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PRESS RELEASE

Hansa Biopharma and Medison Pharma announce positive reimbursement decision in Poland for Idefirix® in highly sensitized kidney transplant patients

- Idefirix® (imlifidase) becomes the first and only product reimbursed for the desensitization of highly sensitized patients waiting for a kidney transplant in Poland
- Reimbursement follows the inclusion of Idefirix® on the shortlist for exceptional innovative treatments with special funding
- The reimbursement decision provides highly sensitized patients in Poland access to Idefirix® to enable kidney transplantation from September 1st, 2022

LUND, Sweden and PETACH TIKVAH, Israel, August 22, 2022: Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, and its partner Medison Pharma, "Medison", a global pharmaceutical company focused on providing access to highly innovative therapies for patients in international markets, today announced that the Polish Ministry of Health has agreed to include Idefirix® on its reimbursement list for desensitization of highly sensitized patients prior to kidney transplantation. This decision follows last year's inclusion of Idefirix® onto the "List of Technologies with a high level of innovation" of the Polish Medical Fund. Based on the decision to grant reimbursement, Idefirix® will be fully financed and available to patients who qualify for a newly established drug program run by multiple transplant centres in Poland from September 1st 2022.[1]

Highly sensitized kidney patients have previously had very limited access to kidney transplants in Poland due to the lack of effective desensitization treatments and they often have no alternative but to remain on long-term dialysis. This can place a significant burden on patients and healthcare systems, due to a reduction in health-related quality of life, an increased risk of mortality and hospitalizations, as well as additional associated costs[2-4]. Roughly 750 kidney transplantations are carried out annually in Poland, with more than 95% of these transplanted from deceased donors.[2]

"We at Hansa alongside our partners at Medison are very pleased to have reached this agreement with the Polish Ministry of Health. We are all commited to significantly improving the lives of highly sensitized patients who are waiting for a potentially life-saving kidney transplant, and the success of this collaboration marks a significant step forward in realizing that commitment", says Søren Tulstrup, President and CEO, Hansa Biopharma.

The decision by the Polish Ministry of Health to grant reimbursement will enable Medison to commercialize Idefirix® in Poland, as part of a multi-territorial agreement between Medison and Hansa for Central Eastern Europe and Israel.[3]

"Thanks to the dedication and collaboration between the Medison and Hansa teams, we are able to provide patients in Poland with access to this breakthrough therapy, as part of our multi-territorial partnership", said Meir Jakobsohn, Founder and CEO of Medison. "We continue to fulfil our vision of creating access to highly innovative products for patients in international markets".

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About Idefirix® (imlifidase)

Imlifidase is an enzyme derived from the bacterium Streptococcus pyogenes and has the ability to specifically target and cleave (or break) all classes of immunoglobulin G (IgG) antibodies.[4] IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor-specific antibodies (DSAs).[5]. Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[6] Once they are inactivated with imlifidase, 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 receiving 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.[5,7,8,9] 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. Imlifidase 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.[10] Imlifidase was granted conditional European Marketing Authorization from the 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 imlifidase should be reserved for patients who are unlikely to be transplanted under the available kidney allocation system, including prioritization programs for highly sensitized patients.[4] 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 available yet.

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%.[11] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide[8]. 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.[12]

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 www.hansabiopharma.com.

About Medison Pharma

Medison is a global pharma company focused on providing access to highly innovative therapies to patients in international markets. Medison is the first to create an international commercialization platform for highly innovative therapies, helping to save and improve lives by making the best available novel treatments accessible to patients in international markets. Medison has a track record of multi-territorial partnerships with leading pharmaceutical and biotech companies seeking to expand their global reach. Medison is also an active investor in disruptive healthcare technologies and provides its partners with exposure to innovation in biotech and digital health. To learn more visit www.medisonpharma.com

References

1. Polish reimbursement list https://www.gov.pl/web/zdrowie/leki-refundowane
2. POLTRANSPLANT, Biuletyn nr 1(30)/2021. https://www.poltransplant.pl/Download/Biuletyn_2021_www.pdf
Hansa. Hansa Biopharma and Medison Pharma announce multiregional commercialization partnership for Hansa's desensitization treatment for kidney transplant in Central Eastern Europe and Israel. Available at

https://investors.hansabiopharma.com/English/press-releases/press-releases-details/2021/Hansa-Biopharma-and-Medison-Pharma-announce-multiregional-commercialization-partnership-for-Hansas-desensitization-treatment-for-kidney-transplant-in-Central-Eastern-Europe-and-Israel/default.aspx.
3. Hansa. Idefirix® Summary of Product Characteristics
4. Lorant T, et al. *Am J Transplant* 2018; 18(11):2752–2762
5. Eurostam Report (A Europe-wide strategy to enhance transplantation of highly sensitized patients on the basis of acceptable HLA mismatches.) Available at: https://cordis.europa.eu/project/id/305385/reporting. Last accessed August 2022
6. Jordan SC, et al. *N Engl J Med* 2017; 377(5):442–453
7. Jordan SC, et al. *Transplantation* 2021; 105(8):1808-1817
8. Winstedt L, et al. *PLoS One* 2015; 10(7): e0132011
9. European Medicines Agency. Available at: https://www.ema.europa.eu/en/news/new-treatment-enable-kidney-transplant-highly-sensitised-patients. Last accessed May 2021
10. 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 August 2022
11. Newsletter Transplant 2020. pp 58–60.