Boston Scientific

Boston Scientific Announces First Implant of TAXUS® Element™ Platinum Chromium Stent

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NATICK, Mass., July 19 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced the beginning of clinical trial enrollment in studies evaluating its third-generation paclitaxel-eluting coronary stent, the TAXUS® Element™ Stent. The TAXUS PERSEUS clinical program will collectively enroll approximately 1,500 patients at 100 U.S. and international centers.

The TAXUS Element Stent features the proprietary Platinum Chromium Alloy, designed specifically for stents. This alloy, coupled with an innovative new stent design, is designed to enable thinner struts, increased flexibility, and a lower profile while improving radial strength, recoil, and radiopacity. In addition, the TAXUS Element Stent platform incorporates new balloon technology, intended to improve upon Boston Scientific's market-leading Maverick® Balloon Catheter technology.

The principal investigator for the trials is Dean J. Kereiakes, M.D., Medical Director at The Christ Hospital Heart and Vascular Center and The Lindner Research Center in Cincinnati. The co-principal investigator is Louis A. Cannon, M.D, of the Cardiac and Vascular Research Center of Northern Michigan in Petoskey, Michigan. Patient enrollment of the TAXUS PERSEUS clinical program began July 13th and is expected to be completed within 12 months.

"With the innovative design of the TAXUS Element Stent System, we anticipate seeing a significant advancement in the performance offered in a drug-eluting stent," said Dr. Kereiakes. "This new platform, designed for improved deliverability, should allow us to bring the long-term proven performance of the TAXUS Stent to even the most complex and challenging anatomy."

The TAXUS PERSEUS clinical program will evaluate the efficacy and safety of the TAXUS Element Stent in two studies.

The first study, TAXUS PERSEUS Workhorse (A Prospective Evaluation in a Randomized Trial of the Safety and Efficacy of the Use of the TAXUS® Element™ Paclitaxel-Eluting Coronary Stent System for the Treatment of De Novo Coronary Artery Lesions), will evaluate the safety and efficacy of the TAXUS Element Stent compared to Boston Scientific's first generation drug-eluting stent, the TAXUS® Express2™ Stent. This study will evaluate 1,264 patients with "workhorse" lesions from 2.75 to 4.0 millimeters. The primary endpoint of the workhorse study is target lesion failure (TLF) at 12 months, and its secondary endpoint is in-segment percent diameter stenosis at nine months.

The second study is the TAXUS PERSEUS Small Vessel study which will compare the TAXUS Element Stent to a historic control (TAXUS V de novo bare-metal Express® Coronary Stent System). This study will include 224 patients with lesions from 2.25 up to 2.75 millimeters. The primary endpoint of the small vessel study is in-stent late loss at nine months, and its secondary endpoint is TLF at 12 months. Study success is dependent on both endpoints.

"We are excited to begin evaluating the TAXUS Element Stent, the third in our deep pipeline of drug-eluting stents, a milestone unmatched by other companies," said Hank Kucheman, Senior Vice President and Group President, Interventional Cardiology. "The Platinum Chromium Alloy and new balloon technologies offered in this system are also being developed in an Everolimus version and is intended to serve as foundational technology in Boston Scientific's dual-drug DES portfolio, including a drug-eluting bifurcation stent and next-generation Everolimus- and Paclitaxel-eluting stents."

The TAXUS Element Stent is under development and is 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: http://www.bostonscientific.com/ .

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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