

## **Boston Scientific Announces Positive Late-Breaking Clinical Trial Data for the HeartLogic™ Heart Failure Diagnostic**

### **Data Presented at Heart Failure Society of America's 21st Annual Scientific Meeting Demonstrate Alert Improves Heart Failure Risk Prediction**

DALLAS and MARLBOROUGH, Mass., Sept. 19, 2017 /PRNewswire/ -- Boston Scientific (NYSE: BSX) today announced new data from the Multisensor Chronic Evaluation in Ambulatory Heart Failure Patients (MultiSENSE) study evaluating the performance of the HeartLogic™ Heart Failure Diagnostic to predict impending heart failure (HF) decompensation. Data from the study were presented as a late-breaking clinical trial at the Heart Failure Society of America's 21st Annual Scientific Meeting in Dallas, and confirmed the HeartLogic Diagnostic accurately enhanced the ability to classify patients at high or low-risk of experiencing a future HF event.

The HeartLogic Diagnostic provides continuous measurement of a patient's heart failure by combining data from sensors evaluating heart sounds, respiration rate and volume, thoracic impedance, heart rate and activity. Current clinical guidelines recommend the use of a blood test to measure natriuretic peptides BNP or NT-proBNP in order to diagnose HF or determine disease severity.<sup>1,2</sup> However, the test can only reflect a snapshot assessment at the time of a blood draw, which loses relevance as a patient's condition changes.

New data from the MultiSENSE trial demonstrated the HeartLogic Diagnostic significantly expanded the ability of a baseline blood test to identify when patients were at an elevated risk of a HF event. The combination of the HeartLogic Diagnostic with a baseline NT-proBNP measurement accurately identified when patients within varying risk groups were at a 23 to 50 times increased risk of experiencing a HF event.

"Through the utilization of the HeartLogic Diagnostic, physicians can more accurately triage appropriate care to this vulnerable patient population in a timely manner, particularly when using the alert in combination with an intermittent measure of NT-proBNP," said John P. Boehmer, M.D., principal investigator and director of the Heart Failure Program at Penn State Health Milton S. Hershey Medical Center and professor of medicine, Penn State College of Medicine

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.

"The data presented today further prove the value of the HeartLogic Diagnostic in the early prediction of HF events," said Kenneth Stein, M.D., senior vice president and chief medical officer, Global Health Policy and Rhythm Management, Boston Scientific. "Our commitment to innovation in heart failure remains steadfast, and we look forward to the seeing continued results of the alert in a clinical setting."

Previously published study data demonstrated that the HeartLogic Diagnostic had an observed sensitivity of 70% as well as the ability to provide weeks of advance notice and low burden for detecting indications of worsening HF.<sup>3</sup>

The company received CE Mark and U.S. Food and Drug Administration approval of the HeartLogic Diagnostic within the Resonate™ family of implantable cardioverter defibrillator and CRT-D systems earlier this year. The new line of devices will become commercially available later this year.

For more information on the HeartLogic Heart Failure Diagnostic, visit [www.bostonscientific.com/heartlogic](http://www.bostonscientific.com/heartlogic).

#### **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](http://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, clinical results, 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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<sup>1</sup> Yancy CW, Jessup M, et al. 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. *Circulation*. 2017;136:e137–e161. DOI: 10.1161/CIR.0000000000000509.

<sup>2</sup> Ponikowski P, Voors AA, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC). *European Heart Journal* 2016;37:2129-2200.

<sup>3</sup> Boehmer, J et al., *JACC-HF*, 2017;5(3), 216 – 256.

SOURCE Boston Scientific

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