

Boston Scientific Begins Enrollment in NECTAR-HF Clinical Trial

NATICK, Mass., Sept. 29, 2011 [PRNewswire](#)/ -- Boston Scientific Corporation (NYSE: BSX) has enrolled the first patients in its NECTAR-HF (**NE**ural **C**ardiac **Ther**Apy fo**R** **H**eart **F**ailure) clinical trial. NECTAR-HF is a prospective, randomized, international clinical feasibility study designed to assess preliminary safety and efficacy of chronic vagal nerve stimulation in heart failure patients. The study will evaluate 96 patients with vagal nerve stimulator implants at multiple centers in Europe.

"Stimulating the vagus nerve in the cervical region is commonly used to treat epilepsy and depression; however, promising pre-clinical data show that this therapy may also help a large population of heart failure patients who are currently not candidates for heart failure device therapy," said Principal Investigator and Steering Committee Chairman Faiez Zannad, M.D., Ph.D., Professor of Therapeutics and Cardiology and Director of Clinical Investigation Center at INSERM in Nancy, France.

The first implants in the NECTAR-HF trial occurred in Barcelona, Spain at Hospital Clinic by Jordi Rumia, M.D., (Maria Angeles Castel Lavilla, M.D., Ph.D. as Principal Investigator) and in Nancy, France at CHU Nancy-Brabois by Mazen Elfarra, M.D., (Prof. Zannad as Principal Investigator).

"NECTAR-HF will study whether vagal nerve stimulation can restore autonomic balance⁽¹⁾ and therefore improve heart function, increase exercise capacity and inhibit the progression of heart failure," said Co-Principal Investigator and Steering Committee member Josep Brugada, M.D., Ph.D., Professor of Medicine and Medical Director of Hospital Clinic in Barcelona.

"Our goal with vagal nerve stimulation therapy is to offer another treatment option for heart failure patients," said Kenneth Stein, M.D., Chief Medical Officer, Cardiac Rhythm Management for Boston Scientific. "This novel technology leverages Boston Scientific's capabilities in cardiac rhythm management device therapy, lead technologies and neuromodulation. This treatment capability is one of our Priority Growth Initiatives, and illustrates our strategy to offer new therapies in high-potential markets that are designed to improve the quality of life for patients."

Congestive heart failure affects nearly 23 million people worldwide, with approximately 2 million new patients diagnosed annually. Despite substantial advances over the past two decades in pharmacological and device therapy, heart failure remains one of the leading causes of morbidity and mortality in the U.S. and most European countries.

About Boston Scientific

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: www.bostonscientific.com.

Cautionary Statement Regarding Forward-Looking Statements

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, vagal nerve stimulation, product performance 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.

(1) The autonomic nervous system is composed of the sympathetic and parasympathetic nervous systems and is responsible for the subconscious regulation of internal organs and glands. Chronic autonomic imbalance is believed to be a risk factor for

the progression of heart failure and adverse cardiovascular events.

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