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PRESS RELEASE

Upcoming KOL Call today: Insights on clinical practice and imlifidase Phase 3 Results

Lund, Sweden, 12 November 2025. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA) today will host a virtual event featuring two distinguished transplant surgeons; Professor Robert Montgomery from NYU Langone Transplant Institute and Professor Matthew Cooper from the Medical College of Wisconsin, to provide deeper insights into the medical journey of highly sensitized patients awaiting a kidney transplant and share perspectives on the clinical relevance of the topline results from the US Phase 3 ConfIdeS study. The event will take place today, Wednesday 12 November, 2025, at 9:00 AM EST / 15:00 PM CET. Click here to join.

After an introduction by Renée Aguiar-Lucander, CEO, Hansa Biopharma, there will be a presentation of the topline results from the US Phase 3 ConfIdeS trial by Richard Philipson, CMO. Philipson will then moderate a discussion reviewing current challenges of highly sensitized patients, the medical need and existing clinical practice for this patient group as well as the clinical relevance of the ConfIdes topline results, and the potential to impact current standard of care within the US transplant community with Dr. Robert Montgomery, MD, PhD, NYU Langone Transplant Institute, and Dr. Matthew Cooper, MD, Medical College of Wisconsin, followed by a Q&A session.

About Robert Montgomery, MD, PhD

Dr. Robert Montgomery is Chair of the Department of Surgery and Director of the NYU Langone Transplant Institute. As a pioneer and international expert in desensitization, he has taken part in numerous research studies, publications, and has received many awards for his work. Throughout his career, Dr. Montgomery has led innovation in transplantation, credited with developing and performing the first 'domino paired donation' and now leading efforts in xenotransplantation. He is also a heart transplant recipient himself. Dr Montgomery acted as Lead Principal Investigator for the ConfIdeS trial.

About Matthew Cooper, MD

Dr. Matthew Cooper is Chief of Transplantation, Director of Solid Organ Transplant, and the Mark B. Adams Distinguished Professor of Surgery at the Medical College of Wisconsin. He currently serves as a board member for the American Society of Transplantation (AST) and the National Kidney Foundation (NKF) and is the Surgical Director for the National Kidney Registry (NKR). Dr. Cooper is a former President of the United Network for Organ Sharing (UNOS) and the Organ Procurement and Transplantation Network (OPTN). He has authored over 260 peer-reviewed manuscripts, 300 abstracts, and 12 book chapters and has received numerous awards in the field of kidney transplantation. Dr Cooper acted as Principal Investigator for the ConfIdeS trial.

Link to Virtual Event: https://lifescievents.com/event/gl39mp2j/

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Notes to editors

About highly sensitized patients

Highly sensitized patients have pre-formed antibodies called donor specific antibodies (DSAs) with a broad reactivity against human leukocyte antigens (HLAs), which can cause tissue damage and potentially transplant rejection.[1] The presence of DSAs means that highly sensitized patients tend to have limited or no access to transplant, as finding a compatible donor organ can be particularly challenging.[2,3] The complexity of their immunological profile means that highly sensitized patients spend longer time than average on transplant waiting lists, with evidence showing that this longer time waiting for a suitable donor relates to an increased mortality risk.[4,5] Across the U.S. and Europe, highly sensitized patients comprise around 10-15% of the total of patients on transplant waiting lists.[6,7]

About IDEFIRIX® (imlifidase)

Imlifidase is an antibody-cleaving enzyme originating from *Streptococcus pyogenes* that specifically targets and cleaves immunoglobulin G (IgG) antibodies and inhibits IgG-mediated immune response.[8] 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. The use of IDEFIRIX should be reserved for patients who are unlikely to be transplanted under the available kidney allocation system, including prioritization programs for highly sensitized patients.[8] IDEFIRIX was reviewed as part of the European Medicines Agency's (EMA) PRIority Medicines (PRIME) program, which supports medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options.[8]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[9] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[1] Once they are inactivated with imlifidase, there is a window of opportunity for the transplant to take place. By the time the body starts to synthesize new IgG, the patient will be receiving post-transplant immunosuppressive therapy to reduce the risk of organ rejection.

The efficacy and safety of imlifidase as a pre-transplant treatment to reduce donor-specific IgG was studied in four phase 2 open-label, single-arm, six-month clinical trials.[7,9-11] Hansa is collecting further clinical evidence and will submit additional efficacy and safety data based on one observational follow-up study and one post-approval efficacy study.

Full product information can be accessed via the initial Summary of Product Characteristics found here.

About kidney failure

Kidney disease can progress to kidney failure or End-Stage Renal Disease (ESRD), identified when a patient's kidney function is less than 15%.[12] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[12] A kidney transplant is the treatment of choice for suitable patients with ESRD because it offers improved survival and quality of life benefits, and is cost savings compared to long-term dialysis. There are approximately 170,000 kidney patients in the U.S. and Europe waiting for a new kidney.[13]

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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