

## PRESS RELEASE

# Hansa Biopharma and Medison Pharma announce multiregional commercialization partnership for Hansa's desensitization treatment for kidney transplant in Central Eastern Europe and Israel

- Imlifidase has potential to become an important new treatment option for highly sensitized kidney patients awaiting a transplant in selected Central Eastern European countries and Israel
- Marketing authorization application for desensitization treatment in kidney transplant filed in Israel earlier this year

Lund, Sweden and Petach Tikva, Israel December 7, 2021. Hansa Biopharma AB, "Hansa" (Nasdaq Stockholm: HNSA), a pioneer in enzyme technology for rare immunological conditions, and Medison Pharma, a global pharma company focused on providing access to highly innovative therapies to patients in international markets ("Medison"), today announce a multiregional agreement for Medison to commercialize Hansa's desensitization treatment for kidney transplants in Central Eastern Europe and Israel. The commercialization is based on current conditional marketing authorization for the EU and the UK, and pending marketing authorization by Israel's Ministry of Health. A respective application for marketing authorization for desensitization treatment in kidney transplant was filed in Israel earlier this year and, if granted, will make Israel the first market outside of Europe where imlifidase is commercialized. Hansa and Medison will be working together to obtain pricing and reimbursement as required depending on the country.

The partnership covers the following countries within the Central Eastern European region: Croatia, Hungary, Poland and Slovenia in addition to Israel.

"This new commercial partnership with Medison Pharma is an important milestone for Hansa as it expands access to imlifidase for highly sensitized patients awaiting kidney transplants," says Søren Tulstrup, President & CEO of Hansa. "Patients with this rare condition currently face long wait times or are unable to find a suitable donor match, due to high levels of preformed antibodies elevating the risk of rejection."

"We are delighted to partner with Hansa Biopharma to accelerate the reach of this novel treatment for kidney disease", says Meir Jakobsohn, Founder and CEO of Medison Pharma. "In our joint commitment to address the unmet medical needs of patients with rare conditions, we look forward to leveraging our commercial platform and providing patients in international markets with access to this much needed therapy."

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Notes to Editors

#### **About 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<sup>2</sup>.

IgG antibodies targeted specifically at the transplanted kidney are known as preformed Human Leukocyte Antigens (HLAs) or donor-specific antibodies (DSAs)<sup>3</sup>. Highly sensitized patients have high levels of these preformed antibodies that can bind to the donor organ damaging the transplant<sup>4</sup>. 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 taking immunosuppressive therapy to continue 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<sup>3,5,6,7</sup>.

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 PRImity MEdicines (PRIME) scheme, which supports medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options<sup>1</sup>.

Imlifidase 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 imlifidase should be reserved for patients unlikely to be transplanted under the available kidney allocation system including prioritization programs for highly sensitized patients<sup>1</sup>. 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%<sup>8</sup>. ESRD poses a significant health burden, affecting nearly 2.5 million patients worldwide<sup>7</sup>. 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<sup>9</sup>.

#### **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](http://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](http://www.medisonpharma.com) and follow us on LinkedIn.

### References

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