

Boston Scientific Receives FDA Approval for WaveWriter Alpha™ Spinal Cord Stimulator Systems

MARLBOROUGH, Mass., December 2, 2020 – Boston Scientific (NYSE: BSX) has received U.S. Food and Drug Administration (FDA) approval for the WaveWriter Alpha™ portfolio of Spinal Cord Stimulator (SCS) Systems. The portfolio, consisting of four MRI conditional,^[i] Bluetooth-enabled implantable pulse generators (IPGs), offers expanded personalization based on patient needs, including rechargeable and non-rechargeable options, and access to waveforms that can cover multiple areas of pain.

Chronic pain, defined as continuous and long-term pain lasting more than six months, impacts more than 50 million people in the U.S. and is the chief cause of disability in American adults.^[ii] SCS therapies provide pain relief by delivering pulses of mild electric current to the spinal cord to interrupt pain signals traveling to the brain.

“We are excited by this earlier-than-anticipated FDA approval for the WaveWriter Alpha SCS Systems which will provide patients with multiple therapy options,” said Maulik Nanavaty, senior vice president and president, Neuromodulation, Boston Scientific. “We look forward to sharing additional details about how our portfolio of SCS devices will usher in a new era of personalization in the treatment of chronic pain during the North American Neuromodulation Society annual meeting.”

Boston Scientific announced the European launch of the WaveWriter Alpha SCS Systems in September 2020. The company expects to commence the U.S. commercial launch during the first half of 2021.

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 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.

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[\[i\]](#) 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

[\[ii\]](#) Institute of Medicine. Relieving pain in America: a blueprint for transforming prevention, care, education and research. Washington, DC: National Academies Press, 2011.

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