



## **HABIT Study Shows That Home BNP Testing May Allow for Earlier Interventions & Facilitate Better Management of Heart Failure Patients**

WALTHAM, Mass., October 4, 2011 /PRNewswire/ -- At the Heart Failure Society of America's 15<sup>th</sup> Annual Scientific Meeting, Alan Maisel, M.D., VA San Diego Healthcare System, announced that B-type natriuretic peptide (BNP) may have utility in monitoring heart failure patients for early warning signs of decompensation in advance of acute presentations.

HABIT, a multi-center study led by Maisel and sponsored by Alere Inc., is the first of its kind to have heart failure patients measure their BNP levels from home every day. 187 subjects were enrolled in the study following hospital discharge for a heart-failure-related event, and BNP levels were measured daily for 60 days using a fingerstick test run on the Alere<sup>TM</sup> Heart Check System. The results of the study demonstrate that BNP levels fluctuate rapidly and frequently in heart failure patients. They also provide insight into new strategies for monitoring these fluctuations, which in turn might lead to the early identification of problems in these patients.

"The results of the HABIT study provide an important advancement in our knowledge about B-type natriuretic peptide in heart failure," said Maisel. "For the first time, we have seen that, in a population of patients discharged with heart failure, natriuretic peptides can rapidly and significantly change from day to day over the course of weeks, illustrating that frequent measurement could be useful in the accurate assessment of heart failure patient status."

BNP is secreted by the heart's ventricles in response to changes in pressure that occur when heart failure develops or worsens. As the symptoms of heart failure become more severe, the level of BNP in the blood increases. For this reason, routine monitoring of BNP levels in outpatient and home settings may be a viable tool for identifying decompensation events earlier and managing them more effectively.

The results of HABIT appear to support this conclusion. "The routine availability of BNP values in established heart failure patients could provide us with the first direct and objective indicator of the heart's response to change in a patient's condition," stated Maisel. "BNP could become an important monitoring tool for use in the homes of patients to manage the disease remotely, thereby identifying decompensation earlier to reduce healthcare costs and downstream re-hospitalizations."

While the results of HABIT suggest that remote BNP monitoring could lead to significant improvements in how heart failure patients are managed, more data is needed to understand the extent to which healthcare providers can intervene with patients and reduce hospitalizations, lower healthcare costs, and enhance quality of life. A further study to investigate these matters as part of the next phase of the trials will be conducted in the US.

This multi-center, interventional trial will be designed to analyze the ability of BNP to improve upon today's tools for managing heart failure and prevent re-hospitalization. In particular, the study will compare today's standard of care, which involves monitoring symptoms of heart failure and body weight changes following hospital discharge under the management of hospital-based outpatient heart failure clinics, to an algorithm that incorporates routine, home BNP measurements and will assess the extent to which this reduces hospital re-admissions and improves patient outcomes. The study is expected to commence in 2012. Alere has also undertaken a multinational study in Europe and Asia to further investigate the utility of home BNP testing coupled with clinical interventions and identify the value of this approach to decreasing HF related events. This study is currently underway and results are expected to be released in 2013.

“The potential value of natriuretic peptide guided heart failure management is clear, and recent results are very encouraging for the approach,” said James Januzzi, M.D., Massachusetts General Hospital, in response to the findings from the HABIT study. “One major limitation of prior studies of biomarker guided treatment for heart failure is that they were focused on the office-based monitoring and management of patients. Ultimately, the ability to take guided heart failure therapy into the home will be a major step forward, and will hopefully allow for more careful surveillance of our patients.”

### **About Alere**

By developing new capabilities in near-patient diagnosis, monitoring and health management, Alere (NYSE: ALR) enables individuals to take charge of improving their health and quality of life at home. Alere's global leading products and services, as well as its new product development efforts, focus on infectious disease, cardiology, oncology, toxicology and women's health. Alere is headquartered in Waltham, Massachusetts.

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