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PRESS RELEASE

Hansa Biopharma and Medison Pharma announce marketing authorization in Israel for Idefirix® (imlifidase) for desensitization treatment of highly sensitized kidney transplant patients

- Israel is the first market outside of Europe to grant regulatory approval for Idefirix®
- The decision by Israel's regulatory authority provides highly sensitized patients in Israel with the opportunity to receive Idefirix® as desensitization treatment
- The approval to use Idefirix® as defined in indication approved by the European Medicines Agency (EMA)[1,2]

Lund, Sweden and Petach Tikva, Israel March 28, 2022. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), the pioneer in enzyme technology for rare immunological conditions, and its partner Medison Pharma ("Medison"), a global pharma company focused on providing access to highly innovative therapies to patients in international markets, today announce that the Israeli Ministry of Health has approved Idefirix® for desensitization treatment of highly sensitized kidney transplant patients in Israel.

Idefirix® is the first and only medicine licensed for desensitization of highly sensitized patients prior to kidney transplantation, allowing these patients to access a life-changing kidney transplantation from a deceased donor.

"The regulatory approval of Idefirix® in Israel represents the first marketing authorization outside of Europe and is a milestone for our collaboration with Medison and more importantly for the highly sensitized patients we are dedicated to serving," says Søren Tulstrup, President and CEO, Hansa Biopharma. "The approval in Israel further demonstrates our commitment to expanding the reach of Idefirix® internationally to patients who are in need of this novel treatment."

Highly sensitized kidney patients have previously had very limited access to kidney transplants due to the lack of effective desensitization treatments, and they often have no alternative but to remain on long-term dialysis. Long-term dialysis can place a significant burden on patients and on healthcare systems and is associated with a reduction in health-related quality of life and increased risk of mortality, hospitalizations and additional costs.[3-5]

"The approval of Idefirix® in Israel is the result of both companies' shared efforts to improve the lives of kidney transplant patients", says Meir Jakobsohn, Founder and CEO of Medison Pharma. "This milestone is the first step in our joint commitment to provide access to this breakthrough therapy to patients across international markets."

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Notes to editors

About 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.[6]

IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor-specific antibodies (DSAs).[7] Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ and damage the transplant.[8] 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, 7,9,10]

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.[2]

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.[2] 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.[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.[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. To learn more visit www.medisonpharma.com and follow us on LinkedIn.

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