AxoGen, Inc. Announces Presentation of Additional Clinical Data For Avance® Nerve Graft

Expanded enrollment of RANGER® Registry provides insight into comparative outcomes in nerve regeneration.

Alachua, FL (PRWEB) February 25, 2015

AxoGen, Inc. (NASDAQ: AXGN), a leading medical technology company with a unique and innovative portfolio of products used to repair injured peripheral nerves, today announced additional clinical data from the RANGER® Study presented by study investigators during the scientific programs at the recent combined annual meetings of the American Association for Hand Surgery (AAHS), American Society for Peripheral Nerve (ASPN) and American Society for Reconstructive Microsurgery (ASRM) held in January 2015.

During the AAHS, meeting, Dr. Bauback Safa of the Buncke Clinic in San Francisco, CA presented results from a clinical study entitled “Outcomes from an Ongoing Multicenter Registry Study on the Use of Processed Nerve Allograft as Compared to Contemporary Controls for Sensory, Mixed and Motor Nerve Reconstructions”. The study reports on the addition of contemporary control arms, dubbed “MATCH”, to the RANGER® Study. This presentation offered multicenter outcomes data directly comparing Avance® Nerve Graft (processed human nerve allograft) with hollow tubes and autograft nerve tissue (transplanted from another site in the same patient) for repair of gaps of 5-65 mm in peripheral nerve tissue. Outcomes from the RANGER® Study continue to demonstrate the successful use of Avance® Nerve Graft in sensory, motor and mixed nerve repairs. In terms of utilization, autograft nerve tissue tended to be used for repair of larger gaps, hollow tubes utilization was typically limited to shorter gaps however Avance® Nerve Graft was used for repair of both long and short gaps in the nerve tissue. While sensory recovery was reported with all three repair approaches, motor recovery was observed only in repairs performed using autograft nerve tissue and Avance® Nerve Graft.

In a second presentation of clinical data, Dr. Safa presented “Impact of Age on Outcomes in Peripheral Nerve Repair with Processed Nerve Allograft”. In this study investigators analyzed data from the RANGER® Study to determine the impact of patient age on outcomes (109 subjects with 151 nerve injuries). The study analyzed 109 subjects with 151 nerve injuries in three age groups, 18-29, 30-49 and 50 years of age and older and found that overall meaningful recovery rates were 78%, 81% and 91% respectively. While
the groups were fairly evenly divided with respect to gap length, injured nerve type and time to repair, the 18-29 age group included 62% more complex injuries than the 50+ age group. The investigators concluded that patient age did not appear to have significant impact on overall functional outcomes when using Avance® Nerve Graft to repair peripheral nerves.

In a third presentation of clinical data, Dr. Brian Rinker of the University of Kentucky presented “Comparisons of Patient Smoking Status and Functional Recovery Following Peripheral Nerve Repair with Processed Nerve Allograft”. In this study, investigators analyzed data from the RANGER® Registry to determine the impact of patient smoking status on functional recovery outcomes. The study analysis of outcomes from smokers and non-smokers found that while both groups returned meaningful levels of functional recovery, the non-smoking group generally returned higher levels of function compared to the smoking population. Dr. Rinker and the investigator team concluded that while smoking did not impede successful regeneration, smoking did play a role in the ultimate degree of functional recovery attained in the subjects in this study.

“The RANGER® Study now has over 600 nerve repairs enrolled across 18 centers and 40 surgeons and we believe it is the largest clinical study in the surgical repair of peripheral nerve gaps. The increasing size and diversification of the study allows for analysis of the many different factors that impact outcomes,” commented CEO Karen Zaderej. “As the robustness of the RANGER® Study continues to grow, we are seeing advancements in the utility of Avance® Nerve Graft across a variety of clinical challenges in peripheral nerve repair and a shift in the clinical understanding of outcomes.”

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 with 18 contributing centers 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 hollow tubes. As of January 2015, more than 600 nerve repairs enrolled across 18 centers and 40 surgeons. 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. Results presented in the referenced abstracts may not represent typical clinical outcomes for individual patients.

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 European countries and includes Avance® Nerve Graft, an off-the-shelf processed human nerve allograft for bridging severed nerves without the comorbidities associated with an additional 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 exclusively by AxoGen. AxoGen maintains its corporate offices in Alachua, Florida and is the parent of its wholly owned operating subsidiary, AxoGen Corporation.

To learn more about AxoGen, visit our website at http://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, including statements about the closing of the over-allotment option and the AxoGen’s proposed use of proceeds. 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, our product development, product potential, or the intended use of proceeds from the offering. 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.