

# Hansa Medical

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Hansa Medical initiates follow up study of patients treated with lead candidate imlifidase (IdeS) prior to kidney transplantation

Hansa Medical today announced that a long-term observational prospective follow up study (ClinicalTrials.gov Identifier: NCT03611621) has been initiated with Hansa Medical as sponsor. The primary objective of the study is evaluation of graft survival in patients who have undergone kidney transplantation after treatment with imlifidase. The study aims to encompass all patients from the Phase II studies with imlifidase in sensitized kidney transplantation patients.

Imlifidase (INN), also known as IdeS, is an enzyme that depletes IgG antibodies fast and effectively. Hansa Medical is developing imlifidase as a proprietary treatment to enable kidney transplantation in sensitized patients, previously unable to undergo kidney transplantation due to the presence of anti-HLA IgG antibodies. Efficacy data reported from three Phase II studies (see Table 1 below) have demonstrated that imlifidase rapidly and significantly reduced anti-HLA antibodies, enabling kidney transplantation.

Imlifidase is currently being evaluated in two studies in highly sensitized patients that do not respond to available desensitization methods. Results from these studies are expected in late Q3 2018 and the goal is to submit applications for market approval, Biologics License Application (BLA) in the US and Market Authorization Application (MAA) in the EU, at the end of 2018 or early 2019.

The initiated long-term observational prospective follow up study (ClinicalTrials.gov Identifier: NCT03611621) aims to encompass all patients from the Phase II studies with imlifidase in sensitized kidney transplantation patients. The primary outcome measure of the study is evaluation of graft survival during a 5-year time frame in patients who have undergone kidney transplantation after imlifidase treatment.

The rationale for the study is to collect data from extended follow up in patients that have received a kidney transplant following imlifidase dosing to provide a better understanding regarding the long-term outcome for these patients. Data of parameters such as patient and graft survival as well as quality of life will be collected. This prospective, observational follow up study of patients who have received imlifidase prior to kidney transplantation will provide important information to future prescribers and patients on long-term outcome of imlifidase mediated transplantation.

Table 1. Overview of completed and ongoing clinical studies with imlifidase in kidney transplantation

Type of study	Clinical trials.gov identifier	Subjects	Status	Publication
Phase I in healthy subjects	NCT01802697	29	Completed	<i>PLOS ONE</i> (2015)
Phase II in sensitized patients	NCT02224820	8	Completed	<i>American Journal of Transplantation</i> (2018)
Phase II in sensitized patients	NCT02475551	10	Completed	<i>The New England Journal of Medicine</i> (2017)

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Phase II in highly sensitized patients	NCT02426684	17	Reporting ongoing. Final results by end of Q3 2018	<i>The New England Journal of Medicine</i> (2017)
Multicenter Phase II in highly sensitized patients (Highdes)	NCT02790437	18	Reporting ongoing. Final results by end of Q3 2018	
Long-term follow up study of patients transplanted in studies NCT02224820, NCT02475551, NCT02426684 and NCT02790437	NCT03611621	Up to 46	Enrolling	

*The information was submitted for publication, through the agency of the contact person set out below, at 8:00 am CEST on August 6, 2018.*

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**About Hansa Medical**

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