
Hansa Medical's clinical Phase I study with IdeS has been initiated

Hansa Medical AB announces that the first healthy volunteer has been dosed with IdeS. The Phase I trial is performed in Sweden and involves 36 healthy volunteers. The study is double blind and randomised, whereby the volunteers will be administered intravenous single doses of either IdeS or placebo. Primary objectives are to study tolerability and safety of IdeS, as well as its effects and pharmacokinetics.

Hansa Medical is developing the biopharmaceutical candidate IdeS as a one-off treatment in conjunction with kidney transplantation. IdeS is an enzyme targeting and inactivating IgG antibodies. For the most part, IgG antibodies are a well functioning part of the human immune system. However, for 15 percent of patients awaiting kidney transplants, some of these antibodies constitute an immediate barrier for transplantation. Patients with high levels of antibodies targeting a potentially new organ are referred to as sensitized. Sensitized patients are normally put on hold for many years before reaching the top of the transplant waiting list. In many cases these patients never become eligible for a kidney transplant at all. The biopharmaceutical candidate IdeS has the potential to become the primary treatment method in facilitating transplantation for sensitized patients. The market potential is estimated to SEK 1 billion.

The objective is to finalize the Phase I study with healthy volunteers in 2013 and initiate a Phase II-study with sensitized transplantation patients in 2014. The patient group sensitized patients is a relatively small patient group but with a significant unmet medical need. The prospect for Hansa Medical to receive orphan drug designation for IdeS is estimated to be most favourable as soon as clinical data has been generated. The investment requirement for bringing the IdeS program to market approval is estimated to be significantly lower than for traditional drug development programs.

For further information, please contact:

Emanuel Björne, CEO Hansa Medical AB

Mobile: +46 707 17 54 77

E-mail: emanuel.bjorne@hansamedical.com

www.hansamedical.com

ABOUT HANSA MEDICAL

Hansa Medical is a drug and diagnostics discovery company focused on inflammatory diseases. The company develops innovative biological pharmaceuticals and diagnostic methods both independently and in partnership with large, established companies. Presently, the company is focusing on three development projects; IdeS, EndoS and HMD-301. New development projects and product candidates generated out of cooperation with medical academic research are continuously evaluated. Major shareholders: Bo Håkansson via Farstorps Gård AB, and Bengt Ågerup via Nexttobe AB. Hansa Medical is listed on NASDAQ OMX First North (HMED) and Remium Nordic AB is the company's Certified Adviser.

Hansa Medical AB
P.O. Box 785
SE-220 07 Lund
Telefon +46 46 16 56 70
Fax +46 46 12 77 75
info@hansamedical.com
www.hansamedical.com

Visiting address:
Scheelevägen 22
Lund, Sweden