



Axonics® Announces First Commercial U.S. Patient Implanted with its Sacral Neuromodulation System

November 1, 2019

IRVINE, Calif.--([BUSINESS WIRE](#))--[Axonics Modulation Technologies, Inc.](#) (NASDAQ: AXNX), a medical technology company that has developed and is commercializing novel implantable rechargeable [sacral neuromodulation](#) ("SNM") devices, today announced the first U.S.-based implantation of the [Axonics r-SNM® System](#) subsequent to its clearance by the United States Food & Drug Administration ("FDA") in September. Following the completion of customary post-approval regulatory activities, the first implant outside of a clinical study setting was conducted in California on October 29.

"This first patient was a perfect candidate for the Axonics device," said Felicia Lane, M.D., Director of Urogynecology, Obstetrics and Gynecology, University of California, Irvine School of Medicine. "Not only did our patient suffer with urinary and bowel dysfunction most of her adult life, her previously implanted SNM device required replacement due to battery depletion in less than four years. Just three short years after her second implant, the device failed due to a fractured lead wire requiring explantation of the entire system. We took this opportunity to implant the long-lived rechargeable system from Axonics which I consider to be state of the art in sacral neuromodulation. At UCI, we pride ourselves in providing our patients with the most effective and reliable treatments, and the Axonics system is a perfect example."

The Axonics r-SNM System offers a long-lived miniaturized neurostimulator that is approximately the size of a USB stick and is qualified to operate for at least 15 years. Unlike some active implantable devices, the Axonics device can safely be left in place during full-body MRI scans.

The patient, Melissa Der Manouel, said, "The original implant gave me symptom relief and a new lease on life, but having to undergo surgery every few years was physically and emotionally taxing. When I learned about the small rechargeable Axonics device that will work for 15 or more years and is MRI compatible, it was the obvious choice. I'm grateful to have this opportunity to greatly improve my quality of life over the long term."

Recently, Axonics received FDA approval granting the Company the right to market its product in the United States for the clinical indication of fecal incontinence. Additional conditions are under FDA review, including overactive bladder (urinary urge incontinence and urinary urge frequency) as well as urinary retention.

Karen Noblett, M.D., Chief Medical Officer of Axonics, commented, "We believe that Ms. Der Manouel is a typical patient who, given the choice, will more often than not select Axonics. In corporate announcements, we often talk about scientific and commercial milestones, but ultimately, helping patients like Ms. Der Manouel achieve tangible, long-term improvement in her bladder and bowel condition and quality of life is the most rewarding aspect of our work. We look forward to helping thousands of additional patients in the United States gain the same clinical, emotional and economic benefits that the Axonics r-SNM System provides."

About Sacral Neuromodulation

Sacral neuromodulation therapy has been employed to reduce urinary and bowel dysfunction symptoms and restore pelvic floor function for the past two decades. These conditions are caused by a miscommunication between the bladder and the brain and significantly impacts quality of life. Overactive bladder affects an estimated 87 million adults in the U.S. and Europe. Another estimated 40 million adults are reported to suffer from fecal incontinence/accidental bowel leakage. Reimbursement coverage is well established in the U.S. and Europe. The Axonics r-SNM System is the first rechargeable SNM system approved for sale in the world, and the first to gain full-body MRI conditional labeling.

About Axonics Modulation Technologies, Inc.

Axonics, based in Irvine, Calif., has developed and is commercializing novel implantable SNM devices. For more information, visit the Company's website at www.axonicsmodulation.com.

Forward-Looking Statements

Statements made in this press release that relate to future plans, events, prospects or performance are forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995. Words such as "planned," "expects," "believes," "anticipates," "designed," and similar words are intended to identify forward-looking statements. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from the expectations expressed in this press release, including the risks and uncertainties disclosed in Axonics filings with the Securities and Exchange Commission, all of which are available online at www.sec.gov. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Axonics undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

Contacts

Axonics' Contact

Axonics Modulation Technologies, Inc.

Dan Dearen, +1-949-396-6320

President & Chief Financial Officer

ir@axonics.com

Investor & Media Contact

W2Opure

Matt Clawson, +1-949-370-8500

mclawson@w2ogroup.com