Axogen Announces Publication of the 100th Peer-Reviewed Clinical Paper Featuring its Product Portfolio for Peripheral Nerve Repair

Publications provide evidence of positive outcomes with Axogen’s products in sensory, mixed and motor nerves, and in short and long gap nerve injuries across an expanding set of applications

ALACHUA, Fla., July 26, 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 publication of the 100th peer-reviewed paper featuring results from clinical studies involving its product portfolio.

The latest paper, Inferior Alveolar Nerve: To Graft or Not to Graft in Ablative Mandibular Resection? by Maryam Akbari, DMD, MPH, MD, and Michael Miloro, DMD, MD was published in the Journal of Oral and Maxillofacial Surgery (J Oral Maxillofac Surg 77:1280-1285, 2019). The study explored factors that influence nerve repair in mandible reconstruction and offered techniques and treatment recommendations on how to incorporate nerve repair into the reconstruction. It joins a robust list of publications which represent a depth of clinical evidence from both sponsored and independent investigator studies that cover a range of nerve repair applications including extremity trauma, oral and maxillofacial reconstruction, breast reconstruction neurotization, and repair following the removal of painful neuromas.

“We are pleased to reach this important milestone, which reinforces Axogen’s ongoing commitment to advancing clinical evidence in peripheral nerve repair and provides evidence of positive outcomes with our portfolio of products,” commented Karen Zaderej, chairman, CEO, and president of Axogen. “We appreciate and share the passion surgeon investigators have for improving clinical outcomes and quality of life for patients with peripheral nerve damage.”

Research findings were shared over the past ten years in over 40 different peer-reviewed scientific journals and academic publications including The Journal of Hand Surgery, Journal of Oral Maxillofacial Surgery Microsurgery, Regenerative Medicine, and Annals of Plastic Surgery. Studies of Avance® Nerve Graft show positive outcomes while eliminating the donor site comorbidities associated with autograft.

The library of 100 publications, spanning the use of Avance Nerve Graft and the Axoguard® family of products, includes:

- Research from nearly 300 surgeon and clinical investigators;
- More than 90 independent non-sponsored papers, which highlights growing surgeon interest and acceptance of the Axogen portfolio of products;
- Repair of digital nerves in 37 publications and repair of mixed and motor nerves in 29 publications, with consistent results in short and long gap nerve injuries and sensory, mixed and motor nerve repairs;
- 18 publications in oral and maxillofacial reconstruction, a growing surgical application; and
- Six publications featuring data reports from the RANGER® Study, with an 85% overall meaningful recovery rate across all nerve repairs in the study.

“Favorable results have been replicated across both sponsored and independent investigator studies evaluating our technology,” said Zaderej. “We are proud of Axogen’s role in revolutionizing the science of nerve repair, and we will continue to sponsor clinical research and pursue new products and applications where we believe we can make a
meaningful difference.”

To learn more about clinical research in peripheral nerve repair or access the complete bibliography of published papers go to [https://www.axogeninc.com/healthcare-professionals/clinical-research/](https://www.axogeninc.com/healthcare-professionals/clinical-research/). To learn more about how peripheral nerves are injured and repaired, or to view stories from patients affected by nerve damage, go to [https://www.axogeninc.com/patient-stories/](https://www.axogeninc.com/patient-stories/).

**About the RANGER Study**
The RANGER Study, A Multicenter Retrospective Study of Avance Nerve Graft Utilization Evaluations and Outcomes in Peripheral Nerve Injury Repair is an active, multicenter clinical database designed to continuously monitor and collect injury, repair, safety, and outcomes data for peripheral nerve injuries repaired with processed nerve allograft (Avance Nerve Graft), nerve autograft, and manufactured conduits. The study currently includes more than 1,800 Avance® Nerve Graft repairs enrolled in more than 30 centers. The RANGER Study is an Axogen sponsored ongoing open label registry study. Each patient outcome is dependent upon the nature and extent of nerve loss or damage, timing between nerve loss and repair and the natural course of the patient’s recovery.

**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 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, our 2019 guidance, statements regarding our assessment of our internal controls over financial reporting, our growth, 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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