Positive results presented at ESOT; imlifidase enabled transplantation in 46 sensitized patients

Lena Winstedt, PhD, Head of Science at Hansa Biopharma, presented positive results from a pooled analysis of Phase 2 trials with imlifidase for desensitization in sensitized kidney transplant patients.

Lund, Sweden September 18, 2019. Hansa Biopharma, the leader in immunomodulatory enzyme technology for rare IgG-mediated diseases, announced that positive imlifidase data were highlighted in a presentation at the 19th Congress of the European Society for Organ Transplantation (ESOT) 2019 in Copenhagen, Denmark.

Lena Winstedt, PhD, Head of Science at Hansa Biopharma, presented "Imlifidase For Desensitization in Sensitized Kidney Transplant Patients: Pooled Analysis of Phase 2 Trials".

The data was based on a pooled analysis of sensitized kidney transplant patients from four single arm, 6-month, open label, Phase 2 trials of imlifidase treatment, prior to deceased and living donor transplantation in sensitized patients.

The analysis included 46 patients whereof 50% had a cPRA of 100%, 85% were crossmatch positive and 70% were re-transplanted. Following imlifidase treatment, the DSA levels rapidly decreased and all crossmatches were converted to negative, thus enabling transplantation of all patients. This is in line with previously reported data on transplantation of highly sensitized patients

While the majority of patients had donor specific antibodies (DSA) rebound post transplantation there was no strong correlation between DSA levels and antibody mediated rejection episodes (AMR). AMR episodes occurred in 33% of patients and were all treated with standard of care therapy. This is within the range of what has previously been reported after transplantation of highly sensitized patients. The estimated mean glomerular filtration rate (GFR "kidney function") was stable around 60 ml/min/1.73 m2 at six months. At study completion, all patients were alive and graft survival was 94% (43/46). Three patients experienced graft loss unrelated to imlifidase.

The overall conclusion is that imlifidase is a promising drug candidate which can rapidly convert positive crossmatch tests to negative and thus enable deceased donor transplantation in highly sensitized patients who would otherwise remain on dialysis.

This was the first time the pooled data on the 46-patient cohort was presented.

The information was submitted for publication, through the agency of the contact person set out below at 08:00 (CET) on September 18, 2019.

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About Hansa Biopharma

Hansa Biopharma 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, imlifidase, is a unique antibody-degrading enzyme to enable kidney transplantation in highly sensitized patients with potential for further development in other solid organ transplantation and acute autoimmune indications. Imlifidase is currently under potential marketing authorization by EMA. 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 and also has operations in the UK and US.

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