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Axogen Inc. Initiates Rolling Submission of Biologics License Application to U.S. Food and Drug Administration (FDA) for Avance Nerve Graft®

ALACHUA, Fla. and TAMPA, Fla., May 16, 2024 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for peripheral nerve injuries, is pleased to announce that it has initiated the rolling submission process with the U.S. Food and Drug Administration for a Biologics License Application (BLA) for licensure of Avance Nerve Graft® on May 15, 2024.

“Today’s milestone represents a significant step in our regulatory transition of Avance Nerve Graft to a biologic,” said Karen Zaderej, chairman, CEO, and president of Axogen, Inc. “I am grateful to our Axogen team and their diligence as we work towards completing the rolling BLA submission process.”

The initial submission to the U.S. FDA includes the complete non-clinical data package for the BLA. Consistent with the agreed schedule, we plan to provide the remaining Clinical and Chemistry, Manufacturing and Controls (CMC) components in the coming months. The rolling submission process allows for the submission of pre-agreed components of the BLA to be submitted as they are completed, which can streamline the regulatory review process.

Avance Nerve Graft was granted a Regenerative Medicine Advanced Therapy (RMAT) designation. The RMAT designation, under the 21st Century Cures Act, aims to streamline the development of regenerative medicine therapies intended for the treatment of serious diseases and life-threatening conditions. 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. RMAT designation provides a number of benefits including FDA guidance on efficient drug development and potential priority review of the BLA. Axogen will request priority review status for this BLA which, if granted, could reduce the standard review timeline from 10 months to the priority timeline of 6 months.

Approximately 45 to 60 days after the final components are submitted, FDA will provide a notification of formal acceptance and the review timeline. We anticipate the BLA filing to be completed in the third quarter of 2024 and we believe the procedural timelines for review combined with the rolling submission process will allow for approval around mid-2025.

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 used across various applications and surgical specialties, including traumatic injuries, oral and maxillofacial surgery, breast reconstruction, and the surgical treatment of pain. These applications encompass both scheduled and emergent procedures. Specifically, scheduled procedures are often pursued by patients seeking relief from conditions caused by a nerve defect or previous surgical interventions. Such procedures include providing sensation for women undergoing breast reconstruction following a mastectomy, nerve reconstruction after the surgical removal of painful neuromas, and oral and maxillofacial procedures, as well as nerve decompression. Conversely, emergent procedures typically arise from injuries that initially present in an emergency room, with specialists intervening either immediately or within a few days following the initial injury. This broad range of applications underscores Axogen’s vital role in addressing diverse patient needs in peripheral nerve repair.

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 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; Avive+ Soft Tissue Matrix™, a multi-layer amniotic membrane allograft used to protect and separate tissues in the surgical bed during the critical phase of tissue repair; 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 markets.
For more information, visit www.axogeninc.com.

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 Company’s statements of its expectations and estimates regarding completion of the rolling BLA submission in the third quarter of 2024, statements of its plan to provide the remaining Clinical and Chemistry, Manufacturing and Controls components of the BLA to the FDA in the coming months, statements of the estimated time of potential BLA approval in mid-2025, and statements of optimism regarding priority review. Actual results or events could differ materially from those described in any forward-looking statements as a result of various factors, including, without limitation, global supply chain issues, hospital staffing issues, product development, product potential, clinical outcomes, regulatory process and potential approvals, 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, potential disruptions due to management transitions, 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.

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