January 18, 2024

Axogen, Inc. Announces Positive Topline Results from REPOSE, a Prospective, Randomized Clinical Trial of Axoguard Nerve Cap

REPOSE® met its primary endpoint of non-inferiority between the pain visual analog scale outcomes for neurectomy with Axoguard Nerve Cap® vs. standard-of-care neurectomy at Month 12.

Axoguard Nerve Cap demonstrated statistical superiority vs. standard-of-care neurectomy in the reduction of total pain reported by participants over the course of follow-up.

ALACHUA, Fla. and TAMPA, Fla., Jan. 18, 2024 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced positive topline results from its REPOSE clinical study comparing standard-of-care neurectomy of symptomatic neuroma to neurectomy and protection of the terminated nerve end with Axoguard Nerve Cap. The post-marketing study met its primary endpoint for reduction in pain as measured by visual analog scale (p-value <0.05).

Additional data analysis found that over the 12-month course of follow-up, the Axoguard Nerve Cap group demonstrated statistical superiority for reduction in the total pain reported by participants compared to the standard-of-care neurectomy group (p-value <0.05).

“We are pleased with the study outcomes and the quality of data gathered in the REPOSE study,” said Lead Investigator Craig Thomajan, DPM, Founder and Managing Partner of Austin Foot & Ankle Specialists. “The data suggest that the addition of Axoguard Nerve Cap to isolate and protect the peripheral nerve ends following a neurectomy is a better treatment option than standard-of-care neurectomy alone for managing symptomatic neuroma pain.”

“This data builds on our body of clinical evidence that supports increased adoption of Axoguard Nerve Cap amongst surgeons and their patients who are seeking solutions that may enhance quality of life following nerve resection to manage chronic neuropathic pain,” commented Karen Zaderej, chairman, CEO, and president. “I am grateful to all study participants and investigators, as well as the Axogen team for their unwavering commitment to delivering improved solutions for patients suffering from peripheral nerve injuries.

About REPOSE®

REPOSE is a multicenter, prospective, randomized, subject blinded comparative clinical trial of standard neurectomy and neurectomy followed by placement of Axoguard Nerve Cap, evaluating recovery outcomes for the treatment of symptomatic neuroma. The post-market study is designed to test for non-inferiority between the pain visual analog scale outcomes for neurectomy with Axoguard Nerve Cap and standard neurectomy. The study design also allows for a sequential test for superiority of neurectomy with Axoguard Nerve Cap, following the non-inferiority analysis.

About Axoguard Nerve Cap®

Axoguard Nerve Cap is a proprietary surgical implant derived from porcine submucosal extracellular matrix that is remodeled during healing and is used to isolate and protect a peripheral nerve end from the surrounding environment to reduce symptomatic or painful neuroma development.

About Axogen

Axogen (AXGN) is the leading Company focused specifically on the science, development, and commercialization of technologies for peripheral nerve regeneration and repair. Axogen employees are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or transection to peripheral nerves by providing innovative, clinically proven, and economically effective repair solutions for surgeons and health care providers. Peripheral nerves provide the pathways for both motor and sensory signals throughout the body. Every day, people suffer traumatic injuries or undergo surgical procedures that impact the function of their peripheral nerves. Physical damage to a peripheral nerve, or the inability to properly reconnect peripheral nerves, can result in the loss of muscle or organ function, the loss of sensory feeling, or the initiation of pain.

Axogen's platform for peripheral nerve repair features a comprehensive portfolio of products that are used across two primary application categories: scheduled, non-trauma procedures and emergent trauma procedures. Scheduled procedures are generally characterized as those where a patient is seeking relief from conditions caused by a nerve defect or surgical procedure. These procedures include providing sensation for women seeking breast reconstruction following a mastectomy, nerve reconstruction following the surgical removal of painful neuromas, oral and maxillofacial procedures, and nerve decompression. Emergent procedures are generally characterized as procedures resulting from injuries that are initially present in an ER. These procedures are typically referred to and completed by a specialist either immediately or within a few days following the initial injury.

Axogen’s product portfolio includes Avance® nerve graft, a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site; Axoguard Nerve Connector®, a porcine submucosa ECM coaptation aid for tensionless repair of severed peripheral nerves; Axoguard Nerve Protector®, a porcine submucosa ECM product used to wrap and protect damaged peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments; Axoguard HA+ Nerve Protector™, a porcine submucosa ECM base layer coated with a proprietary hyaluronate-alginate gel, a next-generation technology designed to enhance nerve gliding and provide short- and long-term protection for peripheral nerve injuries; and Axoguard Nerve Cap®, a porcine submucosa ECM product used to

protect a peripheral nerve end and separate the nerve from the surrounding environment to reduce the development of symptomatic or painful neuroma. The Axogen portfolio of products is available in the United States, Canada, Germany, the United Kingdom, Spain, South Korea, and several other countries.

Cautionary Statements Concerning Forward-Looking Statements

This press release contains “forward-looking” statements as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations or predictions of future conditions, events, or results based on various assumptions and management's estimates of trends and economic factors in the markets in which we are active, as well as our business plans. Words such as “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “projects,” “forecasts,” “continue,” “may,” “should,” “will,” “goals,” and variations of such words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements include the outcome of the REPOSE Clinical study of Axoguard Nerve Cap after full data is available, statements and expectations regarding the adoption of Axoguard Nerve Cap among surgeons and their patients, and statements regarding the use of Axoguard Nerve Cap following a neurectomy being a better treatment option for managing chronic neuropathic pain as compared to standard neurectomy." Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, potential disruptions caused by leadership transitions, global supply chain issues, record inflation, hospital staffing issues, product development, product potential, expected clinical enrollment timing and outcomes, regulatory process and approvals, APC transition timing and expense, financial performance, sales growth, surgeon and product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events, global business disruption caused by Russia’s invasion of Ukraine and related sanctions, recent geopolitical conflicts in the Middle East, as well as those risk factors described under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the most recently ended fiscal year and Part II, Item 1A., “Risk Factors,” for our Quarterly Report on Form 10-Q for the most recently ended fiscal quarter. Forward-looking statements are not a guarantee of future performance, and actual results may differ materially from those projected. The forward-looking statements are representative only as of the date they are made and, except as required by applicable law, we assume no responsibility to publicly update or revise any forward-looking statements.

For more information, visit www.axogeninc.com

Contact:
Axogen, Inc.
Harold D. Tamayo, Vice President of Finance and Investor Relations
htamayo@axogeninc.com

Source: Axogen, Inc.