Boston Scientific

Late-breaking Clinical Trial Data Further Demonstrate Safety and Effectiveness of the RHYTHMIA™ Mapping System

BARCELONA, Spain and MARLBOROUGH, Mass., March 20, 2018 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announced real-world data from the TRUE-HD study during a late-breaking clinical trial session today at the annual congress of the European Heart Rhythm Association (EHRA) in Barcelona, Spain. The data demonstrated the RHYTHMIA™ Mapping System, when paired with the INTELLAMAP ORION™ Mapping Catheter, continues to be safe and effective for mapping and to support treatment of a wide variety of arrhythmias, including a cohort of patients who had unsuccessful ablation of atrial fibrillation using other techniques.

The global TRUE-HD study examined procedural process, acute success and safety for the mapping and ablation of various clinical arrhythmias. Depending on the arrhythmia type, study data showed an acute success rate of up to 95.7%. In 222 patients, procedure process included the creation of validation maps to confirm the termination of an arrhythmia. Utilization of the RHYTHMIA Mapping System vMap™ feature allowed physicians to rapidly assess therapy efficacy and determine if other arrhythmias were present. When completed, validation mapping identified the need for additional ablations in 73.0% of patients.

"This study was the first to perform systematic data collection on a range of arrhythmia types using the RHYTHMIA Mapping System," said Gerhard Hindricks, M.D., principal investigator and head of the electrophysiology department at Leipzig University Heart Center in Germany. "Importantly, validation mapping allowed for precise views of therapy success and the identification of new areas in the heart requiring additional ablations that would have otherwise gone untreated."

The observational, prospective, non-randomized study enrolled 572 patients eligible for cardiac mapping and ablation to treat an arrhythmia, with the exception of those diagnosed with de novo atrial fibrillation. The ablation-related complications were low and similar to those reported in recent literature[1], with only 0.57% potentially related to the mapping catheter.

"The data presented today underscore the value that the RHYTHMIA Mapping System and INTELLAMAP ORION Mapping Catheter bring to physicians as they diagnose and treat a broad array of arrhythmias," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific. "We look forward to the continued expansion of our electrophysiology portfolio and future innovations that ensure physicians are equipped with tools that provide the highest quality care for their patients."

Last year the company launched the next generation RHYTHMIA HDx™ Mapping System featuring an updated design to support future cardiac mapping innovations and improve workflow efficiency.

For more information on the RHYTHMIA HDx Mapping System and the INTELLAMAP ORION Mapping Catheter, visit www.bostonscientific.com/rhythmia.

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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[1] Haegeli LM, Catheter ablation of atrial fibrillation: an update.Eur Heart J., 2014(36): p. 2454-9.

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