Boston Scientific

Boston Scientific Receives FDA Approval of Spinal Cord Stimulation Therapy for People Living with Diabetic Peripheral Neuropathy

Nearly 50% of American adults living with diabetes will be affected by diabetic neuropathy complications in their lifetime[i]

MARLBOROUGH, Mass., Oct. 11, 2023 -- Boston Scientific Corporation today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication of the WaveWriter Alpha™ Spinal Cord Stimulator (SCS) Systems for the treatment of painful diabetic peripheral neuropathy (DPN), a complication of diabetes that can affect the lower extremities of the body.

Diabetic neuropathy is a type of nerve damage throughout the body, often impacting the nerves in the legs and feet. Over time, high blood sugar (glucose) can injure those nerves and it can lead to symptoms of pain and numbness in the legs, feet and hands. [i] Of the 37.3 million Americans that live with diabetes, or 11.3% of the U.S. population, diabetic neuropathy will affect approximately 50% of adults living with diabetes during their lifetime.[ii] For pain management, there are only a few alternatives, which include pain-relieving medications.

As a non-opioid treatment option, the WaveWriter Alpha SCS Systems are for chronic intractable pain of the lower extremities associated with DPN. The system provides therapy for pain relief by sending mild electric pulses to the spinal cord to interrupt pain signals traveling to the brain.

″The use of SCS to support a subset of the diabetes population is an important advancement for one of the fastest growing chronic conditions in the world,″ said Jim Cassidy, president of Neuromodulation, Boston Scientific. ″This expanded indication is another testament to our commitment to delivering a robust portfolio of interventional pain solutions that provides physicians with more treatment choices to help their patients find relief.″

The WaveWriter Alpha SCS Systems were previously approved by the U.S. FDA in December 2020, for the management of chronic intractable pain of the trunk and/or limbs including unilateral or bilateral pain associated with failed back surgery syndrome, complex regional pain syndrome types I and II, intractable low back pain and leg pain. This approval expands the indications to include DPN of the lower extremities for paresthesia-based stimulation.

For more information about chronic pain, visit Pain.com.

About the Boston Scientific Chronic Pain Portfolio

Where many “one-size fits all” treatments fail to provide long-term relief, Boston Scientific understands that it takes personalized pain relief solutions to improve patient outcomes. The WaveWriter Alpha™ Spinal Cord Stimulator (SCS) Systems include a unified portfolio of four MRI conditional[iii], Bluetooth-enabled rechargeable and non-rechargeable implantable pulse generators to provide uncompromised personalization, and for the first time in SCS, Fast Acting Sub-perception Therapy (FAST™), designed to deliver profound paresthesia-free pain relief in minutes. The systems are supported by the Cognita™ Solutions suite of digital tools for patients and physicians. Other solutions include the Vertiflex™ Procedure[iv], a unique treatment clinically proven to provide long-term relief from pain associated with moderate lumbar spinal stenosis, and the Radiofrequency Ablation (RFA) offerings for physicians to help treat chronic pain with a minimally invasive, non-surgical, outpatient procedure that uses thermal energy to interrupt pain signals at their source.

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 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 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 business plans and product performance and impact and new and anticipated product approvals and launches. 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; manufacturing, distribution and supply chain disruptions and cost increases; and future business decisions made by us and our competitors. New risks and uncertainties may arise from time to time and are difficult to predict. 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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[i] Mayo Clinic. Diabetic neuropathy symptoms. https://www.mayoclinic.org/diseases-conditions/diabetic-neuropathy/symptoms-causes/syc-20371580. Accessed October 5, 2023.
[ii] American Diabetes Association. Statistics about diabetes. https://diabetes.org/about-diabetes/statistics/about-diabetes Accessed October 8, 2023.
[iii] The WaveWriter Alpha™ SCS System provides safe access to full-body MRI scans when used with specific components and the patient is exposed to the MRI environment under the defined conditions in the ImageReady™ MRI Full Body Guidelines for WaveWriter Alpha and WaveWriter Alpha Prime Spinal Cord Stimulator System.
[iv] Superion™ Indirect Decompression System
