Boston Scientific

Boston Scientific Receives U.S. FDA Approval for The VICI VENOUS STENT™ System

New Stent System Now Available for Treating Patients with Deep Venous Blockages

MARLBOROUGH, Mass., May 6, 2019 /PRNewswire/ -- Boston Scientific (NYSE: BSX) announced today that the U.S Food and Drug Administration (FDA) has approved the VICI VENOUS STENT™ System for the treatment of iliofemoral venous obstructive disease, which occurs when the flow of blood through the veins located deep in the pelvic region becomes blocked by a blood clot or compressed by anatomical anomalies.

Experience the interactive Multichannel News Release here: https://www.multivu.com/players/English/8475751-boston-scientific-vici-venous-stent-system-fda-approval/

Venous obstructive disease affects nearly 40 percent of the population in the U.S. and can be caused by conditions such as deep vein thrombosis (DVT), post-thrombotic syndrome (PTS) and compressive diseases such as May-Thurner syndrome. In patients with venous obstructions, blood may pool in the legs, resulting in pain, swelling and skin ulcers.

Endovascular treatment for venous obstructive disease is focused on restoring the normal flow of blood from the legs back to the heart. The iliofemoral veins are located deep in the pelvis and may be subject to significant crushing forces from other anatomical structures such as the right common iliac artery. To help solve for this, the VICI stent system was specifically designed to be uniformly strong and crush resistant, capable of restoring blood flow by creating a cylindrical, patent vessel.

"For those suffering from venous obstructive disease, their quality of life may suffer without treatment options optimized for the disease," said Dr. Mahmood Razavi, St. Joseph Hospital, Orange, California. "With the approval of the VICI stent, clinicians now have access to a stent that was purposely developed and engineered to resist the vessel compression and anatomical tortuosity commonly found within the iliofemoral venous system, enabling our ability to deliver best outcomes for our patients."

The approval of the VICI stent was based on data from the VIRTUS study, a prospective, multi-center, single-arm study with 170 patients. The VIRTUS study evaluated the VICI stent in relation to pre-defined objective performance goals in patients with a clinically significant obstruction in the illiofemoral venous outflow tract. It successfully met its primary safety and effectiveness endpoints.

"The FDA approval of the VICI venous stent system is the latest example of our commitment to building the most comprehensive portfolio of technologies specifically developed to meet the needs of physicians treating both chronic and acute venous disease," said Jeff Mirviss, senior vice president and president, Peripheral Interventions, Boston Scientific. "We are pleased to provide this differentiated stent system to U.S. patients suffering from debilitating deep venous disease."

The VICI stent system received CE Mark in 2013. The device was developed by VENITI Inc., which Boston Scientific acquired in August of 2018.

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 clinical outcomes, product launches, 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; the closing and integration of acquisitions; 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.

CONTACTS

Timette Nevala
Media Relations
(763) 494-1284 (Office)
Timette.Nevala@bsci.com

Susie Lisa, CFA
Investor Relations
(508) 683-5565 (office)
BSXInvestorRelations@bsci.com

SOURCE Boston Scientific
