press release

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Hansa Medical and Axis-Shield report most promising results from pivotal clinical trial with HBP-analysis

The clinical study was carried out at Emergency Departments both in Sweden and the US through 2011-2013. Results show that HBP-analysis predicts patients with forthcoming severe inflammatory response to infection (severe sepsis) with significantly higher accuracy than any of the other methods tested. Data will be presented at the 6th Annual Symposium of the International Sepsis Forum in Rio de Janeiro, Brazil, on November 5, 2013.

Background to the study

HBP-analysis is a novel method developed by Hansa Medical to help predict severe sepsis at Emergency Departments (ED). Hundreds of thousands of patients die every year due to severe sepsis as a complication to ordinary infections like urinary tract infection, skin infection or pneumonia. Patients can be efficiently treated but time is critical. A seemingly stable patient can within hours develop organ and/or circulatory failure. This life threatening condition is called severe sepsis. Early treatment is crucial for survival. EDs are in need of predictive diagnostics with high accuracy for early and rapid treatment.

Study results

The pivotal clinical study involved 763 ED-patients. 143 of those were admitted to the ED without signs of severe sepsis. They did however develop organ and/or circulatory failure within 72 hours. The study focused on whether blood sample quantification of HBP in ED-patients had the potential to predict patients' susceptibility to develop severe sepsis. The study shows that HBP-analysis predicts severe sepsis with significantly higher accuracy than any of the other methods tested in the study.

Predictive powers of the HBP-analysis

The HBP-analysis has been compared to those methods most commonly used on the market today: *blood sample quantification of Procalcitonin, Lactate, White Blood Cells and C-Reactive Protein (CRP).* Quantification of Procalcitonin is the most commonly used method for general risk assessment of infectious disease patients. The study showed elevated levels of Procalcitonin in 59% of those 143 ED-patients that later developed severe sepsis. The corresponding value for HBP was 80%.

"HBP-analysis equips Emergency Departments with an effective tool to single out patients at high risk of developing severe sepsis. Hundreds of thousands of lives can be saved and costly intensive care can be cut through the prediction of severe sepsis and early treatment", states Emanuel Björne, CEO of Hansa Medical AB.

Hansa Medical and Axis-Shield Diagnostic Limited (Axis-Shield) signed a collaborative agreement in 2009 for the commercialization of HBP-analysis. Axis-Shield has since carried out further development and launched a CE-certified version. Hansa Medical carries rights to significant royalties from Axis-Shield derived from sales of HBP-analysis. Market estimation points to 3 million analyses per annum in Europe and US alone.

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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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