press release

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Succesfully completed Phase I study with IdeS

The results from the study demonstrate that IdeS is efficacious and well tolerated with a favorable safety profile. IdeS cleaves IgG antibodies efficiently and no intact IgG is detectable in the circulation of healthy subjects within minutes after dosing. The results from the Phase I study are very encouraging and Hansa Medical will file a Phase II study application at the Swedish Medical Products Agency during the first quarter of 2014.

"The Phase I trial demonstrates that IdeS is safe, fast and efficacious at the tested dose levels. For a new desensitization protocol, these are exactly the characteristics transplantation surgeons around the world are looking for. We now look forward to begin a Phase II study with patients awaiting kidney transplantation at Uppsala University Hospital during spring 2014. The performed Phase I study with IdeS is our greatest success to date. We are very happy and proud of this result." states Emanuel Björne, CEO of Hansa Medical AB.

The Phase I study with IdeS was performed March 2013 to January 2014 and included 29 healthy subjects. The study was a double blind, randomized study in healthy subjects administered intravenous single doses of IdeS or placebo. Study objectives were to study safety, tolerability, pharmacokinetics and IgG-cleaving effect of the drug candidate IdeS.

IdeS enables transplantation

Hansa Medical is developing the drug candidate IdeS for treatment in conjunction with kidney transplantation. IdeS is an enzyme that cleaves and inactivates IgG-antibodies. In a healthy individual, IgG-antibodies constitute a well functioning part of the immune system. However, in several medical conditions IgG-antibodies can cause problems.

For 15 to 30 percent of patients waiting for kidney transplantation, so-called donor specific antibodies (antibodies hostile to a potential donor organ) constitute an immediate barrier for transplantation. Today, there are no methods available for fast and efficient reduction of antibody levels prior to transplantation. Consequently, these patients rarely, if ever, qualify for transplantation. Instead, they are referred to many years in dialysis, associated with increased risk of infections, cardiovascular diseases and significantly shortened life expectancy.

The drug candidate IdeS has the potential to become the primary treatment method facilitating transplantation for this group of patients. Estimated market potential point to SEK 1 billion per year in the U.S. and Europe alone.

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 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 clinical development, 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.

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