of high unmet need. Many gene therapies are based on the use of Adeno Associated Viruses (AAV) vectors.[4-7] In some patients the immune system carries antibodies that counteract the gene therapy treatment preventing its success. [5-11] Pre-treatment with imlifidase prior to AAV-based gene therapy treatment has the potential to inactivate antibodies and thereby enable gene therapy in patients with pre-existing antibodies to AAV-based gene therapies.[10] Currently, it is estimated that NAbs on average prevent 1 in 3 people from benefiting from gene therapy treatments. [5-11]

About Hansa Biopharma

Hansa Biopharma AB 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. The company has a rich and expanding research and development program based on its proprietary IgG-cleaving enzyme technology platform, to address serious unmet medical needs in autoimmune diseases, gene therapy and transplantation. The company's portfolio includes imlifidase, a first-in-class immunoglobulin G (IgG) antibody-cleaving enzyme therapy, which has been shown to enable kidney transplantation in highly sensitized patients and HNSA-5487, a next-generation IgG cleaving molecule with redosing potential. 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 www.hansabiopharma.com and follow us on LinkedIn.

ELEVIDYS is a trademark of Sarepta Therapeutics Inc

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