# **LUMINA** Data Demonstrate 70 Percent Greater Low Back Pain Relief with Boston Scientific Precision Spectra™ Spinal Cord Stimulator System

MARLBOURGH, Mass., Dec. 11, 2015 / PRNewswire / -- Final results evaluating the Boston Scientific Corporation (NYSE: BSX) Precision Spectra Spinal Cord Stimulator (SCS) System demonstrate that the device provides more than 70 percent greater low back pain relief than with the previous generation Precision Plus SCS System. The study showed a significant decrease in average pain scores sustained over a two-year period. The improved outcomes were achieved using the Precision Spectra proprietary Illumina™ 3D neural targeting algorithm that is designed to enable precise control with simple, point-and-click targeting. These new LUMINA data are being presented this weekend at the 19th Annual Meeting of the North American Neuromodulation Society (NANS) in Las Vegas, Nevada.

"As the LUMINA data show, the Boston Scientific Illumina 3D Algorithm allows me to treat low back pain more consistently and effectively than before," said James North, M.D. of the Carolinas Pain Institute. "These data are impressive because they demonstrate sustained long term pain relief in an all-comers population; we did not exclude the type of challenging patients that physicians see every day."

Boston Scientific will also host a symposium at NANS highlighting the Precision Spectra MultiWave™ technology, which enables delivery of multiple waveforms, including a wide range of burst waveforms and higher rates. Boston Scientific is also the only company to offer a 3D neural targeting algorithm, engineered to deliver precisely the optimal waveform to the right neural target.

"We designed the Precision Spectra SCS System with the flexibility to deliver multiple waveforms using our powerful Illumina 3D™ Algorithm," said Maulik Nanavaty, president, Neuromodulation, Boston Scientific. "These conclusive LUMINA real-world clinical data demonstrate that the Precision Spectra SCS System is a significant advancement for improving the lives of patients with chronic pain."

The LUMINA cohort includes 213 consecutive patients treated with the Precision Spectra System for up to 24 months post-implant (LUMINA Spectra group); 213 consecutive patients treated with the previous generation system, Precision Plus, in a statistically matched comparison with the Precision Spectra System (LUMINA Precision Plus group); and 100 consecutive patients treated with the Precision Spectra System where disability was measured out to 12 months (LUMINA Physical Function group).

Key findings of the study include:

### LUMINA Spectra group

- Sustained and highly significant reduction in overall pain from an average baseline score of 7.17 to 2.94 at 24 months post-implant (N= 169), as measured on the 0-10 numeric rating scale (NRS).
- In a subset of severe patients (8 or greater baseline pain score) with only low back pain (N=38), a
  sustained and highly significant reduction from an average baseline score of 8.60 to 2.98 at 24 months
  post-implant.

## Comparison between the Precision Spectra and Precision Plus groups

• Responder rates (greater than or equal to 50% pain reduction) at 24 months post-implant for the Precision Spectra System were 74% for overall pain, 81% in leg pain only patients and 71% in low back pain only patients. For low back pain, the improvement with Spectra was more than 70% compared to that of the previous generation group (Precision Plus).

# **LUMINA Physical Function group**

• Clinically significant reduction of greater than 20 points in disability (N=100), maintained out to 12 months, as measured by the Oswestry Disability Index.

#### **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 35 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 <a href="https://www.bostonscientific.com">www.bostonscientific.com</a> 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, clinical data, 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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