Hansa Biopharma
Scheelevägen 22
SE- 223 63 Lund, Sweden
Phone: +46 46 16 56 70

www.hansabiopharma.com

PRESS RELEASE

Hansa Biopharma announces first patient treated in the post-authorization efficacy study (PAES) of Idefirix® (imlifidase) in highly sensitized kidney transplant patients

- The PAES is an open-label Phase 3 study to further investigate the long-term graft survival in 50 highly sensitized patients who have undergone kidney transplantation after Idefirix® administration in the EU[1]
- The PAES is an obligation under the conditional marketing authorization for Idefirix® granted by the European Medicines Agency (EMA) in August 2020[2]
- The study will provide further important insights to the Idefirix® desensitization treatment of highly sensitized kidney transplant patients

Lund, Sweden, July 11, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), pioneer in enzyme technology for rare immunological conditions, announces today that the first patient has been treated in the PAES for Idefirix® as a desensitization treatment for highly sensitized people undergoing a kidney transplant.

"The European approval of Idefirix® was an important milestone for people across Europe who need a kidney transplant and yet have highly sensitized immune systems that make it more likely that their bodies will reject the donor organ," says Dr Oriol Bestard, Chair of Nephrology and Kidney Transplantation at Vall d'Hebron University Hospital in Barcelona and treating physician of the PAES first patient. "Although our allocation system in Spain, being amongst the World's best systems, has improved access to transplantation, also for (very) highly sensitized patients, many are still disadvantaged and in urgent need of more personalized and innovative options. We can now happily report that our patient was the first to receive an Idefirix® -enabled kidney transplant as part of this important study. I am really thankful to all in the team that has been in charge of this dificult-to-treat patient, as it requires an exquisit and coordinated management."

This open-label Phase 3 study will enroll 50 highly sensitized adult kidney transplant patients with positive crossmatch against an available deceased donor to confirm the long-term efficacy and safety of Idefirix®. The PAES is an obligation under the conditional marketing authorization for Idefirix® granted by EMA in August 2020, in order to complete a full marketing authorization for the European Union.

"Idefirix® is the first and only treatment approved to enable kidney transplantation for highly sensitized patients that provides patients access to an effective, rapid and predictable desensitization treatment whose only option is an incompatible deceased kidney organ," says Christian Kjellman, Chief Scientific Officer at Hansa Biopharma. "This truly international European study will help centers accommodate Idefirix®-enabled transplantation, alongside our launch under conditional approval, as Idefirix® becomes increasingly available to patients across Europe following positive reimbursement decisions in the region."

The PAES will enrol patients across multiple countries and centers in Europe and the study will include 50 highly sensitized and crossmatch positive patients to be treated with Idefirix®. The aim of the study is to confirm the long-term efficacy and safety of Idefirix® and the primary objective of the study is to determine the 1-year graft failure-free survival of the Idefirix® treated and transplanted patients. In addition, a total of 50-100 patients undergoing compatible kidney

transplantation at the participating centers will be included and serve as a non-comparative concurrent reference cohort, with no formal comparison, to contextualize the 1-year graft failure-free survival of the Idefirix® treated patients.[1]

"As of 2022, 10-15% of all of kidney patients on waiting lists in the U.S. and Europe are considered highly sensitized," says Vincenza Nigro, Kidney Transplant Franchise Lead at Hansa Biopharma. "Although allocation systems and prioritization programs have improved access to transplantation for highly sensitized kidney patients, many are still disadvantaged and in urgent need of more personalized and innovative options. We must keep striving for equity to address the medical needs of all, including highly sensitized kidney patients, no matter the challenges."

Further details of the trial (EudraCT number 2021-002640-70) can be found on the EU Clinical Trials Register.

--- ENDS ---

For more information:

Klaus Sindahl, *Head of Investor Relations*
M: +46 (0) 709 298 269
E: klaus.sindahl@hansabiopharma.com

Katja Margell, *Head of Corporate Communications*
M: +46 (0) 768 198 326
E: katja.margell@hansabiopharma.com

Notes to editors

About Idefirix® (imlifidase)

Imlifidase is an enzyme derived from the bacterium *Streptococcus pyogenes* and has the ability to specifically target and cleave all classes of immunoglobulin G (IgG) antibodies.[3]

Imlifidase is a promising new strategy for desensitization of transplant patients with donor-specific anti-HLA (Human Leukocyte Antigens) antibodies (DSAs).[4] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[5] 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.[4,6,7,8]

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.[9]

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.[3] 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%.[10] ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide.[7] 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.[11]

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.

References

1. EU Clinical Trials register. EudraCT 2021-002640-70. Available at: https://www.clinicaltrialsregister.eu/ctr-search/trial/2021-002640-70/ES#P. Last accessed July 2022.
2. Summary of risk management plan for Idefirix® (imlifidase). European Medicines Agency. August 2020. Available at: https://www.ema.europa.eu/en/documents/rmp-summary/idefirix-epar-risk-management-plan-summary_en.pdf. Last accessed July 2022.
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 July 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 July 2022
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 July 2022
11. Newsletter Transplant 2020. pp 58–60.