June 9, 2015

# AxoGen, Inc. Announces Completion of a Pilot Clinical Study Assessing Cavernous Nerve Reconstruction with Avance® Nerve Graft Following Radical Prostatectomy

*Study demonstrates technical feasibility and promising ability to restore erectile function and reduce incontinence.*

**ALACHUA, FL – June 9, 2015** – AxoGen, Inc. (NASDAQ: AXGN), a leading medical technology company focused on the peripheral nerve repair market, announced results from a pilot clinical study of cavernous nerve reconstruction during radical prostatectomy procedures using its Avance® Nerve Graft. Cavernous nerves control erectile function and continence in men and injury to these nerves contribute to some of the troubling complications associated with prostatectomy. AxoGen's Avance® Nerve Graft is an off-the-shelf processed human nerve allograft used throughout the body for bridging gaps in peripheral nerves. The use of Avance® Nerve Graft to repair nerve discontinuities after radical prostatectomy represents yet another potential market for AxoGen's products.

The study titled "Robot Assisted Cavernous Nerve Reconstruction with Avance® Nerve Graft following Radical Prostatectomy" (the "Study") included twelve subjects who had at least one cavernous neurovascular bundle resected and repaired with Avance® Nerve Graft during their prostatectomy and were evaluated up to 24 months post-surgery.

In a radical prostatectomy procedure the goal is to remove cancer cells while protecting erectile function and continence. However, in some cases, to ensure cancer control, the tissue and cavernous nerves surrounding the prostate may be damaged or removed. The ability to repair the nerves at the time of surgery may improve rates of erectile function and continence.

The results of the Study, which confirmed the technical feasibility of nerve grafting using the da Vinci® Robotic Surgical System and Avance® Nerve Graft, may offer hope to patients faced with the prospect of impotence and incontinence following radical prostatectomy. According to the CDC, more than 138,000 men undergo a prostatectomy each year to treat cancer.[1] Unfortunately, long-term outcome studies have shown that fewer than 10% of men undergoing non-nerve sparing (bilateral) surgery recover erectile function. [2,3,4] In unilateral nerve-sparing cases (those in which one neurovascular bundle is preserved), just 33-53% of men experience recovery of erectile function.[2,3,4] Subjects in the Study who underwent unilateral nerve-sparing and had their cavernous nerves repaired using Avance® Nerve Graft, reported a return of erectile function of 70%. Additionally, continence was restored in

75% of the subjects at 3 months, 83% at 12 months and 92% at 24 months.

“With the high rates of impotence and incontinence common in prostatectomy procedures due to injuries to the cavernous nerves, there is a need for a nerve repair solution to address this problem,” commented Karen Zaderej, AxoGen President and CEO. “Historically this damage has been difficult to treat. Previous studies, in which nerve tissue harvested from elsewhere in the patient’s body (autograft nerve) was used to repair cavernous nerves, have shown inconsistent results. This Study demonstrates that our off-the-shelf Avance® Nerve Graft offers urologic surgeons a convenient tool to perform a reliable reconstruction of the cavernous nerves and provides patients and their families with a potential option to improve quality of life after radical prostatectomy. AxoGen’s products provide solutions for peripheral nerve repair and we continue to identify impactful opportunities for their use.

**About the Study**

The Study was a single-center pilot study. The primary intent of this Study was to determine the technical feasibility of robotic assisted cavernous nerve reconstruction with the Avance® Nerve Graft following robotic assisted laparoscopic prostatectomy. Subjects were followed prospectively in a non-controlled fashion to assess safety, functional outcomes and quality of life including rates of erectile function and continence. Overall conclusions from this study are the following;

- It is technically feasible to reconstruct neurovascular bundle using Avance® Nerve Graft during robot-assisted laparoscopic prostatectomy. The procedure poses minimal extra burden to the patient without significantly increasing operative time;

- Recovery of erectile function is promising in patients who had normal pre-op function and underwent unilateral nerve-sparing prostatectomy with per protocol-potency population reporting 70% return of erectile function by IIEF-EF domain scores. The mean time to recovery, IIEF-EF domain score ≥13, was 9 ± 6.5 months;

- Recovery of continence is promising in patients who had normal pre-op function and underwent unilateral nerve-sparing prostatectomy. Continence was restored in 75%, 83% and 92% of subjects by 3, 12 and 24 months after surgery, respectively. The mean time of recovery was 4±6.8 months; and

- There were no reported Avance® Nerve Graft related adverse events.

Future randomized, controlled studies in a larger population may be warranted to further characterize the benefits of neurovascular bundle reconstruction with Avance® Nerve Graft during unilateral or bilateral non-nerve-sparing robot-assisted laparoscopic prostatectomy. Additionally, each patient outcome is dependent upon the nature and extent of nerve loss or damage, the timing between nerve loss and repair, and the natural course of the patient's recovery. The results presented here reflect the experience of particular individuals and may not represent typical results.

Details on the Study are available at[https://clinicaltrials.gov/ct2/show/NCT00953277?term=avance+nerve+graft&rank=4](https://clinicaltrials.gov/ct2/show/NCT00953277?term=avance+nerve+graft&rank=4)

1. CDC National Hospital Discharge Survey, 2010

2. Tal R, Valenzuela R, Aviv N, Parker M, Waters WB, Flanigan RC, Mulhall JP. Persistent Erectile Dysfunction Following Radical Prostatectomy: The Association between Nerve-Sparing Status and the Prevalence and Chronology of Venous Leak.**j** J Sex Med. 2009; 6(10):2813-9.
3. Krishnan R, Katz D, Nelson CJ, Mulhall JP. Erectile function recovery in patients after non-nerve sparing radical prostatectomy. Andrology. 2014; 2(6):951-4.
4. Ayyathurai R, Manoharan M, Nieder AM, Kava B, Soloway MS. Factors affecting erectile function after radical retropubic prostatectomy: results from 1620 consecutive patients. BJU Int. 2008; 101(7):833-6.



**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.

**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.

**Contact:**

**AxoGen, Inc.**
Lee Robert “Bob” Johnston, Chief Financial Officer
386.462.6856
InvestorRelations@AxoGenInc.com