

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

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

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CONTACTS:

Nisha Deo
Global Media Relations
Boston Scientific Corporation
508-683-5571 (office)
Nisha.Deo@bsci.com

Simonetta Balbi
PR and Corporate Communication EMEA
Boston Scientific Corporation
+ 39 3387936422 (mobile)
+ 39 0106060281 (direct)
Balbis@bsci.com

Susie Lisa, CFA
Investor Relations
Boston Scientific Corporation
508-683-5565 (office)
investor_relations@bsci.com

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