Boston Scientific

Video: Boston Scientific Announces European Approval and Launch of Platinum Chromium PROMUS® Element™ Stent System

Third-generation drug-eluting stent now available in CE Mark countries

PRNewswire
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(NYSE:BSX)

NATICK, Mass., Nov. 2 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced it has received CE Mark for its PROMUS® Element™ Everolimus-Eluting Coronary Stent System, the Company's third-generation drug-eluting stent (DES) technology. The PROMUS Element system incorporates a unique platinum chromium alloy with an innovative stent design and an advanced catheter delivery system.

To view the Multimedia News Release, go to: http://multivu.prnewswire.com/mnr/bostonscientific/36501/

(Photo: http://www.newscom.com/cgi-bin/prnh/20091102/NY02934)

The Company will begin marketing the PROMUS Element system immediately in the European Union and other CE Mark countries. CE Mark was granted by the Dutch Notified Body KEMA Quality B.V.

The platinum chromium alloy used in the PROMUS Element stent is engineered specifically for coronary stenting. This proprietary alloy offers greater radial strength and flexibility than older alloys such as the cobalt chromium alloy used in the XIENCE PRIME™ DES, and it provides enhanced visibility and reduced recoil. The innovative stent design improves deliverability and allows for more consistent lesion coverage and drug distribution. The advanced catheter delivery system further improves deliverability.

"The platinum chromium alloy and new stent design used in the PROMUS Element stent represent significant innovations in drug-eluting stent technology," said Bruno Farah, M.D., Clinique Pasteur, Toulouse, France. "In my experience, the Element platform offers a stenting option that provides superior deliverability and visibility with excellent comformability and low recoil. I believe it offers performance improvements that could simplify procedures and allow treatment of a broader range of patients."

In addition to the PROMUS Element Everolimus-Eluting Coronary Stent System, the Company plans to offer the TAXUS® Element™ Paclitaxel-Eluting Coronary Stent System. Both Element systems incorporate the platinum chromium alloy with the innovative stent design and advanced catheter delivery system.

"We are proud to introduce our third-generation drug-eluting stent to physicians and patients in Europe and other CE Mark countries," said David McFaul, Boston Scientific Senior Vice President, International. "The PROMUS Element system is the latest example of Boston Scientific's commitment to DES market leadership and continued innovation. We also plan to launch the TAXUS Element system in CE Mark countries next year, giving physicians the choice of two proven drug and polymer combinations - used in millions of patients worldwide - on an entirely new stent platform. We are confident our Element series will further extend our global DES leadership."

The PROMUS Element system is being evaluated in the PLATINUM clinical trial, which completed enrollment of 1,532 patients in September at more than 140 sites worldwide. PLATINUM is a randomized, controlled, pivotal trial designed to support U.S. Food and Drug Administration (FDA) and Japanese Ministry of Health, Labor and Welfare (MHLW) approval of the PROMUS Element system. The TAXUS Element system is being evaluated in the PERSEUS trial, which completed enrollment in October 2008 and will report primary endpoint data at the American College of Cardiology conference in March.

The Company anticipates FDA approval for the PROMUS Element system in 2012. The TAXUS Element system was launched in select international markets in May. CE Mark approval for the TAXUS Element system is expected in the second quarter of 2010, and FDA approval is expected in 2011.

In the U.S., the PROMUS Element and TAXUS Element systems are investigational devices and are limited by applicable law to investigational use only and are not available for sale.

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 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 trials, regulatory approvals, competitive offerings, product performance and our market position. 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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