April 22, 2019

Axogen, Inc. Announces Completion of Planned Interim Analysis and One-Time Enrollment Expansion for RECON® Study

Company to Expand Enrollment by 50 Subjects to Support Planned Power of the Study

ALACHUA, Fla., April 22, 2019 (GLOBE NEWSWIRE) -- Axogen, Inc. (NASDAQ: AXGN), a global leader in developing and marketing innovative surgical solutions for damage or transection to peripheral nerves, today announced completion of the planned blinded interim analysis for its RECON Study. The study will support the submission of a Biologic License Application (BLA) to the FDA for Avance® Nerve Graft.

The FDA-approved RECON Study design includes a Statistical Analysis Plan that outlines a blinded interim analysis of the pooled standard deviation for the primary endpoint measure from the first 80 enrolled subjects. The pooled standard deviation is a key statistical assumption used to determine the appropriate sample size for the study. This interim analysis, conducted by the study's independent statistician, was designed to allow for an increase in the study size if the pooled standard deviation of the first 80 subjects differed from the original study estimate. The analysis only assessed the pooled standard deviation and did not assess variability between the two study groups or include an interim look at study results.

Based on the results of the interim analysis, the study's independent biostatistician recommended continuation of the study with a one-time expansion in enrollment according to a pre-defined sample size re-estimation. The recommendation was reviewed with the FDA, and on April 19, 2019, the FDA provided the company with a Revised Special Protocol Assessment Agreement which confirms the expanded sample size and allows for an increase in the number of study centers.

The study enrollment target will be increased by 50 subjects to a total target of 220 subjects. Axogen may add up to five new study centers, for a total of 25 centers, to support enrollment. During the next few months, Axogen will restart enrollment of subjects with its existing centers and begin recruitment of new centers. Based on anticipated site start-up and historical study enrollment, the Company expects to complete enrollment during the summer of 2020.

RECON is Axogen's phase three pivotal study comparing Avance Nerve Graft to synthetic conduits. The study requires a one year follow up period for all subjects and is designed to assess return of sensation in digital nerve injuries as well as quality of life outcomes and

subject satisfaction.

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 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 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,” “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 regarding our assessment of our internal controls over financial reporting, our growth, or 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 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 discussed under Part I, Item 1A., “Risk Factors,” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, 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.

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