Boston Scientific

VICI VENOUS STENT® System Demonstrates Positive Clinical Outcomes in Patients with Deep Venous Blockages

Results from the VIRTUS Study Show Venous Stent Met Its Primary Effectiveness and Safety Endpoints in Re-establishing Blood Flow at Twelve Months

LEIPZIG, Germany and MARLBOROUGH, Mass., Jan. 22, 2019 /PRNewswire/ -- Today, Boston Scientific (NYSE: BSX) announced positive 12-month data demonstrating that patients who were treated with the VICI VENOUS STENT® System for iliac and femoral vein obstructions exhibited a high rate of patent, or open, target lesions. Primary safety and efficacy results from the VIRTUS trial were presented as a first-time data release at the Leipzig Interventional Course, (LINC), in Leipzig, Germany.

The VIRTUS trial evaluated the VICI stent in patients with clinically significant obstructions in the illiofemoral venous outflow tract resulting from Post Thrombotic Syndrome (PTS) or compressive diseases such as May-Thurner syndrome. These conditions impact the veins located deep in the pelvis and if left untreated, can impair blood flow back to the heart and cause blood to pool in the legs, resulting in pain, swelling and ulceration.

In the VIRTUS trial, the VICI stent met its primary effectiveness endpoint with a primary patency rate of 84.0 percent at 12-months, which was greater than the pre-defined performance goal (PGE) of 72.1 percent (p-value=<0.0001). Nearly all the patients treated with the VICI stent, 98.8 percent, were free from major adverse events at 30 days post-procedure, thus surpassing the pre-defined safety performance goal (PGS) of 94 percent.

"In treating patients with venous obstruction, the primary goal is to restore and maintain vessel patency to ensure the return of blood flow to the heart," said Dr. Mahmood Razavi, Director, Department of Clinical Trials, St. Joseph Heart and Vascular Center, Orange, California and principal investigator of the VIRTUS trial. "In these results, the VICI stent demonstrated excellent performance outcomes in a difficult-to-treat patient population, which translates to improvement of long-term symptoms and enhanced quality of life in these patients."

"Physicians who select endovascular treatment options for their patients with venous disease are not only faced with challenging disease-states but must also account for the unique anatomical presentation of these deep veins that are subject to chronic obstruction and compression," said Ian Meredith, M.D., executive vice president and global chief medical officer, Boston Scientific. "The results from the VIRTUS trial demonstrate the importance of having a therapeutic option that is specifically designed for venous application, thus helping patients avoid recurrent pain, swelling and other debilitating aspects of acute and chronic venous disease."

The VIRTUS IDE trial, submitted in June of 2018, is a prospective, multi-center, single-arm, non-randomized study that included 170 patients with chronic disease; 75 percent of whom were diagnosed as having post-thrombotic lesions and the remaining 25 percent were diagnosed with non-thrombotic lesions (i.e., May-Thurner syndrome).

The VICI stent system was approved for use in Europe and other geographies that recognize CE Mark in 2013. In the U.S., the VICI stent system is an investigational device and is not available for sale. 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 over 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 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.

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