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PRESS RELEASE

Genethon to present preliminary efficacy and safety data from Phase 2 trial of imlifidase as a pre-treatment to GNT-0003 at ESGCT congress 2025

Lund, Sweden, 26 September, 2025. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), today announced that Genethon will present preliminary efficacy and safety data from the first patient treated in the GNT-018-IDES Phase 2 trial of imlifidase and GNT-0003 in severe Crigler-Najjar syndrome at the European Society of Gene and Cell Therapy (ESGCT) 32nd annual congress. On Thursday 9 October, between 8:30 AM and 10:30 AM CEST, Giuseppe Ronzitti, PhD, from Genethon will present pre-clinical data from the Genethon-Hansa collaboration. The clinical data will be presented by Jeremy Do Cao, MD, co-investigator of the clinical trial and paediatrician at Antoine-Béclère Hospital, AP-HP, Paris, France on Friday 10 October, between 9:00 AM and 10:30 AM CEST.

GNT-018-IDES is a single-arm Phase 2 trial sponsored by Genethon evaluating the efficacy and safety of a single intravenous administration of Genethon's gene therapy GNT-0003 following pre-treatment with imlifidase. In this trial, Hansa's first-in-class immunoglobulin G (IgG) antibody cleaving enzyme therapy is being evaluated in patients with severe Crigler-Najjar syndrome and pre-existing antibodies to AAV serotype 8 (AAV8). The trial is set to enroll a total of three patients with severe Crigler-Najjar syndrome, pre-existing anti-AVV8 antibodies and a requirement for prolonged daily phototherapy.

Renée Aguiar-Lucander, CEO, Hansa Biopharma said, "We look forward to the data from the first patient treated in the GNT-018-IDES trial that Genethon will present at ESGCT. This is an important step as we continue to gather evidence on the potential of imlifidase in enabling gene therapy, where presence of anti-AAV antibodies continues to be a barrier that precludes up to 1 in 3 patients from being eligible to receive these treatments."

Speaker	Abstract Title	Presentations details
Giuseppe Ronzitti, Genethon	**INV37:** Harnessing the potential of Immunoglobulin G degrading enzymes (Ide) for the treatment of AAV-seropositive patients	Thursday 9 October, 8:30 AM – 10:30 AM CEST. SESSION 7a: Immune Responses to GT
Jeremy Do Cao, Antoine-Béclère Hospital, AP-HP, France	**OR086:** Overcoming AAV8 Immunity: First Seropositive Crigler-Najjar Patient Treated with GNT0003 Following Imlifidase Pretreatment (GNT-018-IDES clinical trial)	Friday 10 October, 9:00 AM - 10:30 AM CEST. SESSION 11a: Metabolic Diseases II

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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.[1] 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.[1]

About Crigler-Najjar syndrome

Crigler-Najjar syndrome is a rare genetic liver disease characterized by abnormally high levels of bilirubin in the blood (hyperbilirubinemia), which leads to irreversible neurological damage manifested as muscle weakness, lethargy, deafness, mental retardation, and eye movement paralysis. This accumulation of bilirubin is caused by a deficiency of the UGT1A1 enzyme, responsible for transforming bilirubin into a substance that can be eliminated by the body. It can result in significant neurological damage and death if not treated quickly. At present, patients must undergo prolonged daily phototherapy (often more than 10 hours a day, sometimes up to 15 hours a day) to keep their bilirubin levels below the toxicity threshold. Crigler-Najjar syndrome is an ultra-rare disease affecting less than one case per one million people per year. Liver transplantation remains the only definitive cure to date, but is associated with significant morbidity and mortality, as well as graft shortage.[2]

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.[3-5] In some patients the immune system carries antibodies that counteract the gene therapy treatment preventing its success. [4-10] 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.[9] Currently, it is estimated that anti-AVV antibodies on average prevent 1 in 3 people from benefiting from gene therapy treatments. [4-7]

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.

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