Boston Scientific

Boston Scientific Issues Statement Regarding FDA Advisory Committee Meeting on Surgical Mesh to Treat Pelvic Organ Prolapse and Stress Urinary Incontinence

NATICK, Mass., Sept. 9, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today issued the following statement from John Pedersen, Senior Vice President and President of the Company's Urology and Women's Health Division, following the conclusion of a two-day meeting of the U.S. Food and Drug Administration (FDA) Obstetrics & Gynecology Devices Advisory Committee. During the meeting, the Committee heard presentations on the safety, effectiveness and continued classification of surgical mesh as a Class II device to repair pelvic organ prolapse (POP) and stress urinary incontinence (SUI) in women.

"Boston Scientific believes that mesh products are a valuable option for surgeons who treat women with pelvic floor disorders and stress urinary incontinence and that these products offer a safe and effective alternative to non-mesh treatment options. We will continue to work with the FDA and other members of the AdvaMed Working Group to reinforce the safety and effectiveness of these devices.

"Within Class II, FDA has the authority to implement Special Controls to ensure consistency in the evaluation of the safety and effectiveness of products through standardized requirements, including pre- and post-market clinical trials, and the adequacy of labeling information provided to both patients and physicians. We believe that the current 510(k) requirements for Class II devices are appropriate for surgical mesh devices intended to treat pelvic organ prolapse and stress urinary incontinence.

"As part of our commitment to manufacturing and marketing high quality and safe products, we look forward to our ongoing work with the FDA, physicians and others in our industry to ensure that accurate and complete information is provided to healthcare providers and their patients so they can make fully informed decisions regarding these treatment options.

"We appreciated the opportunity to present our perspective on this important issue and anticipate continued government and industry collaboration with respect to this important treatment option."

Pelvic organ prolapse is a common condition that occurs when the tissue and muscles of a woman's pelvic floor deteriorate and no longer support her pelvic organs. This deterioration results in the drop (prolapse) of pelvic organs from their normal position. According to the Women's Health Initiative, nearly 40 percent of women aged 50-79 (41.1 percent with a uterus and almost 38 percent for women without a uterus) present with some form of prolapse(1).

Stress urinary incontinence is the unintentional discharge of urine prompted by a physical movement or activity – such as coughing, sneezing or heavy lifting – that puts pressure (stress) on the bladder. It has been estimated that at least one in three women over age 18 is affected by SUI(2).

Transvaginal mesh is a medical device inserted through a vaginal incision to repair the weakened or damaged tissues in women with POP or SUI. Boston Scientific's Women's Health business offers products for pelvic floor reconstruction, as well as a complete line of mid-urethral sling systems for the treatment of stress urinary incontinence.

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

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 regulatory approval processes, government and industry collaboration, clinical trials, product performance, the importance of surgical mesh as a treatment option 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.

(1) Hendrix S.L., Clark A., Nygaard I., Aragaki A., Barnabei V., McTiernan A. Pelvic organ prolapse in the Women's Health Initiative: gravity and gradividy. Am J Obstet Gynecol. 2002 June. 186(6):1160-6.

(2) Ogah J., Cody J.D., Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2009, Issue 4. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub2

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