Clinical Study Results Demonstrate Therapeutic Advantages Of The Boston Scientific Vercise™ DBS System For Patients With Parkinson's Disease [EN]

Data Presented at the International Congress of Parkinson's Disease and Movement Disorders Demonstrate Superior Therapeutic Window for the Treatment of Parkinson's Disease

A new study has demonstrated a therapeutic advantage for a unique and innovative capability of the Boston Scientific (NYSE: BSX) Vercise™ Deep Brain Stimulation (DBS) System for the treatment of Parkinson's disease (PD). The CUSTOM-DBS clinical study demonstrated that shorter stimulation pulses may offer a clinical advantage over DBS therapy using conventional pulses. The Vercise DBS System is the only commercially available platform with the capability to generate stimulation pulses at the shorter pulse width settings.

Results of the CUSTOM-DBS study were presented at the 18th International Congress of Parkinson's Disease and Movement Disorders in Stockholm, Sweden, by Prof. Dr. Jens Volkmann, professor of Neurology at Universitatsklinikum, in Wurzburg, Germany and primary principal investigator of the trial. The Boston Scientific CUSTOM-DBS study is a randomized, multi-center, double-blind trial evaluating clinical advantages of the Vercise DBS System for patients with PD. Fifteen patients previously implanted with the Boston Scientific Vercise DBS System were programmed and assessed using test and control pulse widths.

The study demonstrated that DBS stimulation with shorter pulses results in larger therapeutic windows that may be advantageous for avoiding stimulation-related side effects. The therapeutic window is the range of electrical currents that provides effective therapy without causing side effects.

In CUSTOM-DBS, patients' DBS implants were stimulated with brief electrical pulses that were shorter than conventional settings. To compare the two settings, efficacy of the stimulation was evaluated using the standard UPDRS III[1] score assessment for PD, and thresholds for achieving efficacy and side effects were measured. The comparisons were randomized and double-blinded, making this one of the first studies to provide Level I evidence of a clinical advantage to specific deep brain stimulation settings, such as shorter pulse widths.

"The results are truly exciting because the key to optimal DBS treatment is first to get accurate targeting and then find an electrode with a large therapeutic window, where a patient is getting the best management of PD symptoms with minimal side effects," said Prof. Dr. Volkmann. "The shorter pulse width settings with the Vercise System required less electrical energy to achieve optimal therapy, suggesting there may also be energy efficiency advantages to these settings as well."

The Vercise DBS System is the first DBS system with multiple independent current control technology designed for accurate neural targeting and precise control of the stimulation therapy for patients with PD.

"The CUSTOM-DBS study distinguishes the Vercise DBS System from other technologies by its ability to provide better outcomes for patients with this new stimulation approach," said Maulik Nanavaty, president, Neuromodulation, Boston Scientific. "Our clinical program demonstrates Boston Scientific's commitment to advancing therapy for patients through clinical evidence that demonstrates meaningful innovation and compelling results."

DBS is a surgical treatment that can help reduce some PD symptoms. It involves the placement of a device that stimulates specific areas of the brain using electrical signals. DBS is typically used to treat people with advanced PD whose symptoms are no longer controlled by medication. PD is a progressive neurological disorder which affects 6.3 million people worldwide.[2]

Boston Scientific is an innovation leader in implantable DBS technology. The Vercise DBS System has both CE Mark and TGA (Australia Therapeutic Goods Administration) approval and is available for sale in Europe, Israel, Australia and select countries in Latin America for PD, and CE Mark approval for intractable primary and secondary dystonia.

In the U.S., the Vercise DBS System is investigational and not available for use or sale. The INTREPID clinical trial began enrollment in the U.S. in mid-2013 to evaluate the safety and effectiveness of the Vercise DBS System for the treatment of Parkinson's disease.

- Unified Parkinson's Disease Rating Scale Part III (UPDRS III)
- https://www.epda.eu.com/en/parkinsons/in-depth/parkinsonsdisease/

About Boston Scientific
Boston Scientific transforms lives through innovative medical solutions that improve the health of patients

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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 our business plans, markets for our products, clinical trials and data impact, 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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