
HMD-301 FOR DIAGNOSIS OF BACTERIAL MENINGITIS: NOVEL CLINICAL RESULTS PUBLISHED

Hansa Medical's clinical research partners have conducted a clinical study displaying that the diagnostic method HMD-301 is able to diagnose bacterial meningitis with an extremely high level of precision. The results of the study have been published in the scientific journal *Critical Care Medicine*, Volume 39, Issue 4, page 812-817.

The clinical study was conducted at the department of infectious diseases at Lund University Hospital and involved 174 patients, each with a suspected infection of the central nervous system. Of these 174 patients, 41 individuals developed bacterial meningitis. Through quantification of the level of HBP in their cerebrospinal fluid, these patients could be distinguished with a sensitivity of 100% and a specificity of 99.2%. The study also involved comparison laboratory tests, which are currently used in clinical practice for the diagnosis of bacterial meningitis: lactate, glucose, total protein level and cell count in the cerebrospinal fluid. The quantification of HBP was the best parameter, as regards both sensitivity and specificity, for the diagnosis of patients with bacterial meningitis.

A diagnosis of bacterial meningitis implies that the outer membrane of the brain is infected with bacteria, most often *Streptococcus pneumoniae* and *Neisseria meningitidis*. The disease is a serious medical condition requiring immediate diagnosis and treatment. Bacterial meningitis has an incidence rate of 1-2 individuals per 100,000 in the western world, and the mortality rate is estimated at approximately 34%, in spite of treatment with antibiotics. Viral meningitis is a type of meningitis resulting from a viral, rather than bacterial, infection. Viral meningitis displays similar clinical symptoms to bacterial meningitis but requires different treatment methods. The diagnostic value of HBP quantification lies in both the diagnosis of bacterial meningitis and in differentiating between bacterial and viral meningitis. Viral meningitis does not result in increased levels of HBP. The incidence rate for viral meningitis is estimated at 5-15 cases per year, per 100,000 individuals. This statistic implies that the incidence rate for bacterial and viral meningitis can be estimated at a total of 60,000 to 160,000 cases per year in the USA, Europe and Japan. The number of patients investigated at emergency clinics, infectious disease clinics and neurology clinics, eligible for a test, is significantly larger than the number of patients infected with the disease. Furthermore, HBP quantification may become a method used to measure the effectiveness of treatment for bacterial meningitis. Hans Medical assesses the analytical requirement for the diagnosis of bacterial meningitis to 500,000 per year.

HMD-301 is Hansa Medical's patented method for the quantification of HBP, which is, primarily, under development for early identification and diagnosis of severe sepsis. The analytical method is currently being developed towards market introduction in 2012, in collaboration with the British-Norwegian diagnostics company, Axis-Shield Diagnostics Ltd. Since the start of the collaboration in 2009, an optimized version of the analysis method has been developed and a major clinical study has been initiated. In addition, Axis-Shield has also entered into an option agreement with the international diagnostics group Bio-Rad Laboratories, in regards to the evaluation of HBP as a biomarker for severe sepsis. The market for the early identification and diagnosis is estimated at amount to 3 million analyses per year. Axis-Shield bears all of the expenses attributable to development and the agreement entails that Hans Medical has the right to comprehensive royalty payments from Axis-Shield for the sale of HBP assays, as well as royalties for up-front payments and milestone payments received by Axis-Shield.

For further information, please contact:

Hansa Medical AB
Emanuel Björne, CEO
Mobile: +46 707 17 54 77
E-mail: emanuel.bjorne@hansamedical.com

ABOUT HANSA MEDICAL

Hansa Medical is a biotechnology research and development company focused on the treatment and diagnosis of inflammatory diseases. The company develops innovative biological pharmaceuticals and diagnostic methods both independently and in partnership with large, established companies. At present, the company is primarily undertaking three development projects: IdeS, anti-alpha-11 and HMD-301. New development projects and product candidates generated through cooperation with medical academic research are continuously evaluated. Hansa Medical is listed on NASDAQ OMX First North, and Remium AB is the company's Certified Adviser.

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

VISITING ADDRESS:
Scheelevägen 22
Lund