August 21, 2023

Axogen, Inc. Begins Processing Avance® Nerve Graft at New State-of-the-Art Facility in Dayton, Ohio

ALACHUA, Fla. and TAMPA, Fla., Aug. 21, 2023 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced the successful first week of processing for Avance Nerve Graft at the newly opened Axogen Processing Center (APC), in Dayton, Ohio.

“We are pleased to mark this significant milestone as we begin processing Avance Nerve Graft in our new APC facility,” commented Karen Zaderej, Axogen's Chairman, CEO, and President. “The APC is a world-class tissue processing center that will support our Biologics License Application (BLA) submission in the first half of 2024 and our long-term growth. The BLA will further solidify our leadership in the nerve market, as we continue to provide surgeons and their patients with improved quality-of-life solutions for nerve-related challenges.”

The commencement of Avance processing in the APC is an important step towards the biologics validation that will support the submission of the BLA. The new 107,000 square feet facility includes ISO14644 clean rooms, internal quality labs, a surgeon and tissue agency training lab, and state-of-the-art support systems and redundancies required of high-quality, biologic processes. The APC provides up to three times the current processing capacity and was designed for future growth and expansion.

“The local team in Dayton has done an impressive job in the construction of this world-class processing center,” remarked Todd Puckett, Vice President, Manufacturing. “We have assembled an excellent team of nearly 100 employees who are deeply committed to honoring the gift of tissue donation as we continue to revolutionize the science of nerve repair. We also appreciate our partnership with the State of Ohio, the City of Vandalia, and the Dayton Development Coalition for their support in the development of the APC.”

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 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 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 statements on the timetable for the BLA submission in the first half of 2024, the role of the APC in supporting the BLA submission, future APC capacity and expansion capabilities, and statements on future growth. Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, statements related to the continued impact of COVID-19, global supply chain issues, record inflation, hospital staffing issues, product development, product potential, expected clinical enrollment timing and outcomes, regulatory process and approvals, APC renovation 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, 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. 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.

Contact:
Axogen, Inc.
InvestorRelations@axogeninc.com

Media Inquiries:
Ignacio Guerrero-Ross, Ph.D.
Russo Partners
646.942.5604
ignacio.guerrero-ros@russopartnersllc.com

Source: Axogen, Inc.