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AxoGen, Inc. Announces Clearance from FDA to Proceed with New Multicenter Comparative Study for Avance® Nerve Graft

Study to compare Company's proprietary processed human nerve allograft to hollow tubes for bridging gaps in peripheral nerve tissue.

ALACHUA, FL, May 4, 2015 – AxoGen, Inc. (NASDAQ: AXGN), a leading medical technology company dedicated to the \$1.6 billion peripheral nerve repair market, announced today that the U.S. Food and Drug Administration (FDA) has given AxoGen clearance to proceed with the "RECON Study" to support an Investigational New Drug Application. The RECON Study is a multicenter, prospective, randomized study to evaluate recovery outcomes of surgical repairs of peripheral nerve discontinuities. The Phase 3 clinical trial will compare AxoGen's Avance® Nerve Graft, an off-the-shelf processed human nerve allograft, to hollow tubes for bridging gaps in peripheral nerve tissue and will support the FDA biologic license application ("BLA") being pursued by the Company.

Pursuant to an enforcement discretion granted by the FDA, Avance® Nerve Graft is currently commercially available while it is transitioned to a biologic product. The FDA provided clearance to AxoGen to proceed with the RECON Study after conducting a period of review of the Study protocols and characterization of Avance® Nerve Graft. The Company intends to move forward promptly with the RECON Study and anticipates that patient enrollment will begin in the second half of 2015.

"We believe that Avance® Nerve Graft will be the first FDA licensed biologic implant for peripheral nerve repair," said Karen Zaderej, AxoGen President and CEO. "The BLA process is rigorous and includes an in-depth review of the basic science, manufacturing, non-clinical testing and clinical outcomes of our human nerve allograft. The transition process has provided AxoGen the unique opportunity to establish the developmental and quality system infrastructure required to earn a biologic product designation while simultaneously executing the commercialization of Avance® Nerve Graft."

About the RECON Study

A Multicenter, Prospective, Randomized, Subject and Evaluator Blinded Comparative Study of Nerve Cuffs and Avance® Nerve Graft Evaluating Recovery Outcomes for the Repair of Nerve Discontinuities (RECON), is a Phase 3 clinical trial developed under a Special Protocol Assessment to support the transition to a licensed biologic. The RECON Study is

anticipated to begin enrollment in the second half of 2015. Enrollment of 150 subjects is expected to take 2 years with subjects being followed for 12 months after surgery.

About AxoGen, Inc.

AxoGen (NASDAQ: AXGN) is a leading medical technology company dedicated to peripheral nerve repair. AxoGen's portfolio of regenerative medicine products is available in the United States, Canada and several other countries and includes Avance[®] Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed 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 nerves, and AxoGuard[®] Nerve Protector, a porcine submucosa ECM product used to wrap and protect injured peripheral nerves and reinforce the nerve reconstruction while preventing soft tissue attachments.

Avance[®] Nerve Graft is processed in the United States by AxoGen. AxoGuard[®] Nerve Connector and AxoGuard[®] Nerve Protector are manufactured in the United States by Cook Biotech Incorporated, and are distributed worldwide exclusively by AxoGen. AxoGen maintains its corporate offices in Alachua, Florida and is the parent of its wholly owned operating subsidiary, AxoGen Corporation.

For more information about AxoGen or to sign up for our news alerts, please visit www.AxoGenInc.com.

Cautionary Statement 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", 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 growth, market size, product development, product potential, or regulatory activity. 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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