First enrolment in EWOLUTION registry to collect real world clinical outcomes for Boston Scientific WATCHMAN™ Left Atrial Appendage closure technology

Boston Scientific Corporation (NYSE:BSX) today announced the first German patient enrolment in the EWOLUTION REgistry on WATCHMAN Outcomes in Real-Life Utilization, a prospective multicentre registry sponsored by the Company's Structural Heart group. The first patient was enrolled by Professor Martin. W. Bergmann from the St. George Hospital in Hamburg, Germany.

The EWOLUTION Registry is a multi-national post market data collection on procedural success, incidence of stroke and mortality of patients implanted with a WATCHMAN™ device. The overall objective of the registry, that will enrol approximately 1.000 patients across 50 centres in 16 countries, is to compile real-world clinical outcomes data and real-world usage data for the WATCHMAN™ device.

"It is a great pleasure to announce that the first German patients of the EWOLUTION Registry on interventional LAA closure (LAAC) in Atrial Fibrillation (AF) patients have been enrolled," said Professor Martin W. Bergmann, St. George Hospital, Hamburg, Germany, and EWOLUTION Registry co-Principal Investigator. "Randomized clinical trials like PROTECT AF, ASAP and PREVAIL have shown the efficacy and safety of LAAC device therapy for stroke risk reduction in non-valvular AF patients. Recent data suggest that the therapy can achieve even better results than the previous gold standard, namely oral anticoagulation with Marcumar."

Currently, the WATCHMAN™ LAA Closure Device is used in Europe to prevent thrombus embolization from the LAA and reduce the risk of life-threatening bleeding events in patients with non-valvular AF who are eligible for anticoagulation therapy or who have a contraindication to anticoagulation therapy. Recently published data from the ALSTER registry summarizing the outcome of 60 patients treated in Hamburg have been able to confirm the positive results in everyday practice.

"The EWOLUTION Registry is the largest registry ever done in the field of LAAC therapy and will provide us with invaluable insights into patient selection and therapeutic strategies in daily practice," said Professor Bergmann.

"The WATCHMAN device is already supported by the largest amount of randomized clinical trial data of any device technology for the prevention of stroke in high risk patients with atrial fibrillation," said Dr Kenneth Stein, Senior VP, Chief Medical Officer Cardiac Rhythm Management at Boston Scientific. "The EWOLUTION Registry will complement that data with an impressive amount of additional information on the real world outcomes of patients being treated with the WATCHMAN device. Studies like EWOLUTION demonstrate our commitment to continue to lead the field by investing in the clinical science necessary to prove the value of our innovative new technologies."

Boston Scientific expects to present preliminary first data from the EWOLUTION Registry by 2015.

The WATCHMAN™ Left Atrial Appendage Closure Device received CE Mark approval in Europe in 2005.

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 new product launches and launch cadence, regulatory approvals, 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/2013-10-30-First-enrolment-in-EWOLUTION-registry-to-collect-real-world-clinical-outcomes-for-Boston-Scientific-WATCHMAN-TM-Left-Atrial-Appendage-closure-technology