Boston Scientific

Late-breaking Clinical Trial Highlights Positive Safety and Efficacy Data for the LUMINIZE™ RF Balloon Catheter

New data showcasing performance of recently acquired RF balloon-based, single-shot ablation technology

LISBON, Portugal and MARLBOROUGH, Mass., March 17, 2019 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announced data from the AF-FICIENT I study during a late-breaking clinical trial session today at EHRA 2019, the annual congress of the European Heart Rhythm Association in Lisbon, Portugal. The data demonstrated positive safety and efficacy results with the LUMINIZE™ Radiofrequency (RF) Balloon Catheter for isolation of pulmonary veins (PV) when treating patients with atrial fibrillation (AF).

Patients with arrhythmias such as AF are often treated with anti-arrhythmic drugs as well as cardiac ablation. The LUMINIZE RF Balloon Catheter uses RF energy – the most common energy source for cardiac ablation procedures – to isolate the areas of the heart muscle responsible for the abnormal heart rhythm. The single-shot catheter also features built-in digital cameras for visual guidance, sensing electrodes on the balloon to assess real-time vein isolation and customizable ablation electrodes with the ability to deliver tailored levels of energy around the circumference of the balloon.

The global AF-FICIENT I study examined acute procedural success and safety for the single-shot LUMINIZE RF Balloon Catheter in two phases. Phase one tested the original design of the device and phase two included changes to enhance maneuverability and add dedicated pacing and sensing electrodes. Phase one study data showed PV isolation was achieved in 88.9% of veins. In phase two, with the enhanced steering capability and electrodes activated, PV isolation increased to 99.4% of veins. Additionally, the median time the balloon was in the left atrium – known as balloon dwell time – decreased from 92 minutes in phase one to 29 minutes in phase two, bringing the total procedure time down to a median 71 minutes.

"The study assessed the safety and effectiveness of isolating PVs through the combined benefits of RF and balloon-based ablation, both of which are found in the LUMINIZE RF Balloon Catheter," said Amin Al-Ahmad, M.D., principal investigator and cardiac electrophysiologist at Texas Cardiac Arrhythmia in Austin, Texas. "The data underscore the potential for this catheter to improve procedural efficacy and patient outcomes."

The prospective, non-randomized, multi-center study enrolled 100 patients with symptoms of paroxysmal – or intermittent – AF. Confirmation of PV isolation was completed with the RF balloon sensing electrodes, a circular mapping catheter, or both. There were no device-related serious adverse events in either phase of the trial, 30 days after the completion of the procedures.

"We are pleased with the data presented today as it highlights the potential benefits of the LUMINIZE RF Balloon Catheter," said Kenneth Stein, M.D., senior vice president and chief medical officer, Rhythm Management and Global Health Policy, Boston Scientific. "By providing real-time visualization both before and during ablation and individualized control of electrode energy levels, this technology may allow physicians to swiftly and accurately isolate veins and decrease procedure times."

Boston Scientific offers innovative EP products and services for the diagnosis and management of cardiac rhythm disorders. The company continues to expand its EP offerings through internal investments and acquisitions, including the purchase of a single-shot cryoablation platform for the treatment of AF. The addition of the cryoballoon platform will position the company as the first to have both cryothermal and RF single-shot, balloon-based ablation therapies in its portfolio.

The LUMINIZE RF Balloon Catheter and the cryoballoon platform are in development, pending CE Mark and are not available for use or sale.

For more information on all product offerings within the Boston Scientific electrophysiology portfolio, 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 40 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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