Boston Scientific

Boston Scientific Receives FDA Approval And CE Mark For AngioJet™ ZelanteDVT™ Thrombectomy Catheter

Catheter used to treat deep vein thrombosis to be commercialized in U.S. and Europe

MARLBOROUGH, Mass., Nov. 30, 2015 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has received United States (U.S.) Food and Drug Administration (FDA) approval and CE Mark for the AngioJet™ ZelanteDVT™ thrombectomy catheter to treat deep vein thrombosis (DVT) in large-diameter upper and lower limb peripheral veins.

The ZelanteDVT catheter is the first AngioJet catheter designed specifically to treat DVT, a challenging condition that may affect up to 2.5 million people in the U.S. and Europe annually, with a majority of cases occurring during or soon after a hospitalization[1, 2]. Offering four times the thrombus removal power of current market-leading AngioJet catheters, the ZelanteDVT catheter was designed to efficiently remove large venous clot burdens and facilitate rapid restoration of blood flow, potentially decreasing procedural time, quickly relieving symptoms and reducing late complications.

"There has been a clinical need for a stronger thrombectomy catheter to support treatment modalities in addressing challenging cases of deep vein thrombosis," said Mitchell Silver, DO, FACC, Riverside Hospital in Columbus, Ohio. "The unique features of the ZelanteDVT catheter make it well-suited to treat a wide range of thrombotic occlusions thus potentially decreasing bleeding risks and reducing patients' need for intensive care stays."

DVT occurs when a blood clot (or "thrombus") forms in one or more of the deep veins, most often in the legs. Left untreated, DVT can lead to serious and even life-threatening complications. The most serious complication of DVT can occur if part of the clot breaks off and travels through the bloodstream to the lungs, causing a life-threatening blockage called pulmonary embolism (PE). If the clot is not removed, it can also cause permanent damage to the valves in the affected veins, a condition known as post-thrombotic syndrome (PTS). Up to half of all patients with DVT will develop PTS within two years of their diagnosis, causing permanent pain, discomfort and swelling of the affected limb that may require frequent hospital visits[3]. Early diagnosis and rapid restoration of blood flow may help decrease the risk of these serious complications and reduce the need for future hospitalizations.

"The new features of the ZelanteDVT catheter represent our focus on improving procedural efficiencies and reducing the economic burden associated with this challenging condition," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "With this addition to our AngioJet portfolio, we are further evolving the current suite of life-changing therapeutic options available to physicians and their patients with deep vein thrombosis."

About the ZelanteDVT Thrombectomy Set
The ZelanteDVT Thrombectomy Set is intended for use with the AngioJet Ultra Console to break apart and remove thrombus, including DVT, from iliofemoral and lower extremity veins greater than or equal to 6.0 mm in diameter, and upper extremity peripheral veins greater than or equal to 6.0 mm in diameter. It is also intended for use with the AngioJet Power Pulse™ technique for the controlled and selective infusion of physician specified fluids, including thrombolytic agents, into the peripheral vascular system.

View or download an image of the ZelanteDVT Thrombectomy Set.

About Deep Vein Thrombosis
Deep vein thrombosis (DVT) occurs when a blood clot (or "thrombus") forms in one or more of the deep veins. DVTs can occur anywhere – most often in the legs. Those at the highest risk of developing DVT are older in age, overweight and inactive. Common symptoms of DVT include swelling, pain, tenderness, warm skin and/or discoloration in the affected leg, leg fatigue as well as surface veins can become more visible. Sometimes, no noticeable symptoms occur. The most serious complication of DVT can occur if part of the clot breaks off and travels through the bloodstream to the lungs, causing a blockage called pulmonary embolism (PE). If the clot is large, it can stop blood from reaching the lungs and can be fatal. To treat DVT, doctors may prescribe medications such as blood thinners; or they may perform interventional procedures to remove or break up a clot, place a filter to capture a clot, or other surgical approaches for clot removal.

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 regulatory approvals, markets for our products, 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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References:

[1] Gerotziafas GT, et al. Prophylaxis of Venous Thromboembolism in Medical Patients. *Curr Opin Pulm Med*. 2004; 10:356-365.

[2] Cohen AT, et al. Venous Thromboembolism (VTE) in Europe. The Number of VTE Events and Associated Morbidity and Mortality. *Thromb Haemost*. 2007 Oct;98(4): 756-64.

[3] Kahn, SR, et al. Determinants and Time Course of the Postthrombotic Syndrome after Acute Deep Venous Thrombosis. *Ann Intern Med*. 2008; 149(10): 698-707.

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