

Boston Scientific Receives CE Mark for Vercise™ Gevia™ Deep Brain Stimulation System

Industry's First MR-Conditional Directional DBS System with Stimulation Visualization

MARLBOROUGH, Mass., June 6, 2017 /[PRNewswire](#)/ -- Boston Scientific (NYSE: BSX) has received CE mark for the Vercise™ Gevia™ Deep Brain Stimulation (DBS) System*, a rechargeable, magnetic resonance (MR) conditional device indicated for the treatment of movement disorder symptoms in patients with Parkinson's disease, dystonia and essential tremor. The system features the Vercise™ Neural Navigator 2 with STIMVIEW Technology, programming software which, for the first time, allows clinicians to visualize the stimulation field while configuring DBS stimulation programs for patients.

DBS therapy involves the placement of a device that stimulates specific areas in the brain using electrical signals. The Vercise Gevia System is a next generation rechargeable platform with an unparalleled 25-year battery life.

The approval expands the Vercise Directional portfolio which is composed of the Vercise Primary Cell (PC) and Vercise Gevia platforms with Vercise Cartesia™ Directional Lead*. The Vercise Directional offerings are the only DBS solutions that finely control the size, shape and direction of stimulation with multiple independent current control technology (MICC). This level of precision in delivering accurate stimulation therapy to the neural target is critical for avoiding unwanted side effects and obtaining optimal DBS outcomes.

"The Gevia System addresses the needs of both patients and physicians with the latest advances in DBS therapy," said Ludvic Zrinzo, M.D., Ph.D., FRCSEd, consultant neurosurgeon, National Hospital for Neurology and Neurosurgery, Queen Square, London. "With the Gevia System, patients benefit from directional stimulation within a rechargeable system while maintaining the ability to have an MRI. This flexibility in DBS therapy is a clear step forward for patients."

The Neural Navigator 2 software enables a physician to visualize how stimulation will be distributed in the brain while programming therapy for a patient. Typically, physicians rely primarily on patient feedback to complete programming. This software provides an additional source of information which is designed to provide optimal therapeutic results.

"I now have the potential to better define the settings that can help patients because I have the ability to visualize their stimulation field while I am programming," said Professor Patricia Limousin, M.D., Ph.D., neurologist, National Hospital for Neurology and Neurosurgery, Queens Square, London. "The Neural Navigator software brings together some of the most critical information I need to customize therapy for patients."

"Five years ago, Boston Scientific was the first to bring an eight contact rechargeable platform offering 25 years of longevity, quickly followed by the introduction of the first directional lead powered by a small primary cell device," said Maulik Nanavaty, senior vice president and president, Neuromodulation, Boston Scientific. "Today, we are thrilled to provide the first rechargeable, directional DBS system that is also Full Body MRI Conditional¹ and the first programming software with STIMVIEW Technology. Boston Scientific is dedicated to providing transformative technology to equip clinicians and improve the lives of patients."

Parkinson's disease is a progressive neurodegenerative disorder that impacts one's ability to move and causes changes in mood, sleep patterns and cognition. It affects nearly 10 million people worldwide.² Dystonia causes muscles to involuntarily contract and affects nearly 72 million people globally and is diagnosed more often in women.³ Essential tremor is the most common movement disorder and is characterized by tremors in different parts of the body. The incidence of essential tremor increase with age with approximately 4 percent of the global population and up to 14 percent of the elderly being diagnosed.⁴

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 35 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](#).

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 our product launches and product performance and impact. 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; the closing and integration of acquisitions; 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.

*The Gevia DBS System, Vercise Primary Cell and Vercise Gevia platforms with Vercise Cartesia Directional Lead are not available for use or sale in the U.S.

1.1.5 Tesla MR conditional when all conditions of use are met

2. http://www.pdf.org/parkinson_statistics
3. <http://www.webmd.com/brain/dystonia-causes-types-symptoms-and-treatments#1>
4. http://www.medscape.org/viewarticle/740330_3

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