

# Hansa Medical

- PRESS RELEASE -  
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## Swedish Medical Products Agency approves Hansa Medical's clinical Phase II-study application with IdeS

**Hansa Medical announces the Swedish Medical Products Agency's approval of the application to carry out a clinical Phase II-study with the drug candidate IdeS. The study's primary objective is to investigate IdeS' efficacy and safety in sensitised kidney transplantation patients. The Phase II-study will be conducted at Uppsala University Hospital and is scheduled to begin in the second quarter of 2014.**

The drug candidate IdeS is developed for fast and efficient inactivation of circulating IgG-antibodies in sensitised patients awaiting kidney transplants. The ambition is to enable transplantation for thousands of patients with kidney disease a few minutes after distributing an intravenous injection with IdeS. In 2013, a Phase I-study on 29 healthy subjects, demonstrated that IdeS is efficacious and is well tolerated with a favourable safety profile.

The approved Phase II-study will explore IdeS' safety and efficacy on anti-HLA antibodies in sensitised patients waiting for kidney transplants. In the second quarter of 2014, Hansa Medical will file an application for a second Phase II-study with the Swedish Medical Products Agency. The second Phase II-study will establish IdeS' efficacy and safety in conjunction with kidney transplantation in sensitised patients. IdeS' combined Phase II-trials will include approximately 15 patients, last for approximately 12 months and begin in the second quarter of 2014.

### **Sensitised patients**

Defining the patient group are individuals immunized to HLA (Human Leukocyte Antigen), a ubiquitous protein on all cell surfaces. Anti-HLA antibodies constitutes an immediate barrier for transplantation of sensitised patients due to the apparent risk of transplant rejection. Sensitised patients in need of transplantation are therefor referred to long-term dialysis, associated with increased risk of infection, cardiovascular disease and a significantly shortened life expectancy.

### **For further information, please contact:**

Hansa Medical AB  
Emanuel Björne, CEO  
Mobile: +46 707 17 54 77  
E-mail: [emanuel.bjorne@hansamedical.com](mailto:emanuel.bjorne@hansamedical.com)

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