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Axogen, Inc. Announces Positive Topline Results from Phase 3 RECON(SM) Study for Avance® Nerve Graft

RECON achieved its Primary Endpoint, a critical milestone toward transitioning Avance Nerve Graft to a licensed biologic and further supporting the expanded adoption of Avance

ALACHUA, Fla. and TAMPA, Fla., May 04, 2022 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, today announced topline results from its RECON Clinical Study comparing Avance Nerve Graft to conduits in digital nerve injuries. The Phase 3 pivotal study met its primary endpoint for the return of sensory function as measured by static two-point discrimination, and the safety profile was consistent with previously published data. This data will support the company's Biologics License Application (BLA) submission in the second half of 2023.

Additional analysis of the study data found:

- Avance demonstrated statistical superiority for return of sensory function (measured by static two-point discrimination) as compared to conduits in gaps greater than 12 mm (p-value 0.021).
- Avance demonstrated statistical superiority for time to recovery of static two-point discrimination as compared to conduits, returning normal sensation* up to 3 months earlier in gaps greater than 10 mm (p-value 0.037).
- Conduit repairs were observed to have an increased likelihood of persistent and unresolved nerve pain with an incidence of 9 (8%) conduit subjects as compared to 2 (2%) Avance subjects.

"I would like to share my appreciation for the RECON investigators and their study teams. Their commitment to the importance of this research was essential in completing a study with this quality of data and rigor of evidence and execution," said Co-Lead Investigator Jonathan Isaacs, MD., Professor and Chair, Division of Hand Surgery Virginia Commonwealth University. "The study data confirmed that as gap lengths increased, Avance returned superior levels of sensation, and this was achieved at earlier time points than those observed for conduits."

"We are thrilled that the RECON study has met its primary endpoint. This is a critical milestone towards transitioning Avance Nerve Graft to a licensed biologic and further supports the expanded adoption of Avance," said Karen Zaderej, chairman, CEO, and

president of Axogen, Inc. “This study will provide Level 1 clinical evidence important to surgeons choosing among treatment options for patients with peripheral nerve injuries. I want to thank all of the participating subjects, clinical sites, investigators, and our Axogen employees who have contributed to this landmark study.”

* Normal Sensation is defined by the Medical Research Council Classification (MRCC) score as S4 or return of static two-point discrimination outcomes of ≤ 6mm.

About RECON
RECON is a multicenter, prospective, randomized, subject and evaluator blinded comparative clinical study of nerve cuffs (manufactured conduits) and Avance® Nerve Graft, evaluating recovery outcomes for the repair of nerve discontinuities. The phase 3 pivotal study is designed to test for non-inferiority between the static two-point discrimination outcomes for Avance Nerve Graft and manufactured conduit. The study design also allows for a sequential test for superiority of Avance Nerve Graft, following the non-inferiority analysis.

About Avance Nerve Graft
Avance Nerve Graft is a biologically active off-the-shelf processed human nerve allograft for bridging severed peripheral nerves without the comorbidities associated with a second surgical site. Avance provides structural guidance for regenerating axons, and revascularizes and remodels into the patient’s own tissue. It is available in a variety of lengths and diameters.

A 2010 written agreement between the FDA and Axogen allows the company to continue marketing Avance as a Human Cells, Tissues and Cellular and Tissue Based Product (HCT/P) while taking the necessary steps to file a Biologics License Application (BLA).

In 2018 the FDA granted a Regenerative Medicine Advance Therapy (RMAT) designation for Avance Nerve Graft. A regenerative medicine therapy is eligible for the designation if it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product has the potential to address unmet medical needs for such a disease or condition. The RMAT designation provides access to a streamlined approval process for regenerative medicine technologies and ensures continued informal meetings with the FDA in support of the BLA for Avance Nerve Graft.

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; 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, 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 impact of COVID-19 on our business, including but not limited to global supply chain issues, hospital staffing challenges and its impact on our business, statements regarding our growth, our financial guidance and performance, product development, product potential, regulatory process and approvals, APC renovation timing and expense, sales growth, product adoption, market awareness of our products, anticipated capital requirements, including the potential of future financings, data validation, expected clinical study enrollment, timing and outcomes, our assessment of our internal controls over financial reporting, our visibility at and sponsorship of conferences and our educational events, regulatory process and approvals and other factors, including legislative, regulatory, political, geopolitical, and economic developments, including global business disruption caused by Russia’s invasion of Ukraine and related sanctions, not within our control. 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 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, 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.

Contact:
Axogen, Inc.
Ed Joyce, Director, Investor Relations

ejoyce@axogeninc.com
InvestorRelations@axogeninc.com

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