Boston Scientific

Boston Scientific Announces Primary Endpoint Results of NECTAR-HF Clinical Trial

Phase II feasibility trial provides first randomized sham-controlled data using vagus nerve stimulation to treat heart failure

MARLBOROUGH, Mass., Aug. 30, 2014 /PRNewswire/ -- Boston Scientific has released the primary endpoint results from its NEural Cardiac TherApy foR Heart Failure (NECTAR-HF) clinical trial, the first and only randomized sham-controlled clinical trial investigating vagus nerve stimulation (VNS) for the treatment of heart failure patients. Faiez Zannad, M.D., Ph.D., Professor of Therapeutics and Cardiology and Director of the Clinical Investigation Center at the Institut National de la Sante et de la Recherche Medicale presented the results at the 2014 European Society of Cardiology (ESC) Congress in Barcelona, Spain. The results will also be published in the European Heart Journal.

The study evaluated 96 New York Heart Association (NYHA) Class II-III patients with heart failure and an ejection fraction of less than 35%. All patients continued receiving optimal medical treatment for heart failure, but were randomized 2:1 to treatment or sham (implanted device but not receiving therapy), respectively.

The trial did not meet the pre-specified six month primary efficacy endpoint of a reduction in left ventricular end systolic diameter as assessed by a blinded echocardiography core laboratory. Quality of life metrics demonstrated significant symptomatic improvement despite the lack of a significant effect on primary and secondary endpoint measures of cardiac remodeling and functional capacity in HF patients.

"The careful design and execution of NECTAR-HF has resulted in high quality data that will improve the understanding of the role of VNS in the treatment of patients with heart failure," said Prof. Zannad, NECTAR-HF Principal Investigator. "Although patients receiving therapy reported feeling better as assessed by quality of life questionnaires, the application of VNS failed to reveal clear benefit when compared to sham, because the effect of therapy was no better than sham on echocardiography derived measurements. Inclusion of an appropriate control group is crucial, and a randomized study like NECTAR-HF should be the benchmark for future studies of novel device therapies for the treatment of heart failure."

After six months of randomization, control patients begin to receive active therapy. All patients are followed through 18 months for the safety endpoint.

"We are pleased to have collaborated with the investigators who have added significantly to the scientific knowledge of vagus nerve stimulation for the treatment of heart failure," said Kenneth Stein, M.D., Chief Medical Officer, Rhythm Management for Boston Scientific. "We remain committed to advancing clinical science, exploring novel therapies, and providing new diagnostic options for patients with heart failure."

***** The implantable VNS system is not available for sale, and is for investigational use only.

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 and connect on Twitter and Facebook.

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This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and 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 new product launches and launch cadence, regulatory approvals, clinical trials, product performance and impact, and competitive offerings. 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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