Boston Scientific

Boston Scientific Launches WaveWriter Alpha™ Spinal Cord Stimulator Systems In U.S.

SCS portfolio features largest portfolio of full-body MRI conditional devices that combine therapy options for personalized pain relief

MARLBOROUGH, Mass., Jan. 14, 2021 /PRNewswire/ -- Boston Scientific (NYSE: BSX) has announced a limited market release of the WaveWriter Alpha™ portfolio of Spinal Cord Stimulator (SCS) systems. The unified portfolio of four MRI conditional, Bluetooth-enabled rechargeable and non-rechargeable implantable pulse generators (IPGs) provides 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.[i] The systems are supported by the Cognita™ Solutions suite of digital tools for patients and physicians.

Experience the interactive Multichannel News Release here: https://www.multivu.com/players/English/8707353-boston-scientific-wavewriter-alpha-spinal-cord-stimulator-systems/

Chronic pain, defined as continuous and long-term pain lasting more than six months, impacts more than 50 million people in the U.S. with 19.6 million adults experiencing high-impact chronic pain that interferes with daily life or work activities.[ii] SCS therapies provide pain relief by sending mild electric pulses to the spinal cord to interrupt pain signals traveling to the brain. Paresthesia-based therapy provides pain relief with a light tingling sensation while paresthesia-free therapy works without that sensation.

Traditional paresthesia-free therapy can take up to a few days or longer to provide pain relief. Boston Scientific's proprietary FAST therapy is designed to provide immediate paresthesia-free pain relief by targeting a new and distinct SCS mechanism of action revealed through a multi-year research collaboration with Duke University.

"We have found that the specific targeting and stimulation parameters of FAST uniquely engage the surround inhibition mechanism to produce rapid and robust pain relief," commented Warren M. Grill, distinguished professor of biomedical engineering, Duke University. "What sets FAST apart from other forms of SCS is that we understand the underlying mechanism, which helps define clinical practices to optimize patient outcomes."

The WaveWriter Alpha SCS Systems are supported by Cognita Solutions to address common challenges in pain management, including raising awareness about drug-free pain management options, helping patients find local physicians, and helping physicians sustain functional outcomes for patients over the long-term.

"It is with great enthusiasm that we embark on the next era of personalization with the WaveWriter Alpha SCS Systems," said Maulik Nanavaty, senior vice president and president, Neuromodulation, Boston Scientific. "Combined with our family of innovative and proven solutions for the treatment of chronic pain, including the Vertiflex™ Procedure and radiofrequency ablation, we are helping physicians provide treatments that span the continuum of care so patients can find access to the medical support they need to live better lives."

The WaveWriter Alpha SCS Systems were approved by the U.S. Food and Drug Administration in December 2020 and is indicated as an aid in 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.

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. 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.

CONTACTS:

Rochelle Silsbee
Media Relations
(818) 812-7320 (office)
Rochelle.Silsbee@bsci.com

Susie Lisa, CFA
Investor Relations
(508) 683-5565 (office)
BSXInvestorRelations@bsci.com

[i] The WaveWriter Alpha™ and WaveWriter Alpha™ Prime Spinal Cord Stimulator Systems provide safe access to full-body 1.5T MRI scans when used with specific components and 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 Systems

[ii] U.S. Department of Health and Human Services (2019, May). Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations. Retrieved from U. S. Department of Health and Human Services website: https://www.hhs.gov/ash/advisory-committees/pain/reports/index.html

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Additional assets available online: Video (3) Photos (3)

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