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Avance® Nerve Graft Receives Regenerative Medicine Advanced Therapy (RMAT) Designation

RMAT Designation reinforces clinical significance of RANGER® registry data and acknowledges the unmet need for improved nerve repair solutions

ALACHUA, Fla., Oct. 29, 2018 (GLOBE NEWSWIRE) -- AxoGen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for damage or discontinuity to peripheral nerves, today reported that the U.S. Food and Drug Administration (FDA) has granted the Regenerative Medicine Advanced Therapy (RMAT) designation to Avance® Nerve Graft.

The RMAT designation, under the 21st Century Cures Act, aims to streamline 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.

"We are excited to be one of the select regenerative therapies to have received the RMAT designation, which highlights both the significance of the data within the RANGER® Registry and the unmet medical need for improved therapies to treat nerve injuries," said Karen Zaderej, chairman, CEO, and president of AxoGen. "Avance® Nerve Graft is a biologically active nerve therapy with more than ten years of comprehensive clinical evidence. The RMAT designation is an important milestone as we progress toward our biologics license application (BLA)."

AxoGen continues to enroll its Pivotal Study, RECON, under the Investigational New Drug (IND) program and anticipates enrollment to be complete by the end of 2018. RECON is the Company's prospective, randomized study in support of the BLA submission, and is expected to enroll 170 patients upon completion.

To streamline the development and approval of regenerative medicine therapies, the RMAT designation provides a pathway for increased interactions with the FDA. In addition, designated therapies may be eligible for priority review and accelerated approval based on surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of clinical sites. For more information on the RMAT designation, please visit:

<https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm537670.htm>.

About AxoGen

AxoGen (AXGN) is the leading company focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair. We are passionate about helping to restore peripheral nerve function and quality of life to patients with physical damage or discontinuity 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, an 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 Avive[®] Soft Tissue Membrane, a minimally processed human umbilical cord membrane that may be used as a resorbable soft tissue covering to separate tissue layers and modulate inflammation in the surgical bed. Along with these core surgical products, AxoGen also offers AcroVal[®] Neurosensory & Motor Testing System and AxoTouch[®] Two-Point Discriminator. These evaluation and measurement tools assist health care professionals in detecting changes in sensation, assessing return of sensory, grip, and pinch function, evaluating effective treatment interventions, and providing feedback to patients on peripheral nerve function. The AxoGen portfolio of products is available in the United States, Canada, the United Kingdom, 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," 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 regarding our assessment on our internal control over financial reporting, our growth, our 2018 and 2019 guidance, product development, product potential, financial performance, sales growth, product adoption, market awareness of our products, data validation, our visibility at and sponsorship of conferences and educational events. The forward-looking statements are subject to risks and uncertainties, which may cause results to differ materially from those set forth in the statements. Forward-looking statements in this release should be evaluated together with the many uncertainties that affect AxoGen's business and its market, particularly those discussed in the risk factors and cautionary statements in AxoGen's filings with the Securities and Exchange Commission. Forward-looking statements are not guarantees 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 law, AxoGen assumes no responsibility to update any forward-looking statements, whether as a result of new information, future events, or otherwise.

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