Boston Scientific Announces Collaboration with Pelvic Floor Disorders Network to Study Treatment Strategies for Uterine Prolapse

NATICK, Mass., June 3, 2013 /<u>PRNewswire</u>/ -- Boston Scientific Corporation (NYSE: BSX) continues to demonstrate its commitment to women's health by providing a research and education grant of more than \$1 million to the Pelvic Floor Disorders Network (PFDN) for the SUPeR clinical trial. The SUPeR study will evaluate treatment outcomes of two different surgical options for women with uterine prolapse, a form of pelvic organ prolapse.

An estimated 28 million women in the United States live with at least one pelvic floor disorder. The two most common conditions are urinary incontinence, which is the inability to hold urine, and pelvic organ prolapse, a medical condition that occurs when the tissue and muscles of the pelvic floor no longer support the pelvic organs, resulting in "sagging" or dropping of organs such as the bladder, uterus or rectum. Women often suffer in silence with these conditions due to embarrassment regarding their symptoms.

The SUPeR study expects to enroll 180 women who are considering surgery for their uterine prolapse and do not plan to have any more children. They will be randomly assigned to either a uterine-preserving transvaginal mesh repair using the Boston Scientific Uphold® LITE Vaginal Support System or traditional surgery that will include a vaginal hysterectomy.

"The data for this study will give physicians reliable evidence from a randomized trial on surgical treatment for women with uterine prolapse," said Charles Nager, M.D., director of the Urogynecology and Reconstructive Pelvic Surgery Division at UC San Diego School of Medicine. "That evidence will help inform clinicians as they make decisions in an effort to provide the best patient care possible."

After surgery, patients will be evaluated every six months for up to five years to determine surgical success, patient safety, cost-effectiveness, quality of life and body image. Data are expected to be available in 2017 and the final results to follow approximately one year later.

"Boston Scientific is dedicated to developing health care solutions that improve patients' quality of life and help restore normalcy," said Michael Phalen, president, Medical Surgery, Boston Scientific. "The Pelvic Floor Disorders Network collaboration will help us understand how our uterine-preserving procedure compares to the current procedure in which a hysterectomy is performed."

The PFDN is funded by the National Institutes of Health and is comprised of eight medical centers and investigators across the United States including Anthony G. Visco, M.D., Duke University; Charles W. Nager, M.D., UC San Diego School of Medicine; Matthew D. Barber, M.D., the Cleveland Clinic; Heidi Harvie, M.D., the University of Pennsylvania; Holly E. Richter, Ph.D., M.D., the University of Alabama at Birmingham; Rebecca Rogers, M.D., the University of New Mexico; Halina M. Zyczynski, M.D., the University of Pittsburgh-Magee; and Charles Rardin, M.D., Women and Infants Hospital at Brown University. The PFDN mission is to determine the best treatment options for women with pelvic floor disorders.

For more information about women's health products from Boston Scientific, please visit: <u>www.pelvic-floor-</u> <u>institute.com</u>. Boston Scientific is also the proud sponsor of the patient website of The American Urogynecologic Society (AUGS), which can be accessed at: <u>www.voicesforpfd.org</u>.

About Boston Scientific

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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 and the importance of their results, 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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