
Hansa Medical receive approval from Swedish Medical Products Agency to begin clinical Phase I study with IdeS

The Swedish Medical Products Agency (MPA) has approved Hansa Medical's clinical trial application for a clinical Phase I study of the biopharmaceutical candidate, IdeS. This first-in-man study will be performed with healthy volunteers in Sweden. The study is double blind and randomised, whereby the volunteers will be administered intravenous single doses of either IdeS or a placebo. Primary objectives are to study tolerability and safety of IdeS, as well as its effects and pharmacokinetics.

"We are both proud and pleased receiving the MPA's decision today. We have been preparing this promising biopharmaceutical candidate for its clinical studies with great diligence and patience. IdeS has significant potential in effectively helping thousands of patients who, today, wait with little to no hope of receiving a transplant. The MPA's approval of the first study with IdeS is a significant step forward for both the project and for these patients. We will initiate the study as soon as possible, and we aim to complete the Phase I study within 2013."

Emanuel Björne, CEO Hansa Medical.

Hansa Medical is developing the biopharmaceutical candidate IdeS as a one-off treatment in conjunction with kidney transplantation. IdeS is an enzyme with strict specificity, 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.

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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.

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