Boston Scientific

Boston Scientific Launches Precision Spectra™ Spinal Cord Stimulator System In The United States

NATICK, Mass., April 12, 2013 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) has received approval by the U.S. Food and Drug Administration and is beginning a limited launch of the Precision Spectra Spinal Cord Stimulator (SCS) System. The Precision Spectra System is the world's first and only SCS system with Illumina 3D™ software and 32 contacts, and is designed to provide improved pain relief to a wide range of patients who suffer from chronic pain. Boston Scientific, the United States market leader in rechargeable SCS devices exiting 2012, is introducing the system at the annual meeting of the American Academy of Pain Medicine in Fort Lauderdale, Florida. Images of the Precision Spectra System can be downloaded here.

More than 100 million Americans suffer from chronic pain. Living in constant pain for an extended period of time can have a devastating impact on quality of life for many patients. Without relief, or the hope for relief, many patients lose the ability to sleep, work and function normally.

Spinal cord stimulators deliver electrical pulses from an implantable pulse generator to leads with stimulating contacts in order to mask pain signals traveling to the brain. The Precision Spectra System features Illumina 3D software designed to improve control of the stimulation field. The software is based on a proprietary computer model that takes into account 3D anatomical structures, including the conductivity of the spinal cord and surrounding tissue. The physician simply selects a desired location on the spinal cord and the programming software creates a customized stimulation field to mask the patient's pain.

"The Precision Spectra System represents a paradigm shift in spinal cord stimulation," said Giancarlo Barolat, M.D., medical director of Barolat Neuroscience in Denver. "The Illumina 3D Software is the first SCS programming technology based on advanced anatomical and scientific principles. When combined with 32 contacts and four lead ports—twice that of any other SCS system—the Precision Spectra technology gives physicians more flexibility to customize therapy for patients."

Until now, SCS systems have offered a maximum of 16 contacts and two lead ports, with each lead port allowing the placement of one lead. Additional lead ports give physicians more flexibility to cover their patients' pain at the time of implant and more flexibility to adapt to changing pain patterns in the future. With more contacts, the Precision Spectra System also offers more coverage of the spinal cord for the management of chronic pain.

"The Precision Spectra System is a major milestone in the advancement of SCS therapy," said Maulik Nanavaty, president of the Neuromodulation business unit at Boston Scientific. "The launch of the Precision Spectra System demonstrates our commitment to bringing meaningful innovations to market that provide more pain relief to a broader spectrum of patients."

INVESTMENT IN CLINICAL STUDIES, NEW PRODUCTS AND INDICATIONS

Boston Scientific expects to make continued investments in clinical studies to further understand the needs of chronic pain patients and has recently begun the following trials:

- OPTIONS Trial: An ongoing prospective, multi-center, single-arm study to further characterize the benefits of having a 32-contact option using the Precision Spectra System.
- MAP Trial: An ongoing cross-sectional, multicenter study to estimate the prevalence of multiple areas of pain in SCS-eligible patients with certain diseases.

In addition to the Precision Spectra System, Boston Scientific has recently launched multiple new products in Europe and the United States, and has received expanded indications in Europe:

- Head-only MRI Conditional CE Mark Approval for the Precision™ Plus SCS System (in the U.S., this is not available for use or sale)
- Peripheral Nerve Stimulation CE Mark Approval for the Precision Plus SCS System (in the U.S., this is not available for use or sale)
- Vercise™ Deep Brain Stimulator System CE Mark approval for Parkinson's Disease (in the U.S., this is an investigational device and not available for sale)
- Infinion™ 16 Percutaneous SCS Lead with U.S. FDA and CE Mark approval

About Boston Scientific

Boston Scientific's Neuromodulation business unit is the innovation leader in implantable pain management technology. Through its investments in technology, clinical science, and world-class service, Boston Scientific Neuromodulation is committed to *Innovation Focused on Pain Relief™*. For more information on SCS, visitChronic Pain Management & Treatment | Pain.com. In 2004, Boston Scientific launched the world's first rechargeable SCS device, the Precision™ System, which was also the world's first 16-contact implantable SCS device. Today, more than 60,000 patients worldwide have been treated using Boston Scientific SCS systems.

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 30 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 new product launches and launch cadence, product development, regulatory approvals, 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.

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