Boston Scientific

Boston Scientific Announces FDA Approval of Innovative Heart Failure Lead

PRNewswire-FirstCall
NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., April 17 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) approval of the ACUITY® Steerable left ventricular lead for use with cardiac resynchronization therapy defibrillators and cardiac resynchronization therapy pacemakers, both of which treat heart failure. This product features a deflectable tip for precise placement of the lead even in difficult-to- access branch vessels on the left side of the heart. A lead is an insulated wire that carries the heart signal to the implanted device and delivers energy from the device to the heart. In most cases, leads are passed into the heart through veins.

"The ability to place a left ventricular lead precisely where it will stimulate the heart most effectively is a key factor in providing patients with optimal cardiac resynchronization therapy," said Dr. Stephen Mester, Medical Director of Electrophysiology Lab, Tampa General Hospital. "The ACUITY Steerable lead's deflectable tip control is similar to an electrophysiology catheter and allows me to easily maneuver it into side- branch vessels." Dr. Mester served as Principal Investigator for the ACUITY Steerable lead clinical trial.

"Our Cardiac Rhythm Management group is moving in the right direction with this product approval and yesterday's announcement that the warning letter has been resolved," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "We look forward to making this lead available to physicians so they can offer this advanced therapy to their heart failure patients."

The ACUITY Steerable lead, which will be broadly available in July, also provides physicians with four configurations for stimulating the left side of the heart, which Boston Scientific refers to as Electronic Repositioning™. This unique ability allows physicians to change the stimulation site non- invasively after implant, which helps avoid the need for an additional surgical procedure. Boston Scientific is the only company that provides physicians with four left ventricular pacing configurations.

In addition to the ACUITY Steerable lead approval, Boston Scientific has also received five other approvals from the FDA for software upgrades and other enhancements designed to improve the performance of existing CRM products.

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, integration of acquired companies, 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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