Hansa Medical

Hansa Medical Reports Positive Final Top Line Results from Two Phase 2 Studies of Imlifidase for Kidney Transplantation

- Imlifidase meets all primary and secondary endpoints in both studies
- Treatment with imlifidase enables highly sensitized patients to receive lifesaving transplants
- Hansa Medical plans to submit BLA and MAA filings in Q4 2018 or Q1 2019
- Company to host conference call today, September 27 2018 at 2pm CEST (5am PDT, 8am EDT, 1pm BST)

Lund, Sweden, September 27, 2018- Hansa Medical AB (NASDAQ Stockholm: HMED), the leading biopharma company focusing on inhibition of immunoglobulin G (IgG)-mediated immunopathologies, announced today the successful completion of two Phase 2 clinical studies of imlifidase for kidney transplantation in highly sensitized patients, enabling transplantation in all 35 patients.

The trials were single arm, open label studies to assess the safety and efficacy of imlifidase with either a deceased or living donor kidney. The studies enrolled a total of 35 highly sensitized patients who had either failed previous attempts of desensitization or were highly unlikely to receive a compatible kidney transplant. The Hansa Medical sponsored multicenter Highdes study enrolled 18 patients at five sites in the U.S., France and Sweden; the U.S. investigator-initiated study enrolled 17 patients at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center, Los Angeles.

Summary of Results

- Imlifidase enabled kidney transplantation for all 35 highly sensitized patients. Graft survival at study completion, six months post-transplantation, was 91%. 32 patients were off dialysis with good kidney function with estimated glomerular filtration rate (eGFR) within the expected range. Three patients experienced graft loss unrelated to the treatment with imlifidase.
- Following imlifidase treatment, patients had a rapid cross-match conversion and a clinically significant reduction in DSAs, enabling transplant.
- All study participants were highly sensitized, representing a patient population highly unlikely to receive a compatible kidney transplant. Patients had a median calculated Panel Reactive Antibody (cPRA) >99.5%, with over half having a cPRA of 100%. The mean time on dialysis prior to imlifidase treatment and transplantation was >7 years. The majority of patients had previous failed kidney transplants.
- Preliminary data demonstrate that <25% of patients experienced clinical or subclinical episodes of acute antibody mediated rejection (AMR), which is lower than expected for a highly sensitized patient population after desensitization. All AMR episodes were effectively treated. Approximately 20-60% of sensitized patients desensitized with experimental protocols such as plasma exchange, experience AMRs[1].
- Results demonstrate favorable safety profile after six-month follow-up.

"Imlifidase represents a major breakthrough in the ability to offer lifesaving transplants for highly sensitized patients. These patients are very difficult or impossible to transplant, and face an extremely poor prognosis, with mortality rates on dialysis exceeding that of most forms of cancer," said Robert A. Montgomery, M.D., Director, NYU Langone Transplant Institute, New York City, USA and lead investigator of the Highdes study.

"The presence of donor specific antibodies prevents transplantation for most highly sensitized patients. Imlifidase continues to demonstrate strong risk benefit profile in breaking down this previously insurmountable immunological barrier, enabling transplantations that otherwise would not be possible to

perform," said Stanley Jordan, M.D., Director of Kidney Transplantation and Transplant Immunology at the Kidney and Pancreas Transplant Center at Cedars-Sinai Medical Center, Los Angeles, USA and lead investigator in the Cedars-Sinai study.

Three of the 35 patients experienced graft loss. In all three cases the kidneys never started to function, which was unrelated to the intervention with imlifidase. In one case, it was due to hyper-acute rejection not related to IgG antibodies; in the two other cases the transplanted kidneys failed to recover after transplantation, likely due to transplant recipient co-morbidities. The majority of the patients in these studies represent the most highly sensitized patients on the organ donor waiting list by any standard. All 35 patients had either failed previous attempts of desensitization or were not candidates for living donor desensitization methods. Observed frequencies of infections in the clinical studies are in line with what is expected for kidney transplantation patients in general. Full results of the studies (ClinicalTrials.gov identifiers NCT02790437 and NCT02426684) will be presented at an upcoming medical meeting.

"The outcome of these studies demonstrates that imlifidase enables organ transplantation for highly sensitized patients, who would otherwise remain on dialysis with a poor quality of life and increased mortality, at a high cost. Our ambition now is to seek a path towards regulatory approval from the U.S. Food and Drug Administration and the European Medicines Agency based on the strong clinical data generated to date, and we expect to file for marketing authorization in Q4 2018 or Q1 2019," said Søren Tulstrup, President and CEO of Hansa Medical AB.

The Company will host a conference call today, September 27 2018 at 2pm CEST (5am PDT, 8am EDT, 1pm BST) to present the top line results. Slides used in the presentation will be live on the Company's website during the call under Events & Webcast. To participate in the telephone conference, please call:
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A link to audio cast can be found on the Hansa Medical website under Events & Webcasts or here: https://tv.streamfabriken.com/pressconference-sep-2018

This is information that Hansa Medical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below at 08:00am CET on September 27, 2018.

About imlifidase

Imlifidase (previously known as IdeS) is an enzyme that specifically cleaves IgG antibodies, thereby inhibiting the IgG-mediated immune response. Hansa Medical is developing imlifidase as a proprietary treatment to enable kidney transplantation in sensitized patients, previously unable to undergo transplant surgery due to the presence of Donor Specific Antibodies (DSAs). Efficacy data reported from four Phase 2 studies have demonstrated that imlifidase rapidly and significantly reduced these DSAs, enabling transplantation. In addition to transplantation, imlifidase is being evaluated in a clinical Phase 2 study in anti-GBM antibody disease, a rare autoimmune disorder, and imlifidase has potential applications in a variety of additional autoimmune diseases. Imlifidase is protected by a strong patent portfolio and results of studies with imlifidase have been published in multiple peer reviewed scientific journals.

About Sensitized Patients

Many patients on the waiting list for organ transplantation carry antibodies to human leukocyte antigen (HLA), which is known as being 'sensitized'. When these antibodies are targeted towards the HLA of a potential donor, called DSAs, the transplanted organ can be significantly compromised. Patients who are highly sensitized, with high levels of DSAs, will have a very low likelihood of finding a donor towards which they will not have DSA. Therefore, they may not be able to receive a transplant at all and remain on dialysis in a debilitating disease state. Current desensitization methods are not feasible for most highly sensitized patients. Imlifidase's rapid cleavage of all IgG antibodies, desensitizes sensitized patients,

enabling deceased donors kidney transplantation. Two thirds of kidney transplantations in the U.S. and Europe are from deceased donors.

About Hansa Medical
Hansa Medical is a biopharmaceutical company developing novel immunomodulatory enzymes for organ transplantation and acute autoimmune diseases. The Company's lead product, imlifidase (IdeS), is a proprietary antibody-degrading enzyme in late-stage clinical development for kidney transplant patients, and has significant potential for further development in other solid organ transplantation and in acute autoimmune indications. Hansa also has a strong pipeline of preclinical projects that may provide a second wave of potential drugs. Under the project name NiceR, the Company is developing novel immunoglobulin-cleaving enzymes for repeat dosing in relapsing autoimmune diseases and oncology. Hansa Medical is based in Lund, Sweden, and its shares are listed on Nasdaq Stockholm (ticker: HMED).

References

1. Abu Jawdeh et al. Clin Transplant. 2014 Apr;28(4):494-507

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