

## **FDA Advisory Panel Votes Favorably on the Boston Scientific WATCHMAN™ Left Atrial Appendage Closure Device**

PR Newswire

The U.S. Food and Drug Administration (FDA) Circulatory System Devices Panel of the Medical Devices Advisory Committee voted favorably by a majority, Yes: 13, No: 1, that the benefits of the WATCHMAN Left Atrial Appendage Closure device outweigh the risks. The FDA Panel was further asked if there is reasonable assurance that the device is safe, the Panel voted Yes: 13, No: 1. On the question of reasonable assurance of efficacy, the Panel voted Yes: 13, No: 1. The FDA will take into account the Panel's vote in its decision on approval of the WATCHMAN device. The company expects a decision from the FDA in the first half of 2014.

"We are pleased with the outcome of today's Panel, which represents an important milestone toward making this innovative technology available to patients with AF at higher risk for stroke who need an alternative to long-term warfarin therapy," said Kenneth Stein, M.D., Chief Medical Officer, Cardiac Rhythm Management, Boston Scientific. "We appreciate the opportunity to present our comprehensive data supporting the WATCHMAN technology and look forward to continuing discussions with the FDA regarding the Panel's comments."

The vote of the committee followed a review of clinical data from two randomized control trials, PROTECT AF and PREVAIL, as well as from the CAP (Continued Access Protocol) registry. WATCHMAN is the most studied left atrial appendage closure device and the only one with long-term clinical data from 2,000 patients and with almost 4,900 patient-years of follow-up in clinical trials. The WATCHMAN device received CE Mark in 2005. In the United States, WATCHMAN is an investigational device, limited to investigational use and not available for sale.

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