

First Patient Treated In The Boston Scientific ZERO AF Clinical Trial To Evaluate The Safety And Performance Of The Blazer® Open-Irrigated Temperature Ablation Catheter

NATICK, Mass., Jan. 16, 2013 [PRNewswire/](#) -- The first patient has been treated in the Boston Scientific Corporation (NYSE: BSX) ZERO AF clinical trial to evaluate the safety and effectiveness of the Blazer® Open-Irrigated Temperature Ablation Catheter in patients with symptomatic, drug refractory paroxysmal atrial fibrillation. This international, multi-center study will include up to 33 sites in the United States, Europe and Asia-Pacific, and as many as 472 patients. The results of the ZERO AF trial are expected to be used to support a U.S. Food and Drug Administration regulatory submission for a paroxysmal atrial fibrillation indication.

Atrial fibrillation is a disorder that disrupts the ability of the heart to beat regularly and pump blood efficiently. It affects approximately 15 million people worldwide and can lead to complications such as stroke or heart failure. Paroxysmal atrial fibrillation is a type of atrial fibrillation in which the irregular heartbeat starts up very quickly, stops spontaneously and abruptly returns to the normal rhythm resulting in patients feeling symptomatic. Catheter ablation, a procedure in which localized electrical energy is delivered into the heart tissue aimed at restoring the continuous normal rhythm, is a common treatment for many heart rhythm disorders including paroxysmal atrial fibrillation.

The Blazer Open-Irrigated Catheter is the latest addition to the extended families of Boston Scientific Blazer catheters. It is the company's first entry into the open-irrigated catheter segment and is approved for use in CE Mark countries and Canada. The Blazer Open-Irrigated Catheter offers the Total Tip Cooling™ design, engineered to consistently cool the entire tip of the electrode during radiofrequency energy delivery.

"The Blazer Open-Irrigated Catheter combines an advanced tip design for irrigated ablation with the reliability of the proven Blazer platform," said Andrea Natale, M.D., executive medical director and principal investigator, Cardiac Electrophysiology, Texas Cardiac Arrhythmia in Austin, Texas.

The first U.S. procedure was performed at St. David's Medical Center in Austin by J. David Burkhardt, M.D., also part of Texas Cardiac Arrhythmia. "As expected, the Blazer Open-Irrigated catheter handled well, consistent with my previous experience using other Boston Scientific Blazer catheters," said Dr. Burkhardt.

"This initiative exemplifies our new mission statement: Boston Scientific is dedicated to transforming lives through innovative medical solutions that improve the health of patients around the world," said Joe Fitzgerald, president of the Cardiac Rhythm Management business at Boston Scientific. "Launching this trial highlights our continued commitment to clinicians and patients through the expansion of our Electrophysiology ablation business including the high-growth segment of complex ablations."

Electrophysiology is a 2.5 billion dollar market growing at a double-digit pace and represents a key growth area for Boston Scientific. In the United States, the Blazer Open-Irrigated Catheter is an investigational device and is not available for 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 30 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 us at www.bostonscientific.com.

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 markets for our products, our business plans, regulatory approvals, clinical trials, product performance and competitive offerings. 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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