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Plenary Presentation at the 2019 American Transplant Congress Demonstrates Significant Reduction in Time on the Waitlist for Patients Treated with Imlifidase Compared to Matched Controls; Session Wins ATC’s People’s Choice Award

Lund, Sweden, June 7, 2019 - Hansa Biopharma AB (“Hansa”) (NASDAQ Stockholm: [HNSA](#)), the leader in immunomodulatory enzyme technology for rare IgG-mediated diseases, announced today that IDEFIRIX™ (imlifidase), the company’s novel IgG-degrading enzyme, was highlighted in three presentations at the 2019 American Transplant Congress (ATC), which was held from June 1 – 5, 2019 in Boston, Massachusetts, USA.

In a plenary presentation on June 5, 2019, Dr. Edmund Huang, MD, Associate Professor and Transplant Nephrologist at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center in Los Angeles, presented *“Three-year Outcomes of Highly-sensitized Kidney Transplant Recipients Desensitized with IgG Endopeptidase.”* The plenary abstract, by Dr. Huang and Stanley Jordan M.D., Director Kidney Transplantation and Transplant Immunology at the Cedars-Sinai Medical Center in Los Angeles, won the ATC’s People’s Choice Award, as voted by the ATC attendees to be the most impactful to the transplant community.

In his presentation, Dr. Huang reported a statistically significant reduction in time on the waitlist for transplantation among imlifidase treated patients compared to similarly sensitized matched controls. The matched control analysis showed statistically significant shorter time to transplant in both the current and previous U.S. Kidney Allocation System (KAS).

“Our matched control analysis showed statistically significant shorter time to transplant in the pre and post- KAS era. We are therefore convinced that Imlifidase complements the new KAS system and will facilitate reduced time to kidney transplantation in highly sensitized patients.” commented Dr. Huang

“We have previously demonstrated that treatment with imlifidase enables life-saving kidney transplantation that would otherwise not be possible. This matched control analysis further illustrates shorter time to transplant for these highly sensitized patients” commented Dr. Jordan.

The presentation also reported follow up data from the U.S. investigator-initiated Phase 2 study of imlifidase for kidney transplantation in highly sensitized patients. Results show excellent graft survival out to three years with graft survival in line with deceased donor transplantation of non-sensitized patients. One death, unrelated to imlifidase treatment and the kidney transplant, occurred 10 months after transplant. There were sporadic cases of late rebound DSA, but most remained DSA-free up to 36 months post-transplant.

In an oral presentation on June 2, 2019, Robert A. Montgomery, M.D., Director, NYU Langone Transplant Institute, New York City, presented *“Safety and Efficacy of Imlifidase in Highly-Sensitized Kidney Transplant Patients: Results from a Phase 2 Study.”*

“The safety and efficacy data on imlifidase provide hope to highly sensitized patients, who today are very difficult or impossible to transplant, and face an extremely poor prognosis. Six months follow up results continue to show that imlifidase has enabled all patients to undergo transplantation resulting in good kidney function and graft survival,” Robert A. Montgomery, M.D., Director, NYU Langone Transplant Institute, New York City.

In a poster session on June 2, 2019, Dr. Matthew J. Everly, Director of the Terasaki Research Institute in Los Angeles, presented *“A Prognostic Drug Development Tool to Assess the Transplantability at the Time of Listing for Kidney Transplant Candidates.”*

In his poster session Dr. Everly reported on the results of simulations done in highly sensitized patients, which demonstrated that transplant rates could be increased by 25% if there were a therapy to address the HLA antibody barrier.

References

1. <https://optn.transplant.hrsa.gov>

The information was submitted for publication, through the agency of the contact person set out below at 08:00am CET on June 7, 2019.

About IDEFIRIX™ (imlifidase)

IDEFIRIX (imlifidase) is an enzyme that specifically cleaves immunoglobulin G (IgG) antibodies, thereby inhibiting the IgG-mediated immune response. Hansa is developing IDEFIRIX as a proprietary treatment to enable kidney transplantation in sensitized patients, previously unable to undergo transplant surgery due to the presence of Donor Specific Antibodies (DSAs). Efficacy data reported from four Phase 2 studies have demonstrated that IDEFIRIX rapidly and significantly reduced all DSAs, enabling transplantation. In addition to transplantation, IDEFIRIX is being evaluated in a Phase 2 clinical study in anti-GBM antibody disease, a rare autoimmune disorder, and IDEFIRIX has potential applications in a variety of additional autoimmune diseases. IDEFIRIX is protected by a strong patent portfolio and results of studies with IDEFIRIX have been published in multiple peer reviewed scientific journals.

About Highly Sensitized Patients

Many patients on the waiting list for organ transplantation carry antibodies to human leukocyte antigen (HLA), which is known as being 'sensitized.' Antibodies targeted towards HLA of a potential donor, called Donor Specific Antibodies (DSAs), can significantly compromise the transplanted organ. Patients who are highly sensitized, with high levels of DSAs, will have a very low likelihood of finding a donor towards which they will not have DSA. Therefore, they may not be able to receive a transplant at all and remain on dialysis in a debilitating disease state indefinitely. Current desensitization methods are not feasible for most highly sensitized patients. IDEFIRIX's rapid cleavage of all IgG antibodies, eliminates DSAs, enabling deceased donor kidney transplantation. Two thirds of kidney transplantations in the U.S. and Europe are from deceased donors.

About Hansa Biopharma

Hansa Biopharma AB (NASDAQ Stockholm: HNSA) is harnessing its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer. The Company's lead product, IDEFIRIX (imlifidase), is a unique antibody-degrading enzyme in late-stage clinical development to enable kidney transplantation in highly sensitized patients, with additional clinical studies in acute autoimmune indications. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Biopharma is based in Lund, Sweden.



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