press release

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All healthy subjects have been treated in Hansa Medicals´ Phase I-study with IdeS

All healthy subjects have been recruited and dosed in Hansa Medicals' Phase I-study with drug candidate IdeS. The results are anticipated for release in early 2014.

The Phase I-study is a double blind, randomized study in healthy subjects administered intravenous single doses of IdeS or placebo. Study objectives are to study safety, tolerability, pharmacokinetics and IgG-cleaving effect. The aim is to initiate a Phase II-study with sensitized transplantation patients in 2014.

"The dosing in the Phase I-study with IdeS is now completed. We look forward to communicate the results from the study as soon as we have finalized our analyses and the study data has been summarized. We anticipate announcement of the results in early 2014.", says Emanuel Björne, CEO Hansa Medical AB.

IdeS creates transplantability

Hansa Medical is developing the biopharmaceutical candidate IdeS as a single dose treatment in connection with kidney transplantation. IdeS is an enzyme targeting and inactivating IgG antibodies. Normally, 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. These patients are rarely transplanted. Instead they are directed to long term dialysis which is associated with cardiovascular diseases and significantly shortened life expectancy. 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 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 favorable 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.

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ABOUT HANSA MEDICAL

Hansa Medical pursues clinical development and commercialization of innovative pharmaceuticals and diagnostic methods for the benefit of patients with serious and rare inflammatory diseases. The portfolio includes a marketed diagnostic product, a drug candidate in Phase I trial, and a preclinical research project. Major shareholders are 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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