

# PRESS RELEASE



## Hansa Biopharma has agreed with the FDA on a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients in the U.S.

**Lund, Sweden December 13, 2019** Hansa Biopharma, the leader in immunomodulatory enzyme technology for rare IgG-mediated diseases, today announced the outcome of a November 20th meeting with the U.S. Food and Drug Administration (FDA) to discuss a regulatory path forward for imlifidase in kidney transplantation of highly sensitized patients. Upon agreement with the FDA, following submission of a final study protocol, the Company will conduct a randomized, controlled clinical study in a limited group of highly sensitized kidney patients using a surrogate endpoint. Results from this clinical study could support a future submission of a Biologics License Application (BLA) in the U.S. under the accelerated approval pathway.

The November 20th meeting was a follow-up to the End-of-Phase 2 meeting the Company had with the FDA in December 2018. At the prior meeting, the FDA provided positive feedback on the data generated on imlifidase from the four completed Phase 2 imlifidase studies and requested additional analyses in the context of the new U.S. Kidney Allocation System (KAS) and the unmet medical need.

Since the prior FDA meeting, Hansa Biopharma has submitted the results from a matched control analysis showing significant shorter time to transplant in both the current and previous KAS. The results from this complementary analysis, together with other additional information that was provided to the FDA in the wake of the End-of-Phase 2 meeting, have further strengthened the evidence of the potential benefit imlifidase could provide to patients in the context of the new KAS and impacted the design of the randomized, controlled study requested by the Agency as part of a BLA submission.

The new study will target a limited and well defined population with the highest unmet medical need, consisting of very highly sensitized kidney patients with a cPRA level of  $\geq 99.9\%$  who are waiting for a deceased donor transplantation. FDA acknowledged that this represents a patient population with a serious condition. These patients have very limited access to transplantation and the only available therapy today is waiting on dialysis for a compatible transplant. In 2019, around 3,000 patients were registered on the waiting list in the US with a cPRA level of 99.9% or above.

The study discussed with the FDA includes approximately 50 patients to be randomized when a donor kidney becomes available to either imlifidase or to a control arm that will continue on the waitlist. A surrogate endpoint measured in the form of eGFR (kidney function) will be used to demonstrate the clinical benefit of imlifidase over the control group after 12 months.

"I am very pleased that we now have a regulatory path towards a BLA that also could support accelerated approval and I am confident that we will be able to demonstrate significant clinical benefit of imlifidase also in the context of the U.S. Kidney Allocation System and file a BLA by 2023", says Søren Tulstrup, President & CEO at Hansa Biopharma. "This brings hope to the many highly sensitized patients on dialysis in the United States who are waiting for a kidney transplant, but are more likely to die waiting or be removed from the waitlist than receiving a transplant because of preexisting HLA antibodies".

This is information that Hansa Biopharma AB is obliged to make public pursuant to the EU Market Abuse Regulation.

The information was submitted for publication, through the contact person set out below, at 08:35 a.m. (CET) on December 13, 2019.

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### About Hansa Biopharma

Hansa Biopharma is leveraging its proprietary immunomodulatory enzyme technology platform to develop treatments for rare immunoglobulin G (IgG)-mediated autoimmune conditions, transplant rejection and cancer.

The Company's lead product candidate, imlifidase, is a unique antibody-cleaving enzyme that potentially may enable kidney transplantation in highly sensitized patients with potential for further development in other solid organ transplantation and acute autoimmune indications. Imlifidase is currently under review for marketing authorization by EMA. Hansa's research and development program is advancing the next generation of the Company's technology to develop novel IgG-cleaving enzymes with lower immunogenicity, suitable for repeat dosing in relapsing autoimmune diseases and oncology.

Hansa Biopharma is based in Lund, Sweden and also has operations in Europe and US.

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In Europe, the European Medicines Agency (EMA) is currently reviewing a Marketing Authorization Application with regards to imlifidase for the European market. The review process is on track and Hansa Biopharma expects to submit responses to the Day 120 questions on December 23, 2019. An opinion from the Committee for Medicinal Products for Human Use (CHMP) is expected during the second quarter 2020.

Hansa Biopharma will be hosting a conference call with President & CEO, Søren Tulstrup and SVP & Chief Scientific Officer, Christian Kjellman. Additional details on the outcome of the FDA meeting and the trial design will be presented on the call, and there will be an opportunity for the audience to ask questions.

**Conference Call “Regulatory update – Imlifidase in the US”**

A conference call will take place December 13, 2019 at 15:00 CET.

The audio cast will be recorded and subsequently be available on the Hansa website <https://hansa.eventcdn.net/201912/>

Participants dial-in numbers  
(no passcode is required)

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