Boston Scientific Lotus™ Valve System demonstrates strong performance and safety profile at six months

These and Other Studies Reinforce Global Commitment to the Development of Innovative Therapies to Improve Care for Patients with Cardiovascular Disease

Reinforcing its position as a global leader in bringing new therapies to patients with heart and cardiovascular disease, Boston Scientific Corporation (NYSE: BSX) reported favorable results in studies related to cardiac resynchronization therapy (CRT), platinum chromium stent platforms and transcatheter aortic valve replacement (TAVR).

The company presented new data on nearly a dozen cardiology-related clinical trials at the American College of Cardiology's (ACC) 63rd Annual Scientific Session, which took place March 29 – 31 in Washington, D.C.

Patients with mild heart failure have lower mortality rates with CRT defibrillators
In the longest follow-up of CRT for patients with mild heart failure to date, Boston Scientific announced significant findings from the continued analysis of the landmark MADIT-CRT study, demonstrating a significant and sustained survival benefit in the indicated population. The long-term results, presented by Dr. Ilan Goldenberg, director of the department of cardiology at Leviev Heart Center, Sheba Medical Center, Tel Hashomer, Israel, demonstrated a 41 percent relative reduction in the risk of death in patients who received a Boston Scientific defibrillator with CRT compared to patients who received a defibrillator alone. In addition to the mortality benefit, the results demonstrate that these patients experienced a 62 percent relative reduction in the risk of experiencing a first heart failure event when compared to patients who didn't receive CRT therapy.

The MADIT-CRT trial compares ICD to CRT-D therapy in patients with mild heart failure. In this global multicenter study of 1,691 patients, more than 80 percent of patients who received CRT therapy were still alive at seven years. Boston Scientific has responded to longer patient survival by developing CRT defibrillators (CRT-D) with the greatest projected battery longevity in the industry, of up to eight years. The longer lasting CRT-D devices from Boston Scientific may reduce the need for additional device implants in patients with heart failure, and could ultimately reduce health care costs.

"Patients and their physicians should be encouraged by the low mortality rate for heart failure patients receiving CRT-D therapy," said Kenneth Stein, M.D., chief medical officer, Rhythm Management, Boston Scientific. "The life expectancy of this patient population emphasizes the need for the Boston Scientific longer lasting battery technology, which can minimize the requirement for additional device implants, reducing risks to patients and thus reducing costs for the global health care system."

Boston Scientific platinum chromium coronary stent platform demonstrates low event rates through four years
Demonstrating design leadership in drug eluting stent (DES) technology, Boston Scientific released new data that continue to reinforce the advantages of platinum chromium stents. Data from the PLATINUM Workhorse clinical trial were presented by Dean Kereiakes, M.D., F.A.C.C., The Christ Hospital Heart and Vascular Center, Cincinnati, Ohio. The trial compared the safety and effectiveness of the Boston Scientific Platinum Chromium Everolimus-Eluting Stent System (PtCr EES) to the Abbott Laboratories Cobalt Chromium Everolimus-Eluting Stent System (CoCr EES). The results show low event rates out to four years with PtCr EES confirming excellent long-term performance. At four years, the PtCr EES also continued to demonstrate advantages over the CoCr EES.

Key findings from the study include the following:

- The PtCr EES had a 23 percent lower four-year target lesion revascularization (TLR) than the CoCr EES (4.6 percent to 5.9 percent; p=0.24). This is the lowest TLR rate in any pivotal U.S. Food and Drug Administration (FDA) trial for a DES at four years.

- Both the PtCr EES and CoCr EES demonstrated low rates of ARC definite/probable stent thrombosis of 0.7 percent out to four years.

- Trial results also confirmed a previously reported significant reduction in unplanned (bail-out or emergency) stenting with the PtCr EES compared to the CoCr EES (5.9 percent vs. 9.8 percent, p=0.004), including a significantly lower rate of inadequate lesion coverage (1.4 percent vs. 3.4 percent, p=0.01).

These clinical observations reinforce the results of comparative bench and pre-clinical studies, which have demonstrated the enhanced visibility and deliverability of the PtCr EES relative to the CoCr EES. The reduction in bail-out stenting has also been tied to cost savings per procedure.

"The questions of whether stent metal alloy composition and platform design affect late clinical outcomes are very important," said Dr. Kereiakes. "The data suggest that the greater flexibility and conformability of the platinum chromium platform, as reflected by less vessel straightening and increased fracture resistance when compared with the cobalt chromium platform, translate into exceptional long-term clinical outcomes."

The Promus PREMIER™ Everolimus-Eluting Platinum Chromium Coronary Stent System was recently approved by the FDA. The principal safety and effectiveness data for the Promus PREMIER Stent System are derived from the global PLATINUM Clinical Trial Program, a series of clinical trials conducted on the PROMUS Element™ Stent System, and the NG PROMUS Clinical Trial. The Promus PREMIER Stent System, with its enhanced stent delivery system, offers physicians improved performance in treating patients with coronary artery disease.

Boston Scientific Lotus™ Valve System demonstrates strong performance
The Boston Scientific Lotus™ Valve System advanced TAVR technology continued to demonstrate impressive performance at three months, according to new data presented at ACC 2014.

The REPRISE II clinical trial, evaluating the Lotus™ Valve System in symptomatic patients with severe aortic valve stenosis considered at high risk for surgical valve replacement, demonstrated favorable safety and efficacy outcomes out to three months with 85 percent of patients having no paravalvular aortic regurgitation. The data were presented by Professor Ian Meredith, director of MonashHeart at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE II trial. REPRISE II is an ongoing prospective, single-arm study that has enrolled 120 patients at 14 sites in Australia, France, Germany and the U.K. An additional 130 patients will be enrolled in an extension of REPRISE II at 16 sites in Australia and Europe, and enrollment in this extension of REPRISE II is expected to be complete in April 2014.

Key findings from the study include the following:

- At 90 days, an impressive 85.4 percent of patients had no paravalvular aortic regurgitation by independent core lab assessment. In addition, no cases of severe paravalvular aortic regurgitation occurred in any patient at 90 days. There were two cases of moderate paravalvular aortic regurgitation (2.1 percent) and in 12.5 percent of patients, paravalvular regurgitation was considered mild.

- The primary device performance endpoint of 30-day mean aortic valve pressure gradient, as assessed by an independent core laboratory, was met as the 30-day mean aortic valve pressure gradient of 11.5±5.2 mm Hg was significantly ($P<0.001$) less than the performance goal of 18 mm Hg. At 90 days, the mean aortic valve pressure gradient remained low and stable at 11.5±5.4 mm Hg.

- All-cause mortality at 90 days was 5 percent.

- No instances of non-study valve implantation, unplanned use of cardiopulmonary bypass, valve embolization, valve-in-valve or ectopic valve placement occurred.

- The disabling stroke rate at 90 days was 2.5 percent.

One-year results from REPRISE I, a prospective, single-arm feasibility study of patients with severe symptomatic aortic stenosis conducted in Australia, were presented in May of 2013 at EuroPCR by Professor Meredith and published online ahead of print by EuroIntervention. The data demonstrated sustained safety and performance of the Lotus™ Valve System out to one year with no moderate or severe paravalvular aortic regurgitation in any patient.

About the Lotus™ Valve System
The Lotus™ Valve System is a differentiated second-generation TAVR technology, consisting of a pre-loaded, stent-mounted tissue valve prosthesis and catheter delivery system for guidance and percutaneous placement of the valve. The low-profile delivery system and introducer sheath are designed to enable predictable and precise placement, as well as bi-directional atraumatic repositioning and retrieval at any time prior to release of the aortic valve implant. The device also employs a unique Adaptive Seal™ feature designed to minimize the incidence of paravalvular regurgitation, which has proven to be a predictor of mortality. The Lotus™ Valve System has CE Mark approval and is available for sale in CE Mark countries. In the U.S., the Lotus™ Valve System is an investigational device and not available for sale.

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.

The Boston Scientific Lotus™ Valve System advanced TAVR technology continued to demonstrate impressive performance at three months, according to new data presented at ACC 2014.

The REPRISE II clinical trial, evaluating the Lotus™ Valve System in symptomatic patients with severe aortic valve stenosis considered at high risk for surgical valve replacement, demonstrated favorable safety and efficacy outcomes out to three months with 85 percent of patients having no paravalvular aortic regurgitation. The data were presented by Professor Ian Meredith, director of MonashHeart at Monash Medical Centre in Melbourne, Australia, and principal investigator of the REPRISE II trial.

REPRISE II is an ongoing prospective, single-arm study that has enrolled 120 patients at 14 sites in Australia, France, Germany and the U.K. An additional 130 patients will be enrolled in an extension of REPRISE II at 16 sites in Australia and Europe, and enrollment in this extension of REPRISE II is expected to be complete in April 2014.

Key findings from the study include the following:

- At 90 days, an impressive 85.4 percent of patients had no paravalvular aortic regurgitation by independent core lab assessment. In addition, no cases of severe paravalvular aortic regurgitation occurred in any patient at 90 days. There were two cases of moderate paravalvular aortic regurgitation (2.1 percent) and in 12.5 percent of patients, paravalvular regurgitation was considered mild.

- The primary device performance endpoint of 30-day mean aortic valve pressure gradient, as assessed by an independent core laboratory, was met as the 30-day mean aortic valve pressure gradient of 11.5±5.2 mm Hg was significantly ($P<0.001$) less than the performance goal of 18 mm Hg. At 90 days, the mean aortic valve pressure gradient remained low and stable at 11.5±5.4 mm Hg.

- All-cause mortality at 90 days was 5 percent.

- No instances of non-study valve implantation, unplanned use of cardiopulmonary bypass, valve embolization, valve-in-valve or ectopic valve placement occurred.

- The disabling stroke rate at 90 days was 2.5 percent.

One-year results from REPRISE I, a prospective, single-arm feasibility study of patients with severe symptomatic aortic stenosis conducted in Australia, were presented in May of 2013 at EuroPCR by Professor Meredith and published online ahead of print by EuroIntervention. The data demonstrated sustained safety and performance of the Lotus™ Valve System out to one year with no moderate or severe paravalvular aortic regurgitation in any patient.

About the Lotus™ Valve System
The Lotus™ Valve System is a differentiated second-generation TAVR technology, consisting of a pre-loaded, stent-mounted tissue valve prosthesis and catheter delivery system for guidance and percutaneous placement of the valve. The low-profile delivery system and introducer sheath are designed to enable predictable and precise placement, as well as bi-directional atraumatic repositioning and retrieval at any time prior to release of the aortic valve implant. The device also employs a unique Adaptive Seal™ feature designed to minimize the incidence of paravalvular regurgitation, which has proven to be a predictor of mortality. The Lotus™ Valve System has CE Mark approval and is available for sale in CE Mark countries. In the U.S., the Lotus™ Valve System is an investigational device and 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 30 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.comand 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 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.

ATTENZIONE: In alcuni paesi europei (Belgio, Bulgaria, Cipro, Estonia, Francia, Grecia, Irlanda, Italia, Lituania, Lussemburgo, Malta, Polonia, Paesi Bassi, Portogallo, Romania, Slovacchia, Slovenia, Spagna e Ungheria), la pubblicità di dispositivi medici presso il pubblico non è consentita. Pertanto, se stai visitando questo sito da uno dei paesi elencati e non sei un operatore sanitario, devi abbandonarlo immediatamente, poiché le informazioni visualizzate potrebbero non essere consentite dalla legge del tuo paese di residenza. Se ignori questo avviso, Boston Scientific declinerà ogni responsabilità che deriva dall'accesso alle informazioni contenute.

---

https://news.bostonscientific.eu/2014-04-01-Boston-Scientific-Lotus-TM-Valve-System-demonstrates-strong-performance-and-safety-profile-at-six-months