February 18, 2021

Axogen Sponsored REPOSE℠ Study Completes Pilot Phase Analysis

Pilot study demonstrates clinically significant improvement for subjects with chronic neuropathic pain

ALACHUA, Fla., Feb. 18, 2021 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for damage or transection to peripheral nerves, today announced completion of pilot phase analysis for its REPOSE clinical study.

Analysis of the REPOSE study's 15-subject single arm pilot phase demonstrated that subjects experienced a clinically significant reduction in pain from baseline at each of the 3, 6, 9, and 12 month timepoints following surgical excision of the neuroma and placement of Axoguard Nerve Cap® ($p<0.0001$). Specifically, the study observed a mean reduction in pain of 69 points at 3 months and 80 points at 12 months as measured on the 100-point Visual Analog Scale (VAS). Additionally, subjects experienced clinically meaningful improvements in Fatigue, Physical Function, Sleep Disturbance, Pain Interference, Pain Intensity, and Pain Behavior as measured by the validated PROMIS® questionnaires, and pain medication utilization data showed positive indicators for a reduction of pain medication burden, including opioids, following the procedure.

"Neuroma pain can be a challenging clinical condition to manage, and results from historical treatment options, both surgical and pharmacological, can be limited," said Craig Thomajan, DPM, FACFAS, FAENS, Peripheral Nerve Surgeon at Austin Foot and Ankle Specialists, and the lead clinical investigator for REPOSE. "We are pleased with the early successes from REPOSE and are excited to continue this meaningful study. Access to impactful technologies for the treatment and prevention of symptomatic neuromas offers patients an opportunity for reduced pain and improved quality of life."

"We are pleased that the analysis of this pilot phase clinical data demonstrates the potential impact our Axoguard Nerve Cap can have on symptomatic neuroma pain. The outcomes reinforce the assumptions used in our study modeling and exceed those reported for standard neurectomy," said Karen Zaderej, chairman, CEO, and president. "We believe the comparative phase of the study will support the role of Axoguard Nerve Cap in the management of symptomatic neuroma. We continue to be committed to providing surgeons with clinical evidence advancing the science of nerve repair, including surgical treatments that provide clinically meaningful improvements for patients suffering with chronic nerve pain."

Enrollment in the comparative phase of REPOSE is underway and the company expects

enrollment to be completed in the first quarter of 2022, assuming limited impact from COVID-19.

About REPOSE
A Multicenter, Prospective, Randomized and Subject Blinded Comparative Study of Axoguard Nerve Cap and Neurectomy for the Treatment of Symptomatic Neuroma and Prevention of Recurrent End-Neuroma Pain (REPOSE) is the company's post-market study comparing placement of Axoguard Nerve Cap to standard neurectomy alone for subjects with symptomatic neuroma pain. The study design includes a 15 subject open label pilot phase and up to 86 subjects in a randomized comparative phase. The study requires a one year follow up period for all subjects and is designed to assess changes in pain scores as measured by Visual Analog Scale, quality of life outcomes, medication usage, and subject satisfaction.

About Axoguard Nerve Cap
Axoguard Nerve Cap is 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. Axoguard Nerve Cap provides protection for a peripheral nerve end or stump where repair is unattainable or not desired.

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, including 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 extracellular matrix (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 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; and Avive® Soft Tissue Membrane, a processed human umbilical cord intended for surgical use as a resorbable soft tissue barrier. The Axogen portfolio of products is available in the United States, Canada, the United Kingdom, South Korea, and several other European and international 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. The forward-looking statements may include, without limitation, statements related to the expected impact of COVID-19 on our business, statements regarding our growth, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and educational events. The forward-looking statements are and will be subject to risks and uncertainties, which may cause actual results to differ materially from those expressed or implied in such forward-looking statements. Forward-looking statements contained in this press release should be evaluated together with the many uncertainties that affect our business and our market, particularly those discussed under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K, as amended on Form 10-K/A, for the fiscal year ended December 31, 2019, as well as other risks and cautionary statements set forth in our filings with the U.S. Securities and Exchange Commission. 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, whether as a result of new information, future events, changed circumstances, or otherwise.

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