

Boston Scientific Announces Positive Results Of HeartLogic™ Heart Failure Diagnostic Service

Late-Breaking Trial Data Presented at AHA Scientific Sessions Demonstrate Success of Alert to Predict Worsening Heart Failure

NEW ORLEANS and MARLBOROUGH, Mass., Nov. 16, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced results from the first clinical trial evaluating the performance of the HeartLogic™ Heart Failure Diagnostic Service to predict impending heart failure (HF) decompensation. Data collected from the Multisensor Chronic Evaluation in Ambulatory Heart Failure Patients (MultiSENSE) study were presented as a late-breaking clinical trial at the American Heart Association (AHA) Scientific Sessions 2016 in New Orleans, and confirmed the HeartLogic alert provided a highly sensitive and timely predictor of a future HF event.

Data from the MultiSENSE trial demonstrated the HeartLogic alert had an observed sensitivity of 70% and a low unexplained alert rate (alerts not followed by a HF event) of 1.47 per patient per year. Additionally, the trial data demonstrated the HeartLogic alert could successfully notify clinicians of an associated HF event – defined as hospitalizations with HF as the primary diagnosis and HF outpatient treatment with intravenous therapy – with a 34-day median alert window.

"The primary endpoints were exceeded and demonstrated that this algorithm, which mimics the activity and analysis of a clinician by combining multiple measurements evaluating different aspects of heart physiology, is a strong predictor of heart failure events," said John P. Boehmer, M.D., principal investigator and medical director of the Heart Failure Program at The Pennsylvania State University College of Medicine and The Penn State Hershey Medical Center. "The study illustrates compelling performance of the HeartLogic algorithm for the detection of worsening heart failure and lays the foundation for future studies of the alert in clinical practice."

The study included 900 patients who had enhanced sensor data collection enabled in their cardiac resynchronization therapy defibrillator (CRT-D) systems and were followed for up to one year in either a development or test cohort. Information from the 500 patients within the development set was used to construct the HeartLogic composite index and alert algorithm by combining heart sounds, respiration rate and volume, thoracic impedance, heart rate and activity. The 400 patients within the test set were sequestered for subsequent independent validation of HeartLogic.

"The successful results from this study and the development of the HeartLogic service are foundational to our continued development of differentiated solutions for the management of heart failure," said Kenneth Stein, M.D., senior vice president and chief medical officer, Global Health Policy and Rhythm Management, Boston Scientific.

The company has submitted a design dossier for CE Mark and a premarket approval application for U.S. Food and Drug Administration approval of the HeartLogic service and plans to conduct post-approval studies, including Multiple cArDiac seNsors for mAnaGEMENT of Heart Failure (MANAGE-HF), to further evaluate the alert.

The HeartLogic Heart Failure Diagnostic Service is not currently available for use or sale.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life

by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on [Twitter](#) and [Facebook](#).

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding our business plans and product performance and impact. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – *Risk Factors* in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – *Risk Factors* in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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