Press Release

B·R·A·H·M·S Announces New Blood Test Better Predicts Heart Failure Outcomes in Emergency Setting

Data Presented in a Late Breaker Presentation at AHA Shows MR-proADM Surpasses Industry Standard

New Orleans, LA, November 11, 2008 -- B·R·A·H·M·S today announced positive results from the company's BACH (Biomarkers in Acute Congestive Heart Failure) Multinational Study comparing its new blood test, MR-proADM (Mid-Regional pro-Adrenomedullin) to BNP and NT-proBNP, the current industry standard tests used in acute care settings worldwide, as a prognostic indicator in patients with heart failure. The results demonstrated that the MR-proADM test was accurate for prognosis of outcome of acute heart failure, quantitatively superior to both BNP and NT-proBNP. The data were presented by Prof. Stefan D. Anker, M.D., Ph.D., Department of Cardiology, Charité - Universitätsmedizin Berlin, at the American Heart Association's (AHA) Scientific Sessions 2008 in New Orleans, LA. Early in 2008, MR-proADM was CE labeled and is currently marketed in the European Union.

"We are very pleased with the results of the BACH study. This pivotal heart failure trial shows MR-proADM is particularly strong in predicting heart failure outcomes up to four weeks after initial assessment," stated Dr. Anker, co-principal investigator.

"The results of the BACH MR-proADM study are truly significant for emergency physicians as acute heart failure in patients is difficult to diagnose since symptoms of heart failure are common to other medical conditions such as pneumonia and COPD," said W. Frank Peacock, M.D., Vice Chairman of Emergency Department, Cleveland Clinic Foundation. "Delayed treatment can lead to respiratory compromise and sudden death; if approved in the U. S., the MR-proADM test will help ensure patients are accurately diagnosed and rapidly receive the treatment they need."

"We are very excited about the results of this study. Upon regulatory approval in the U.S., our MR-proADM test may enable physicians to better manage patients presenting shortness of breath to the emergency room, potentially resulting in improved patient outcomes," said Bert Valada, President and CEO of B·R·A·H·M·S USA. "The results of this study, along with the results of our BACH MR-proANP study presented at the 2008 ESC Congress, confirm the company's commitment to the discovery and development of highly effective biomarker tests for the diagnosis, treatment and management of life-threatening diseases. The results of the BACH study complement the success of the Procalcitonin Kryptor, the company's test for the diagnosis of severe bacterial infections, introduced in the U.S. earlier this year."

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Study Design

The BACH study was an international, multi-center, prospective, multi-marker trial evaluating the diagnostic and prognostic accuracy of B·R·A·H·M·S' biomarkers in 1641 patients presenting with shortness of breath to participating emergency rooms. Patients were enrolled at fifteen sites in eight countries. Study objectives were two primary endpoints: first to demonstrate that MR-proADM better predicted 90-day mortality than either BNP or NT-proBNP, second, as presented earlier this year at the 2008 ESC (European Society of Cardiology) Congress, that MR-proANP (Mid-Regional pro-Atrial Natriuretic Peptide) is non-inferior to BNP for the diagnosis of acute heart failure.

MR-proADM Study Results

The prognostic accuracy of MR-proADM (73.1%) was superior to BNP (60.6%, $p<0.001$) and NT-proBNP (63.0%, $p<0.001$). These findings held true for all enrolled patients (130 deaths) and for the 477 heart failure patients who were admitted to the hospital (all $p<0.001$), satisfying the primary and secondary prognostic endpoints of the BACH MR-proADM study. The hazard ratios (HRs) comparing the 2nd, 3rd, and 4th ADM quartiles to the first in all 1641 patients were 7.4 (95%Cl 2.2-24.8, $p=0.001$), 10.7 (3.3-35.0, $p<0.001$), and 26.8 (9.5-85.1, $p<0.001$), respectively. Of 1641 patients included in the study, 568 (34.6%) had a diagnosis of heart failure and 65 (11.4%) died within 90 days.

Results from the BACH MR-proANP study were presented earlier this year at the 2008 ESC Congress. The results demonstrated MR-proANP is non-inferior to BNP and NT-proBNP in the diagnosis of acute heart failure. In patient subgroups where BNP and NT-proBNP values proved difficult to interpret, MR-proANP provided additive value for the diagnosis of acute heart failure. Additionally, the study demonstrated that a combination of the biomarkers PCT (Procalcitonin) and MR-proANP helps in the discrimination of patients with pneumonia in comparison to those with acute heart failure.

About MR-proADM

Adrenomedullin (ADM), a multifunctional peptide associated with the control of microcirculation, synthesized by a variety of tissues including heart and kidney regulates blood vessel dilation and plays a key role in many cardiac and infectious diseases. MR-proADM (Mid-Regional pro-Adrenomedullin), a stable mid-region fragment of ADM, is more readily measurable than ADM. MR-proADM is secreted in equimolar quantities and therefore provides an accurate measure of ADM release. B·R·A·H·M·S' MR-proADM test measures levels of ADM and indicates dysfunction in the lining of blood vessels.

About MR-proANP

Atrial Natriuretic Peptide (ANP) is predominantly produced in the atrium of the heart and comprises 98% of the natriuretic peptides in the circulation. ANP is involved in natriuresis, diuresis, vasodilation and cardiovascular homeostasis. Although this peptide is unstable, this novel assay detects the corresponding prohormone fragment: the Mid-Regional pro-Atrial Natriuretic Peptide (MR-proANP). In contrast to the material peptide, MR-proANP is a stable and reliable surrogate measurement of atrial natriuretic peptide levels.

About Shortness of Breath and Heart Failure

Shortness of breath (SOB), also called dyspnea, is difficulty in breathing or painful breathing. Shortness of breath is commonly a sign of a medical condition, including asthma, respiratory infections and heart failure.

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In heart failure patients, SOB is indicative of the heart's inability to pump enough blood to adequately oxygenate the body's tissues. An estimated 3 million U.S. patients visit hospital emergency rooms with symptoms of heart failure each year. It costs more than $20 billion annually to diagnose and treat the disease.

About B·R·A·H·M·S

B·R·A·H·M·S is a global biotechnology company committed to improving healthcare through the discovery and development of new, innovative biomarkers for the diagnosis, treatment and therapeutic management of life-threatening diseases. With its more than 350 employees, the company's goal is to extend its large portfolio of new biomarker tests for infectious and cardiovascular diseases as well as other clinical applications. B·R·A·H·M·S develops and markets its patent-protected products worldwide to hospitals, laboratories and licensees.

B·R·A·H·M·S AG has its headquarters near Berlin, Germany.

B·R·A·H·M·S USA is focused on the research and development of a number of biomarkers which have demonstrated potential efficacy in the diagnosis of infectious and cardiovascular diseases. MR-proANP, MR-proADM, CT-proAVP/Copeptin and CT-proET-1 are among the biomarkers currently being studied by the company.

B·R·A·H·M·S USA markets Procalcitonin®, the company's FDA-cleared marker for sepsis. The B·R·A·H·M·S PCT sensitive Kryptor® test enables physicians to determine whether an infection is bacterial or viral in nature and provides actionable information on the severity of a patient's condition less than an hour after a blood sample is drawn.

For more information, please visit www.brahms-usa.com and www.brahms.de.

B·R·A·H·M·S Aktiengesellschaft	Tel.: +49.(0)3302.883 – 0	Seite / Page 3
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