Boston Scientific

Boston Scientific Begins Groundbreaking Clinical Trial Comparing Spinal Cord Stimulation to Spine Reoperation In Patients With Failed Back Surgery Syndrome

EVIDENCE Trial to study Boston Scientific's Precision Plus™ Spinal Cord Stimulator System

NATICK, Mass., May 3 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced the start of patient enrollment in the EVIDENCE Clinical Trial, which compares the therapeutic effectiveness and cost effectiveness of spinal cord stimulation (SCS) therapy to spine reoperation in patients with failed back surgery syndrome (FBSS). The first patient was enrolled by Joseph Buwembo, M.D. and Krishna Kumar, M.D., F.R.C.S.C., at Regina General Hospital in Regina, Saskatchewan, Canada.

EVIDENCE is a randomized, controlled trial enrolling 132 patients at 20 sites worldwide. Patients in the SCS arm of the trial will receive the Boston Scientific Precision Plus™ Spinal Cord Stimulator System.

The trial will examine treatment response rates (leg pain relief with no request for the alternative therapy) at six and 24 months. Successful patient response is defined as having greater than or equal to 50 percent relief of pain in the lower extremities compared to pain levels prior to the intervention.

"The standard approach to patients who continue to have persistent back and leg pain after lumbosacral spine surgery has been to look for another surgical treatment," said Richard B. North, M.D., neurosurgeon at The Sandra and Malcolm Berman Brain and Spine Institute in Baltimore, and Principal Investigator of the trial. "Following the positive, single-center trial we conducted at Johns Hopkins, the EVIDENCE multi-center trial will provide important data on the comparative effectiveness of SCS versus surgical spine reoperation in the management of chronic pain in FBSS patients."

"Ultimately, this study may provide support to shift SCS earlier in the treatment paradigm for patients who suffer chronic pain resulting from FBSS," said Dr. Kumar. "EVIDENCE may also demonstrate the cost effectiveness of SCS compared to reoperation."

"The EVIDENCE trial is the first multi-center, randomized, controlled trial to include rechargeable SCS devices like the Precision Plus System," said Michael Onuscheck, Senior Vice President and President of Boston Scientific's Neuromodulation Division. "We are pleased to sponsor this groundbreaking trial, which will help physicians better understand the treatment options available to patients with FBSS."

About the Precision Plus Spinal Cord Stimulator System

The Precision Plus Spinal Cord Stimulator System delivers electrical signals that travel along nerve fibers through the spinal cord to the brain. The System masks pain signals by delivering doses of electricity to change pain signals into signals that the brain interprets as a pleasant sensation called paresthesia. Spinal cord stimulation is prescribed for patients with chronic pain in the trunk and/or limbs who have not received adequate relief from physical therapy, pain medications, prior surgeries or other methods. The System is indicated for use as an aid in the management of chronic pain in the trunk and/or limbs, including unilateral or bilateral pain associated with FBSS and intractable lower back and leg pain. Patients interested in Boston Scientific's Precision® technology can visit www.ControlYourPain.com for more information.

About failed back surgery syndrome

FBSS is defined as persistent or recurrent pain following one or more lumbosacral spine surgical procedures. The pain associated with FBSS is commonly neuropathic and is often described by patients as shooting or burning. SCS is particularly effective in treating neuropathic pain.

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 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 clinical trials, regulatory approvals, competitive offerings and product performance. 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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