

UK's NICE Recommends Spinal Cord Stimulation for Patients with Chronic Neuropathic Pain

NATICK, Mass., Oct. 27 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) today welcomed an announcement by the U.K.'s National Institute for Health and Clinical Excellence (NICE) recommending the use of spinal cord stimulation (SCS) for patients with chronic neuropathic pain. In its comprehensive final guidance, NICE confirmed that SCS is both safe and clinically effective in these patients. Importantly, NICE also concluded that SCS is cost-effective when used to treat patients with chronic neuropathic pain, despite the use of conservative modeling techniques in the appraisal.

"This is a very positive decision for National Health Service (NHS) patients suffering from chronic neuropathic pain," said Dr. Sam Eldabe, Consultant in Anaesthesia and Pain Management at James Cook University Hospital in Middlesbrough, the U.K. "Overall, this technology appraisal -- and the resulting guidance -- will be an important resource demonstrating the efficacy and cost-effectiveness of SCS as a treatment for chronic pain worldwide."

The recommendation paves the way for better patient access to SCS therapy. The NHS in England and Wales is directed to provide funding and resources for NICE-approved technologies normally within three months of publication date.

The NICE appraisal reviewed the clinical data available for patients with either Failed Back Surgery Syndrome or Complex Regional Pain syndrome(1). It concluded that the trial data provided solid clinical evidence that SCS is an effective treatment for neuropathic pain. As a result, NICE has formally recommended SCS as an effective treatment for adult patients in England and Wales who have suffered chronic pain of neuropathic origin for at least six months, despite conventional medical management.

NICE noted that any medical assessment recommending SCS should involve a multidisciplinary team experienced in treatment of chronic pain and should take into account patient needs and severity of pain. In order to select the appropriate SCS system, patients' stimulation requirements and anticipated longevity of device use should also be considered. SCS is not recommended as a treatment option for adults with chronic pain as a result of ischemia except in a clinical trial setting where it may prove useful in this indication.

Neuropathic pain is a debilitating form of chronic pain resulting from injury to the peripheral or central nervous system. Chronic pain is one of the most underestimated health care problems, with estimates of prevalence varying widely(2). Currently, conventional treatments to alleviate chronic neuropathic pain combine different therapies that may include drugs (such as anti-depressants and opiates), non-pharmacological treatments (such as physiotherapy and acupuncture) or surgical intervention.

Boston Scientific's Precision™ SCS neuromodulation system is engineered to precisely target pain and maintain therapy over time, and it is designed to fit a patient's lifestyle. The small device is implanted under the skin and provides pain relief by delivering electric signals that mask the pain by inducing a tingling sensation. Patients can control their treatment using a remote control device that activates the implant.

"At Boston Scientific, we pride ourselves on delivering innovative treatments that can change patients' lives," said David McFaul, Boston Scientific Senior Vice President, International. "Our Precision spinal cord stimulation system is rechargeable and combines breakthrough technology with features designed to enhance patient convenience. It allows pain specialists to offer cost-effective treatments for chronic pain and help improve the quality of patient care."

The Precision SCS system was launched in the United States in 2004 and in Europe in 2005. To date more than 20,000 Precision SCS systems have been implanted worldwide. The Precision SCS system is distributed by Boston Scientific's Neuromodulation group.

About NICE

The National Institute for Health and Clinical Excellence is an independent organization that provides recommendations on the use of new and existing medicines and treatments in England and Wales. For more information, please visit: [\(http://www.nice.org.uk/\)](http://www.nice.org.uk/).

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: <http://www.bostonscientific-international.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, reimbursement, cost effectiveness, competitive offerings, product performance and our market position. 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 thereafter. 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.

References

1. National Institute for Health and Clinical Excellence (NICE). Spinal Cord Stimulation for chronic pain of neuropathic and ischemic origin. Technology appraisal No. TA-159 (October 2008). London: NICE, 2008.
2. Torrance T, Smith BH, Bennett MI, Lee AJ. The epidemiology of chronic pain of predominantly neuropathic origin. Results from a general population survey. J Pain 2006;7(4):281-9.

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