Boston Scientific

Solyx™ Single-Incision Sling System Demonstrates Treatment Success, Meeting All Endpoints, in Three-Year Study of Women with Stress Urinary Incontinence

Data Support Minimally Invasive Single-Incision Mesh Procedure as a Durable, Safe and Effective Treatment for Stress Urinary Incontinence, a Condition that Affects 18 Million American Adults

CHICAGO and MARLBOROUGH, Mass., Oct. 10, 2018 -- Boston Scientific Corporation (NYSE: BSX) today announced that its Solyx™ Single Incision Sling (SIS) System achieved treatment success, meeting all primary and secondary endpoints in a three-year study of 281 women with stress urinary incontinence (SUI). The trial also demonstrated that the Solyx SIS System was non-inferior to the gold-standard transobturator mid-urethral sling (TMUS) procedure for the long-term successful treatment of these patients.

The full study results, which include durable efficacy and safety data for the Solyx SIS System, will be presented on October 11 at 4:10 pm CT during a late-breaking clinical trial session at Pelvic Floor Disorders Week, the annual scientific symposium of the American Urogynecologic Society.

SUI – also known as bladder leakage – is the involuntary loss of urine during physical activity, such as coughing, laughing or lifting. The condition occurs when the muscles that support the bladder and regulate the release of urine, weaken. SUI affects 18 million adults in the U.S., 85% of them women. One in two women aged 65 and over report urinary incontinence symptoms, which can have a significant impact on their daily lives.

“These findings provide a high degree of evidence supporting the safety and effectiveness of the Solyx SIS System, as compared to transobturator mid-urethral sling (TMUS) procedures, and reinforce the use of a minimally invasive procedure for SUI,” said Amanda B. White, MD, principal investigator, University of Texas Dell Medical School. “The results have the potential to impact millions of women with SUI by offering confirmation about the Solyx SIS System as a viable, first-line surgical treatment option for these patients.”

This prospective, parallel cohort, post-market surveillance 522 study, evaluated 281 patients at 21 sites over 36 months to compare efficacy and adverse events for non-inferiority of the Solyx SIS System versus TMUS performed using the Obtryx™ II Sling System. The U.S. Food and Drug Administration has required post-market surveillance 522 studies be conducted by all manufacturers of certain mesh products. This study is the first of three 522 post-market surveillance studies that Boston Scientific will complete, with the remaining data expected in 2019.

“This trial exemplifies our rigorous commitment to patient safety and our drive to positively impact the lives of the 31 million women with pelvic floor disorders,” said David Pierce, executive vice president and president, MedSurg. “Our journey doesn’t stop there. We have invested in 16 additional pelvic floor studies to continue building the body of clinical evidence for our women’s health products, including mesh sling systems.”

Study sites were assigned to a cohort group, SIS or TMUS, based upon documented competency with the cohort device. The primary endpoint was treatment success defined by a composite of objective measure (negative cough stress test) and any subjective self-reported improvement in SUI using the Patient Global Impression of Improvement (PGI-I) at 36 months. Secondary endpoints included adverse events and indication for reoperation or retreatment. A non-inferior margin of 15 percent and 10 percent was prespecified for the primary efficacy and safety measures, respectively.

The results showed that the SIS group was non-inferior to the TMUS group in composite treatment success with both intention-to-treat (ITT) and per protocol analyses. At 36 months, the treatment success was 90.4 percent (94/104) in the SIS group and 88.9 percent (96/108) in the TMUS group ($P = 0.93$), in the ITT population, based on available cases. Rates of device- and/or procedure-related serious adverse events at 36 months in the SIS group were non-inferior to the TMUS group. Similar proportions of mesh-related complications, dyspareunia, pelvic pain and urinary retention were observed between the two treatment groups.

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 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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