Boston Scientific

Boston Scientific announces clinical data from chronic pain portfolio at the 2024 American Society of Pain & Neuroscience Conference

Five-year pooled results for Intracept™ Intraosseous Nerve Ablation System demonstrate significant pain and function improvements in patients with vertebrogenic low back pain

MARLBOROUGH, Mass. and MIAMI BEACH, Fla. July 15, 2024 – Boston Scientific Corporation (NYSE: BSX) today announced the presentation of positive five-year pooled results for the Intracept™ Intraosseous Nerve Ablation System that measure outcomes across three clinical trials in the treatment of vertebrogenic low back pain. The data were presented at the sixth annual American Society of Pain & Neuroscience (ASPN) conference, held in Miami Beach, Florida, on July 11-14, 2024.

More than 30,000 patients have now been treated with the Intracept system, which utilizes the only U.S. Food and Drug Administration cleared device for the treatment of vertebrogenic low back pain. This distinct type of pain is caused by damage to vertebral endplates, the interface between the disc and the vertebral body.

"These aggregated five-year results further demonstrate the safety, efficacy and reproducibility of the Intracept system in providing lasting vertebrogenic pain relief," said Ray Baker, M.D., vice president and chief medical officer, Neuromodulation, Boston Scientific. "The data included at ASPN also underscore our focus on delivering a portfolio of clinically proven solutions that transform the lives of patients with chronic pain."

Intracept system: Five-year outcomes from three long-term follow-up studies

Outcomes from a five-year follow-up study of vertebrogenic pain patients treated with the Intracept system utilized the patient-reported Oswestry Disability Index (ODI) and visual analog scale (VAS) compared to a baseline (n=249). Findings included:

- Clinically and statistically significant improvements in pain (measured by VAS on a 0-10 scale) and function (measured by ODI on a 0-100 scale) from baseline to five years
  - 83% of patients reported a ≥ 2-point reduction in VAS from baseline ($p<0.0001$)
  - 78% of patients had a ≥ 15-point reduction in ODI from baseline ($p<0.0001$)
- Nearly 66% of patients had a 50% or more reduction in pain relief ($p<0.0001$)
- Nearly one-third of patients reported being 100% pain free after five years ($p<0.0001$)

In total, 15 abstracts and posters were presented at the 2024 ASPN conference that featured the company's clinical data. Additional data highlights from ASPN include:

U.S. multicenter, observational real-world study of patients using the FAST™ Therapy (Fast-Acting Sub-Perception Therapy) with WaveWriter Alpha™ Spinal Cord Stimulation (SCS) System

Key findings included:

- Patients who preferred the use of FAST Therapy achieved durable and robust pain relief out to 12-months follow up (n=89)
- Outcomes among 289 patients assessed at mean last follow up include:
  - A 5.5-point reduction in numeric rating scale (NRS) pain score, from 7.8 to 2.3 ($p<0.0001$) on a 0-10 scale
- A responder rate of 91% of patients reported a 50% or greater reduction in pain
- A NRS pain score of ≤2 reported in 61% of patients

European observational study clinical outcomes using new FAST-SCS for chronic pain

Outcomes were reported from a multicenter, observational case series of patients permanently implanted with a FAST-enabled SCS system.

- Significant improvements in disability (29-point reduction in ODI) and quality of life were observed in patients assessed at last mean follow up
- In the 12-months and 24-months follow-up visits (n=86 and 52 respectively), those patients had a 5.1 and 5.6-point NRS reduction ($p<0.0001$) in overall pain

Prospective, multicenter study utilizing an SCS system designed to engage surround inhibition using FAST Therapy

Outcomes measured the effectiveness of FAST and additional SCS therapy options for chronic pain in a prospective, multicenter, single-arm clinical study that has enrolled 42 subjects.

- Chronic pain patients treated with FAST achieved significant and durable sub-perception pain relief with associated improvement in disability and satisfaction up to 12-months follow up
- A mean 5-point reduction in verbal rating scale (VRS) for low back pain ($p<0.0001$) at 12-months follow up
- A responder rate of 91% of patients reported a 50% or greater reduction in pain
- The sub-perception pain relief was achieved within minutes of FAST activation; mean time to pain relief (≥50%) is 2.6 minutes

For more information about the impact of chronic pain and interventional treatment options, visithttps://www.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, product performance and impact, and clinical trials. 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, political, competitive, reimbursement and regulatory conditions; manufacturing, distribution and supply chain disruptions and cost increases; disruptions caused by cybersecurity events; disruptions caused by extreme weather or other climate change-related events; labor shortages and increases in labor costs; new product introductions; expected procedural volumes; demographic trends; the closing and integration of acquisitions; intellectual property rights; litigation; financial market conditions; the execution and effect of our business strategy, including cost savings and growth initiatives; 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 ("SEC"), 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, except as required by law. This cautionary statement is applicable to all forward-looking statements contained in this press release.

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*Intracept Procedure = Intracept Intraosseous Nerve Ablation System

† Superion™ Indirect Decompression System

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https://stage.mediaroom.com/bostonscientific/announces-clinical-data-from-chronic-pain-portfolio-at-ASPN-2024