Boston Scientific

Boston Scientific Receives U.S. FDA Approval For Blazer™ Open-Irrigated Catheter

FDA approval granted on the heels of CE Mark for the IntellaTip MiFi™ open-irrigated catheter

MARLBOROUGH, Mass., March 10, 2016 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the Blazer™ Open-Irrigated (OI) radiofrequency ablation catheter. The Blazer OI catheter has been approved to treat Type I atrial flutter, an abnormal rhythm of the upper chambers of the heart. The approval of the Blazer OI catheter marks the first time Boston Scientific will offer an open-irrigated catheter to the U.S. market.

The Blazer OI catheter is designed for use in ablation procedures to restore a normal heart rhythm for patients in atrial flutter. During the procedure, localized electrical energy is delivered through an electrode on the tip of a catheter into the heart muscle, creating heat to destroy a small area of the tissue responsible for the abnormal heart rhythm. The newly-approved Blazer OI catheter features Total Tip Cooling™ technology intended to cool the catheter tip consistently during the ablation procedure, improving the quality of the ablation lesion.

The Blazer OI catheter was granted approval based on data from the BLOCk-CTI clinical trial, a prospective, randomized trial that enrolled 302 patients at 24 sites in the U.S. and evaluated the safety and effectiveness of the Blazer OI catheter in patients with sustained or recurrent Type 1 atrial flutter.

"Successful results from the BLOCk-CTI trial demonstrate that the Blazer open-irrigated catheter is safe and effective for the ablation of atrial flutter," said Tom McElderry, M.D., principal investigator, associate professor and section chief of electrophysiology at the University of Alabama at Birmingham. "This newly approved ablation tool was built on the proven Blazer platform of therapeutic catheters and facilitates excellent maneuverability, consistent cooling and stability during procedures."

In January, the company also received CE Mark for the IntellaTip MiFi™ open-irrigated (OI) catheter for use in all cardiac ablation procedures. The IntellaTip MiFi OI catheter is designed to provide physicians precise, multidimensional information via mini-electrodes which deliver a highly localized signal reflecting exactly what is happening at the tip of the catheter in real-time during the ablation procedure. The IntellaTip MiFi OI catheter also features the same Total Tip Cooling technology as the Blazer OI catheter.

"These approvals attest to our continued focus and expansion in the electrophysiology space," said Kenneth Stein, M.D., Chief Medical Officer, Cardiac Rhythm Management. "The Blazer and IntellaTip MiFi open-irrigated catheters provide electrophysiologists with technology that leverages our established platforms to help improve the health of patients around the world."

In the U.S., the IntellaTip Mifi OI catheter 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 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 regulatory approvals. 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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