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PRESS RELEASE

Hansa Biopharma presented new data on imlifidase at the European Society for Organ Transplantation (ESOT) Congress

- Hansa presented two abstracts on imlifidase, adding to the body of evidence that supports the use of imlifidase in enabling transplantation in highly sensitized patients
- Hansa also hosted a symposium at ESOT with five experts on enabling transplantation for highly sensitized patients

Lund, Sweden September 1, 2021. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), the pioneer in enzyme technology for rare immunological conditions, today announced two abstracts presented at the European Society for Organ Transplantation (ESOT) Congress, August 29-September 1, 2021. The biennial ESOT Congress, which typically brings approximately 3'500 medical experts together in pursuit of improved outcomes within transplantation, is among the most important international congresses in the field.

As a part of ESOT, Hansa presented an abstract titled "*Rabbit anti-thymocyte globulin as induction therapy following desensitization with imlifidase"*. This paper aimed to determine the most appropriate time to initiate rabbit anti-thymocyte globulin therapy (rATG) after transplantation enabled by imlifidase. Anti-thymocyte globulin agents like rATG are used as induction agents to prevent cell-mediated allograft rejection, however, the IgG cleavage mechanism of imlifidase has the potential to inactivate rATG. Thus, determining when the earliest time point to start rATG therapy while avoiding most of the cleavage activity of imlifidase is important to improving our knowledge of the various treatment approaches for patients receiving a kidney transplant.

The cleavage pattern of rATG was investigated in serum samples taken from 11 healthy subjects treated with 0.25mg/kg of imlifidase. Serum samples were collected pre-imlifidase through 14 days post-imlifidase and were incubated with a fixed concentration of 50 µg/mL rATG. Imlifidase serum concentration in the subjects declined rapidly and at 96 hours the concentration was 0.5 mg/mL, though with large individual variation (<0.1-1.8 mg/mL). At this time point, the level of imlifidase had decreased sufficiently to avoid complete cleavage of rATG in 8 of 11 subjects. These results suggest that rATG may be initiated as early as 4 days post-imlifidase, as some early cleavage at the start of therapy is not anticipated to have a negative overall effect on the rATG treatment. These results will need to be confirmed with *in vivo* data.

Accepted as a poster presentation at ESOT, the abstract "*Patterns of IgG rebound after imlifidase treatment"* examines the patterns and timing of rebound for the antibodies that are suppressed by imlifidase treatment, specifically anti-drug antibodies (ADA IgG), immunodominant donor-specific antibodies (DSA IgG), and vaccine antigen-specific IgG (V IgG). These were compared to the total IgG pool in immunosuppressed kidney transplant patients.

In the 10 patients included in the study, IgG rebound generally occurred between 3 and 14 days after dosing, and varied significantly between the patients analyzed. Initial DSA IgG rebound was faster than that of total IgG, but then maintained a steady state below pre-dose levels. ADA IgG rebounded at a similar rate to DSA IgG but to a higher magnitude. The rebound of V IgG was concurrent with the rebound of total IgG. These rebound patterns are

consistent with expectations and the results of other clinical trials examining antibody rebound post imlifidase treatment.

“The data presented this year at ESOT showcases our continued commitment to build a robust body of evidence that supports the use of imlifidase in enabling transplantation in highly sensitized patients”, said Christian Kjellman, Chief Scientific Officer at Hansa Biopharma. “ESOT is always a key event in the calendar, providing us with the opportunity to share our experience and learn from other members of the transplant community. We look forward to connecting with our stakeholders on how we can continue to work collaboratively on bringing transformative therapies like imlifidase to patients.”

At ESOT, Hansa also hosted an expert symposium titled ‘Roadmap to Transplant for the Highly Sensitized Patient’ chaired by Prof. Lucrezia Furian from the University Hospital Padova, Italy. During this symposium, several experts discussed key approaches to enabling kidney transplants for those patients who are least likely to be offered a compatible transplant and stand to benefit most from treatments like imlifidase. Prof. Furian was joined by several eminent colleagues in transplant medicine, Prof. Stanley Jordan M.D. Ph.D from Cedars Sinai Hospital, Los Angeles; Prof. Nizam Mamode M.D. from Guys Hospital, London; Prof. Denis Glotz from Hospital St Louis, Paris; and Dr. Oriol Bestard from University Hospital Vall d’Hebron, Barcelona.

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Notes to Editors

About Idefirix® (imlifidase)

Imlifidase is an enzyme derived from the bacterium *Streptococcus pyogenes*, with the ability to specifically target and cleave (or break) all classes of immunoglobulin G (IgG) antibodies.[1]

IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor-specific antibodies (DSAs).[2] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ damaging the transplant.[4] Once they are inactivated with Idefirix®, there is a window of opportunity for the transplant to take place. By the time the body starts renewing the depleted antibodies, the patient will be taking immunosuppressive therapy to continue to reduce the risk of organ rejection.

The efficacy and safety of Idefirix® as a pre-transplant treatment to reduce donor-specific IgG was studied in four phase 2 open-label, single-arm, six-month clinical trials.[2,3,4,5]

Hansa is now 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. Idefirix® was reviewed as part of the European Medicines Agency’s PRIority MEdicines (PRIME) scheme, which supports medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options.[6]

Idefirix® was granted conditional European Marketing Authorization from the European Medicine’s Agency (EMA) in August 2020 for the desensitization treatment of highly sensitized adult kidney transplant patients with a positive crossmatch test against an available deceased donor. The use of Idefirix® should be reserved for patients unlikely to

be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients.[1] Conditional approval allows the Agency to recommend a medicine for marketing authorization in cases where the benefit of a medicine's immediate availability to patients, outweighs the risk that not all the data are yet available.

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%.[7]**Error! Bookmark not defined.** ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[5] A kidney transplant is the treatment of choice for suitable patients with ESRD because it offers improved survival and quality of life benefits compared to long-term dialysis. There are approximately 80,000 kidney patients on transplant waiting lists across the European Union.[7]

Full product information can be found here

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.

References

[1] Hansa. Idefirix® Summary of Product Characteristics. August 25 2020.
[2] Jordan SC, et al. *N Engl J Med 2017*; 377(5):442-453.
[3] Lorant T, et al. *Am J Transplant* 2018;18(11):2752-2762
[4] Winstedt L, et al. *PLoS One* 2015; 10(7): e0132011
[5] NIH (2018). What is kidney failure? Available at: https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/what-is-kidney-failure. Last accessed: July 2021
[6] European Medicines Agency. Available at: https://www.ema.europa.eu/en/news/new-treatment-enable-kidney-transplant-highly-sensitised-patients. Last accessed: July 202
[7] Newsletter Transplant 2020. Available at: https://www.edqm.eu/en/news/newsletter-transplant-2020-now-available. Last accessed: July 2021