Boston Scientific Updates PREVAIL Late Breaking Clinical Trials Presentation

PR Newswire

NATICK, Mass., March 6, 2013 /PRNewswire/ -- The Boston Scientific Corporation (NYSE: BSX [1]) PREVAIL clinical trial results will be presented in a Late-Breaking Clinical Trial presentation at the 62nd Annual Scientific Sessions of the American College of Cardiology, and will include all three co-primary endpoints that evaluate safety and efficacy of the WATCHMAN® Left Atrial Appendage (LAA) Closure device in patients with nonvalvular atrial fibrillation versus long-term warfarin therapy. This will be the first time all three co-primary endpoints in the PREVAIL study will be presented.

The preliminary results of the PREVAIL Trial will be presented on March 9 in San Francisco, California by David R. Holmes Jr. , M.D., Mayo Clinic, Rochester, Minn., at 9:10 a.m. PT, in the Moscone Center, South, Esplanade Ballroom.

Specifically, Dr. Holmes will present preliminary analysis on the following co-primary endpoints:

- Acute (7-day) occurrence of death, ischemic stroke, systemic embolism and procedure or device related complications requiring major cardiovascular or endovascular intervention
- Comparison of composite of stroke, systemic embolism, and cardiovascular/unexplained death at 18 months follow-up
- Comparison of ischemic stroke or systemic embolism occurring from greater than 7 days post randomization to 18 months follow-up

"This is truly a late-breaking clinical trial presentation," said Kenneth Stein , M.D., chief medical officer, Cardiac Rhythm Management, Boston Scientific. "The last patient six-month follow-up occurred in January and the team has been working diligently to complete the preliminary analysis of the data. The acute procedural results were completed first, and we announced earlier this week that those results would be presented. We are pleased to announce that the preliminary analysis of the other two endpoints will now be presented as well. The final fully monitored and adjudicated analysis will be completed in the coming weeks and is expected to be used to support our comprehensive clinical module PMA filing of the WATCHMAN device. This filing is also expected to include Protect AF four-year outcomes data, the WATCHMAN Pilot study six-year data, the ASAP study and the CAP registry data update."

The WATCHMAN device was approved for sale in Europe in 2005 and some countries in Asia in 2009. It is already commercially available in 40 countries worldwide. In the United States, WATCHMAN is an investigational device, limited by

applicable law to investigational use and not available for sale. Results from the PREVAIL confirmatory study are expected to be submitted for approval by the U.S. Food and Drug Administration (FDA). The device was developed by Atritech, which Boston Scientific acquired in March 2011. Please visit http://www.bostonscientific.com/watchman-eu/ [2] for more information. Images of the WATCHMAN device are available for download at http://bostonscientific.mediaroom.com/image-gallery?mode=gallery&cat=1760 [3].

Both the Mayo Clinic and Dr. Holmes have a financial interest in technology related to this research.

The clinical data results are embargoed until the time of the scientific presentation.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 30 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com [4] and connect on Twitter [5] and Facebook [6].

Source URL (retrieved on *10/01/2014 - 11:08am*):
http://www.mdtmag.com/news/2013/03/boston-scientific-updates-prevail-late-breaking-clinical-trials-presentation

Links:
[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=BSX
[2] http://www.bostonscientific.com/watchman-eu/
[3] http://bostonscientific.mediaroom.com/image-gallery?mode=gallery&cat=1760
[4] http://www.bostonscientific.com/
[5] http://twitter.com/bostonsci
[6] http://www.facebook.com/bostonscientific