New Data Continue to Show Significant and Sustained Blood Pressure Reduction With Boston Scientific Vessix™ Renal Denervation System [EN]

REDUCE-HTN Data Presented Today at TCT Demonstrate Excellent Safety Profile

Patients treated with the Boston Scientific (NYSE: BSX) Vessix™ Renal Denervation System experienced a significant and sustained reduction in blood pressure, according to new data presented today at the Transcatheter Cardiovascular Therapeutics (TCT) Conference in San Francisco. An interim analysis of 139 patients enrolled in the REDUCE-HTN post market study affirms the device safety profile and effective treatment for resistant hypertension.

"In the REDUCE-HTN study, 85 percent of patients treated with the Vessix System experienced a clinically-meaningful decrease in blood pressure," said Professor Horst Sievert, M.D., Ph.D., director of the CardioVascular Center Frankfurt, Sankt Katharinen Hospital in Frankfurt, Germany, and principal investigator in the REDUCE-HTN clinical program. "In my opinion, the large patient cohort and rigorous analysis of the study suggest that renal denervation using bipolar technology will be an important part of the treatment algorithm for a wide variety of patients with resistant hypertension."

Renal denervation with the Vessix System is a minimally-invasive procedure in which a balloon catheter is fed through the arterial vascular system and positioned in the renal arteries, the major blood vessels that lead to the kidneys. The physician then delivers low-power radiofrequency (RF) energy to disrupt the nerves surrounding the renal arteries in which hyperactivity contributes to uncontrolled high blood pressure. The Boston Scientific Vessix System is the only renal denervation system to utilize bipolar energy to disrupt these nerves, providing a more localized and precise approach.

The REDUCE-HTN post market study enrolled 146 patients at 23 centers in Europe, Australia and New Zealand and is evaluating the ability of the Vessix System to reduce blood pressure at six months compared to the pre-treatment baseline blood pressure. Patients enrolled in the program are required to have a systolic blood pressure of at least 160 mmHg despite taking three or more antihypertensive medications.

Interim data highlights of the study include:

- A significant 24.6 mmHg reduction in systolic blood pressure ($p<.0001$) at six months
- A sustained 29.6 mmHg reduction in systolic blood pressure in the subset of patients for whom 12-month data are available
- A clinically-meaningful decrease in office systolic blood pressure at both six and 12 months in 85-percent of patients in the trial
- Success reducing blood pressure in a variety of subgroups, including both men and women, patients with Type-2 diabetes and patients age of 65 or older
- A strong safety profile with no occurrence of prespecified acute safety events and eight procedure-related serious adverse events (5.5 percent) among the 146 patients
- A wide range of anatomies were treated, including accessory renal arteries

"Despite the broad availability of antihypertensive medications, high blood pressure, which puts millions of people at increased risk for major cardiovascular events including heart attack and stroke, remains a silent killer," said Jeff Mirviss, president, Peripheral Interventions, Boston Scientific. "REDUCE-HTN provides the most robust dataset on multi-electrode renal denervation to date and adds to the growing body of clinical evidence supporting the use of bipolar energy delivery in treating patients with resistant hypertension. We look forward to initiating the Vessix Global Clinical Program and bringing this promising technology to more patients worldwide."

The Vessix System is a highly-differentiated and advanced renal denervation system that features an intuitive push-button interface, a short 30-second treatment time and an over-the-wire, balloon-based approach familiar to most cardiac and vascular specialists. The Vessix System has both CE Mark and TGA approval and is currently available for sale in Europe, the Middle East, Australia, New Zealand and select markets in Asia. The Vessix System is an investigational device and not available for sale in the United States.

About the Vessix Global Clinical Program
Boston Scientific collaborates with researchers, physicians and hospital systems worldwide to advance the science of cardiovascular medicine. A key component of that commitment is the Vessix Global Clinical Program, which includes both the REDUCE-HTN and RELIEVE Clinical Series. The REDUCE-HTN Clinical Series plans to enroll more than 1,200 resistant

hypertension patients worldwide and already includes the largest cohort of patients studied following treatment with a multi-electrode renal denervation system. The RELIEVE Clinical Series includes pre-clinical, clinical and investigator initiated research evaluating the Vessix System technology in additional disease states including end-stage renal disease, heart failure, atrial fibrillation and diabetes.

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, 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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https://news.bostonscientific.eu/2013-10-28-New-Data-Continue-to-Show-Significant-and-Sustained-Blood-Pressure-Reduction-With-Boston-Scientific-Vessix-TM-Renal-Denervation-System-EN