FDA Approves Boston Scientific's Genesys HTAâ„¢ System

Boston Scientific

NATICK, Mass., May 18 /PRNewswire-FirstCall [1]/ -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) approval of its Genesys HTA™ System for the treatment of menorrhagia. The Genesys HTA System is a next-generation endometrial ablation system designed to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia.

Menorrhagia is abnormally heavy and prolonged menstrual bleeding. An estimated 10 million women in the U.S. suffer from this condition.

The Genesys HTA System represents a significant advance in Boston Scientific's endometrial ablation technology. It features a smaller and lighter console, simplified set-up requirements, and an enhanced graphic user interface which offers step-by-step guidance through the procedure. The System also incorporates several technology upgrades designed to improve operating performance while delivering the same proven clinical therapy of the Company's current HTA Endometrial Ablation System.

"FDA approval of the Genesys HTA System is the latest example of our commitment to developing products in the Women's Health arena that improve patients' lives," said John Pedersen, Senior Vice President and President of Boston Scientific's Urology and Women's Health Division. "We are pleased we will be able to offer this next-generation system to U.S. patients suffering from menorrhagia."

The System received CE Mark approval in January.

"The new Genesys HTA System has streamlined the procedure set-up and provides my patients an effective means to address their menorrhagia," said Christopher Guyer, M.B., B.S., M.R.C.O.G., a gynecologist at Queen Alexandra Hospital, Portsmouth, U.K.

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 [2].

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of 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.

SOURCE [3]

Links:
[1] http://www.prnewswire.com/
[2] http://www.bostonscientific.com/
[3] http://bostonscientific.mediaroom.com/index.php?s=43&item=922