Axonics® Announces 2-Year Topline Clinical Results from ARTISAN-SNM Pivotal Study

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IRVINE, Calif.--(BUSINESS WIRE)--Jul. 27, 2020-- Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing novel implantable sacral neuromodulation (SNM) devices for the treatment of urinary and bowel dysfunction, today announced completion of 2-year follow-ups and topline clinical results from its ARTISAN-SNM pivotal study that was conducted to evaluate the safety and efficacy of the Axonics r-SNM System®.

The 2-year study results demonstrate that patients implanted with the Axonics r-SNM System continue to receive clinically meaningful and statistically significant improvements in urinary urgency incontinence symptoms and quality of life. At 2 years, 88% of all implanted patients were therapy responders, consistent with the 89% therapy responder rate reported at 1-year. Eighty percent of patients achieved >75% improvement, with 37% being completely dry. There were no serious adverse or unanticipated device related events.

“The responder rate from the ARTISAN-SNM study continues to be the highest success rate reported in SNM literature and confirms sustained efficacy,” said Karen Noblett, M.D., a board-certified urogynecologist and chief medical officer of Axonics. “Americans with urgency incontinence are undertreated and struggle to find long-term relief. The persistent robust response and patient satisfaction with the Axonics r-SNM System demonstrates that there is an easy to use, highly efficacious treatment available to those suffering from this condition.”

Due to COVID-19, upcoming medical meetings and conferences have been cancelled or restricted to virtual meetings. Detailed study results will be presented to interested parties by study investigators via an Axonics-hosted webinar to be announced in the coming weeks.

ARTISAN-SNM study

The ARTISAN-SNM study is a 129-patient single-arm, prospective, multi-center, unblinded pivotal clinical study to evaluate the safety and efficacy of the Axonics r-SNM System. The study was conducted in 14 centers in the U.S. and five centers in Western Europe. All patients diagnosed with urinary urge incontinence were implanted with a tined lead and the Axonics miniaturized rechargeable neurostimulator in a non-staged procedure. Efficacy data was collected using a 3-day bladder diary, a validated quality of life questionnaire (ICIQ-OABqol), and a subject satisfaction questionnaire. Therapy responders at follow-up were identified as patients with at least a 50% reduction in urinary urgency incontinence episodes compared to baseline. Completion of 2-year follow-ups concludes the ARTISAN-SNM study.

About Axonics Modulation Technologies, Inc.

Axonics, based in Irvine, Calif., has developed and is commercializing novel implantable SNM devices for patients with urinary and bowel dysfunction. 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. The Axonics SNM therapy, which has been clinically proven to reduce symptoms and restore pelvic floor function, is now being offered at hundreds of medical centers across the U.S. and in dozens of select hospitals in Western Europe. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. The Axonics System is the first long-lived rechargeable SNM system approved for sale in the world, and the first to gain full-body MRI conditional labeling. For more information, visit the Company’s website at www.axonics.com.

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