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Axogen RECON(SM) Clinical Study Completes Subject Follow-up

RECON is a pivotal study supporting the Company's Biologics License Application (BLA) for Avance® Nerve Graft

ALACHUA, Fla. and TAMPA, Fla., Sept. 01, 2021 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for damage or discontinuity to peripheral nerves, today announced that the RECON Clinical Study supporting its Biologics License Application (BLA) for Avance Nerve Graft has completed follow-up of study subjects.

RECON reached its enrollment target of 220 subjects in July 2020. The study remains on schedule with a top line study data read-out expected in the second quarter of 2022, followed by filing of the BLA submission in 2023. RECON compares Avance Nerve Graft to manufactured conduits in digital nerve injuries with a primary endpoint of recovery of static two-point discrimination, a measure of sensation, and secondary endpoints for quality of life and subject satisfaction. The BLA will transition Avance Nerve Graft from a human tissue product to a biological product.

"We are pleased to have reached this milestone and thank the study investigators and research teams for their dedication and commitment to this landmark study," commented Karen Zaderej, chairman, CEO, and president of Axogen. "The RECON study is designed to provide Level 1 clinical data for our BLA, and will provide additional evidence for surgeons in their clinical decision making for the repair of peripheral nerve injuries."

About the RECON Clinical Study

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 September 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.

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