

Hansa Medical

- PRESS RELEASE -
February 18, 2015

Comments to CEO presentation at Redeye on 17 February 2015 at 18.30

The presentation made by Hansa Medical AB (publ) CEO Fredrik Lindgren contained certain data relating to Hansa Medical's phase I study. This press release contains certain clarifications and supplementary information relating to the study.

Hansa Medical completed a phase I study in healthy subjects in 2013. This first-in-human study was a double blind and randomized study with single ascending doses of IdeS. The study was conducted in Lund, Sweden after approval from Swedish regulatory and ethical authorities. The objective was to assess safety, efficacy, pharmacokinetics, and immunogenicity of IdeS in healthy human subjects following intravenous administration over 15 minutes. Each dose group consisted of 4 subjects receiving IdeS and 2 subjects receiving placebo and in total five dose groups were exposed. The starting dose was 0.01 mg/kg body weight (BW) and the highest dose group received 0.24 mg/kg BW.

In total 20 subjects were exposed to IdeS and already at the lowest dose a partial effect, i.e. single cleaved IgG, could be observed in occasional subjects. Full IgG cleavage within a few hours after dosing was achieved at 0.12 and 0.24 mg/kg BW in all subjects and noteworthy single cleaved IgG was observed already during dosing. IdeS created an IgG-free window of between one and two weeks after which newly synthesized IgG started to appear. IdeS had a short serum half-life and the main fraction of IdeS was eliminated during the first 24 hours after treatment. As expected, anti-drug antibodies developed after dosing. The antibodies reached peak levels two to four weeks after dosing and were normalized within 6-12 months. No severe adverse events were reported and the proportion of adverse events was comparable between IdeS and placebo treated subjects.

The conclusion based on the first-in-human study was that IdeS proved to be safe, well tolerated and effective.

"This phase I study is the proof-of-concept study for IdeS and forms the basis for further development of IdeS in various IgG-mediated conditions. The study has generated additional patent opportunities and it will be available in its full extent through publication in a peer reviewed journal." says Christian Kjellman, Chief Scientific Officer of Hansa Medical AB.

About Hansa Medical AB

Hansa Medical is a biopharmaceutical company focused on novel immunomodulatory enzymes. Lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Other projects include HBP (a market introduced diagnostic marker for severe sepsis) and EndoS (an antibody-modulating bacterial enzyme in pre-clinical development). The company is based in Lund, Sweden. Hansa Medical's share (HMED) is listed on NASDAQ First North in Stockholm with Remium Nordic AB as Certified Adviser. Major shareholders are Farstors Gård AB and Nexttobe AB.

About IdeS

IdeS, a unique molecule with a novel mechanism, is a bacterial enzyme that cleaves human IgG antibodies. IdeS degrades all IgG specifically, swiftly and efficiently. IdeS has been tested for safety and efficacy in numerous *in vitro* and *in vivo* models. During 2013, a Phase I clinical trial on 29 healthy subjects was conducted, demonstrating IdeS as efficacious and well tolerated with a favorable safety profile. During 2014 and 2015, a Phase II clinical trial in sensitized patients awaiting kidney transplantation has been conducted. Preliminary data shows that IdeS has very good efficacy in highly sensitized patients on the kidney transplant waitlist. The study shows that IdeS has the capacity to make sensitized

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patients eligible for transplantation by decreasing HLA antibodies to levels acceptable for transplantation. In addition to transplantation, IdeS has potential indications within a variety of rare autoimmune diseases including anti-GBM disease. IdeS is protected by several patents and has been published in numerous peer review journals.

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