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PRESS RELEASE

Hansa Biopharma announces long term follow-up data demonstrating 3-year graft survival of 84% after imlifidase treatment and transplantation

- Three-year overall allograft survival was 84% in crossmatch positive patients treated with imlifidase.
- In patients with a cPRA of ≥99.9%, three-year allograft survival was 92%
- Data published in an article accepted by the American Journal of Transplantation

Lund, Sweden July 9, 2021. Hansa Biopharma, "Hansa" (Nasdaq Stockholm: HNSA), the pioneer in enzyme technology for rare immunological conditions, today announced three-year follow-up data in crossmatch positive patients who received imlifidase prior to kidney transplantation.[1]

As reported in the article, which has been accepted for publication in the American Journal of Transplantation, 84% of patients still had a functioning allograft after three years, three allograft losses occurred during the first six months with two further losses occurring between two and three years. After 3 years, patient survival rate was 90%, three deaths occurred between 6 months and 1 year and no deaths occurred between 1 year and 3 years. At three years, mean estimated glomuleral filtration rate (eGFR) was 55 mL/min/1.73m^2.

"We are extremely pleased with these data that support the growing evidence base behind imlifidase", said Christian Kjellman, Chief Scientific Officer at Hansa Biopharma. "The 3-year outcome results published today demonstrate that imlifidase is a potent option to enable transplantation among patients who have a significant immunologic barrier to successful kidney transplantation".

The rate of acute antibody-mediated rejection ("AMR") was 28% within the first month (n=11) following transplant, with four additional AMRs occurring between 2 and 6 months bringing the rate up to 38%. Few AMRs were reported beyond the first 6 months and only one patient recorded with an early AMR had an AMR during the follow-up period. All AMRs were treated with standard therapies and no graft losses were attributed to AMRs.

In the subset of patients deemed most highly sensitized and unlikely to be transplanted (n=13) with a calculated panel reactivity ("CPRA") of ≥99.9%, graft survival was 92% and kidney function improved over time with a mean eGFR of 60 mL/min/1.73m2 at three years. As expected, there was a high rate of AMR in this group (38%; n=5) within the first 14 days, with two further AMRs occurring between 5 and 6 months from transplantation. However, all these AMRs were treated with no graft losses attributed to the AMRs.

The frequency or severity of early AMR was not substantially different from what is expected and reported in highly sensitized candidates receiving incompatible kidneys. Overall, data from this study indicate that the incidence of AMR after imlifidsase is comparable to other desensitization protocols and manageable in this high-risk population and the long-term safety profile has indicated no increase in the rates of infection or malignancy.

Currently, around 10-30% of patients on transplant waiting lists are highly sensitized.[2] Highly sensitized patients are less likely to be offered a transplant, spend much longer on waiting lists, and have a higher chance of dying whilst waiting for a suitable donor.[3] There are approximately 80,000 kidney patients on transplant waiting lists across the European Union.[4]

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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.[5]

IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor-specific antibodies (DSAs).[6] 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.[6,7,8,9]

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.[10]

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.[5]. 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%.[4] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[9] 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.[4]

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

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