HANSA BIOPHARMA

Conference Call

Update on the regulatory path for imlifidase in the US

Lund, December 13, 2019

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Regulatory update on the path forward for imlifidase in the US

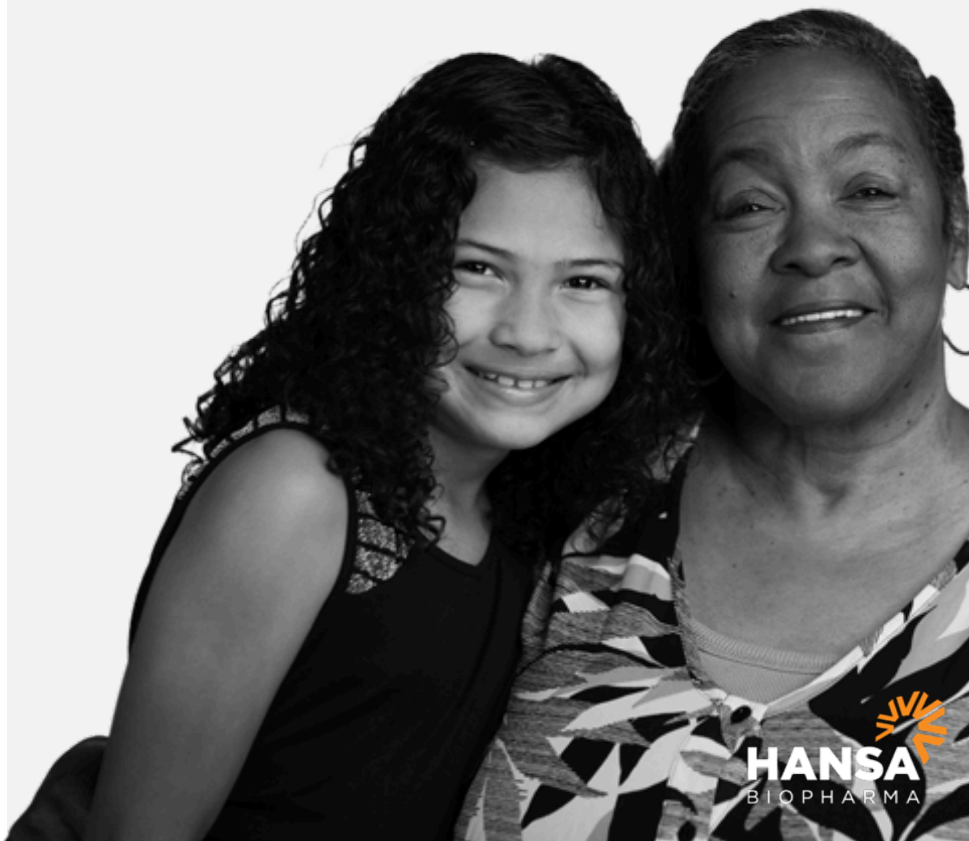
Today's agenda

1) Context of the November 20, 2019 meeting
2) Outcome of our recent regulatory meeting with the FDA
3) Clinical trial design of the new study
4) Concluding remarks and Q&A

Nov 20th meeting with the FDA was a follow-up to the End-of-Phase 2 meeting in December 2018

Additional analyses completed have further strengthened the evidence of imlifidase

- At the prior meeting, the FDA provided positive feedback on the data generated on imlifidase from the four completed Phase 2 imlifidase studies, but requested additional information
- 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 Kidney Allocation System (KAS)
- The results from matched control analysis, together with other additional information, have further strengthened the evidence of the potential benefit imlifidase could provide to patients in the context of the new KAS



Hansa Biopharma agreed with the FDA on a regulatory path forward for imlifidase in the US

New clinical study to support BLA submission

- Hansa Biopharma to conduct a randomized, controlled clinical study in a limited group of highly sensitized kidney patients using a surrogate endpoint
- The new study provides a regulatory path forward for imlifidase in the US and the results from the new clinical study could support a BLA filing in the US by 2023 under the accelerated approval pathway
- The study design will target a limited group of patients with a cPRA level of ≥99.9% on the kidney waitlist. – a patient group with a very high unmet medical need
- In 2019 there are around 3,000 patients registered on the waitlist in the US with a cPRA level of 99.9% or above. This patient group has with very limited access to transplantation and the only available therapy today is waiting on dialysis

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Hansa Biopharma to conduct a randomized, controlled clinical study in ~50 patients in the US

Clinical trial design of the new study

- The new study will be a randomized controlled clinical study targeting approximately 50 waitlisted patients, awaiting a deceased donor transplantation with a cPRA of 99.9% and above
- The patients will 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 in the context of the U.S. Kidney Allocation System
- Results from this clinical study can support a future submission of a Biologics License Application (BLA) in the U.S. by 2023 under the accelerated approval pathway

Q&A


…at Hansa Biopharma we envision a world where all patients with rare immunologic diseases can lead long and healthy lives...


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