Boston Scientific Launches Trial To Evaluate Neurostimulation For Treatment Of Chronic Migraine [EN]

First Patient Treated in OPTIMISE Clinical Trial Evaluating Safety, Efficacy of Occipital Nerve Stimulation Using Precision™ System

Boston Scientific Corporation (NYSE: BSX) has launched a clinical trial to determine whether occipital nerve stimulation (ONS) using the Precision™ System can safely and effectively treat chronic migraine when used in conjunction with anti-migraine medications. The OPTIMISE trial -- a multi-center, randomized, placebo-controlled study -- is expected to be used to support various regulatory approvals of this novel therapy for chronic migraine.

The first patient to undergo this procedure was treated at Mercy Hospital in Springfield, Mo., by Benjamin Lampert, M.D., using the Boston Scientific Precision System, which features multiple independent current control (MICC) technology. With ONS, a small programmable implanted device sends electrical impulses to the greater occipital nerve, which runs from the top of the spinal cord to the base of the scalp. Initial studies suggest that by stimulating the occipital nerve, it may be possible to mask the pain associated with chronic migraine[1-3].

"By directly targeting the occipital nerve with neurostimulation, we are potentially able to offer patients an effective and relatively low-risk therapy," said Richard Lipton, M.D., professor of neurology and director of the Montefiore Headache Center at Albert Einstein College of Medicine in New York and principal investigator for the study. "I am excited to further evaluate the clinical utility of the Boston Scientific Precision System with MICC technology as a treatment for chronic migraine."

Migraine is a neurological disorder affecting one in 10 adults worldwide. Sufferers have headaches that last more than four hours a day with some adults experiencing headaches 15 or more days per month. Migraine is considered by the World Health Organization (WHO) to be one of the top disabling conditions worldwide. Despite the available treatment options, many migraine patients are unable to find relief.

The Precision System for chronic migraine is investigational. It is currently available as an approved treatment in the U.S., Canada, Europe and Australia as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome and intractable low back pain and leg pain.

"We believe that the Boston Scientific neurostimulation therapy for migraine has enormous potential to help migraine sufferers worldwide," said Maulik Nanavaty, president, Neuromodulation, Boston Scientific. "Launching this study highlights our continued commitment to bringing innovations in pain management to market to ensure we are meeting the needs of clinicians and patients alike."

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 markets for our products, our business plans, clinical trials, 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]Saper, J.R., Dodick, D. W., Silberstein, S. D., McCarville, S., Sun, M., Goadsby, P. J., and O. Investigators, Occipital nerve stimulation for the treatment of intractable chronic migraine headache: ONSTIM feasibility study. Cephalalgia, 2011. 31(3): p. 271-285.
[2]Bennett, D., Webster, Lynn, Lampert, Benjamin A., Lubenow, Timothy R., Sharan, Ashwini, Whiten, Darren, Jaax, Kristen N., Occipital nerve stimulation: surgical technique

and outcomes from the PRISM study of ONS for drug-refractory migraine, in 13th North American Neuromodulation Society Annual Meeting. 2009: Las Vegas, NV.
[3]Silberstein, S., Dodick, D., Saper, J., Huh, B., Reed, K., Narouze, S., Bacon, D., Mogilner, A., Banks, J., Cady, R., Black, S., Slavin, K., Goldstein, J. Markley, H. Deer, T., Levy, R., Mekhail, N., The safety and efficacy of occipital nerve stimulation for the management of chronic migraine, in 15th Congress of the International Headache Society. 2011: Berlin, Germany.

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