Boston Scientific

FDA approves Boston Scientific Spinal Cord Stimulator Systems for treatment of non-surgical back pain

Supported by the positive one-year SOLIS randomized control trial results

MARLBOROUGH, Mass., Feb. 6, 2024 -- Boston Scientific Corporation (NYSE: BSX) today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication of the WaveWriter™ SCS Systems for the treatment of chronic low back and leg pain in people without prior back surgery, commonly referred to as non-surgical back pain (NSBP).

″Diagnosing and treating chronic low back pain can be challenging,″ said James North, M.D. Carolinas Pain Institute and principal investigator of the SOLIS trial. ″The new indication for NSBP expands the use of the WaveWriter SCS Systems to patients who have had limited options for treating their lower back pain.″

First-line treatment for people with chronic back pain is usually limited to conventional medical management such as physical therapy and medication, which are not effective for many people. Effective chronic pain management may lead to improved quality of life[i] and reduced opioid use.

″Early and effective intervention with SCS therapy is associated with long-term success and improved outcomes for people living with chronic back pain,″ said Jim Cassidy, president, Neuromodulation, Boston Scientific. ″Today's approval, combined with the recent indication for diabetic peripheral neuropathy, extends the reach of our robust portfolio to help physicians deliver individualized care across a wide spectrum of lower back pain issues.″

The expanded indication is backed by positive one-year data from the SOLIS (SCS as an Option for Chronic Low Back and/or Leg Pain Instead of Surgery) randomized control trial, which met its primary endpoint (≥50% reduction in pain) at three-month interval and demonstrates that the WaveWriter SCS Systems provide significant and sustained pain relief. Followed out to one year, 84% of patients treated with the WaveWriter Systems reported significant pain relief of ≥50% and sustained improvement in their ability to participate in activities of daily living, with a mean 25-point improvement in disability as measured by the Oswestry Disability Index.

For more information about the impact of chronic pain and interventional treatment options, visit **Pain.com**.

About the Boston Scientific Chronic Pain Portfolio

The Boston Scientific portfolio of advanced chronic pain management solutions is designed to deliver lasting relief to improve the quality of life for the millions of people living with pain worldwide. Supported by robust clinical evidence, the comprehensive suite of transformative therapies includes the WaveWriter Alpha™ Spinal Cord Stimulator System, Intracept™ Procedure, Radiofrequency Ablation, and the Vertiflex™ Procedure† to provide safe and effective therapy options that help physicians address the unique needs of their patients.

About Boston Scientific
Boston Scientific transforms lives through innovative medical technologies that improve the health of patients around the world. As a global medical technology leader for more than 40 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 health care. Our portfolio of devices and therapies helps physicians diagnose and treat complex cardiovascular, respiratory, digestive, oncological, neurological and urological diseases and conditions. Learn more at **www.bostonscientific.com** and connect on **LinkedIn** and **X**, formerly Twitter.

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 business plans 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; manufacturing, distribution and supply chain disruptions and cost increases; 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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References:

†Superion™ Indirect Decompression System

[i] Wu A, March L, Zheng X, Huang J, Wang X, Zhao J, Blyth FM, Smith E, Buchbinder R, Hoy D. Global low back pain prevalence and years lived with disability from 1990 to 2017: estimates from the Global Burden of Disease Study 2017. Ann Trans Med 2020; 8(6): 299-313.
