



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

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IRVINE, Calif.--(BUSINESS WIRE)--Sep. 10, 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, has reported full 2-year clinical results from its ARTISAN-SNM pivotal study.

Key clinical results at 2-years include:

- **Responder rate:** 88% of all implanted participants (n=129) were therapy responders at 2-years, defined as a $\geq 50\%$ reduction in urgency incontinence episodes compared to their baseline.
 - Results are consistent with the 89% therapy responder rate reported at 1-year post implant.
 - Completers analysis (n=121) demonstrated 93% therapy responder rate at 2-years post implant.
- **Urinary Urge Incontinence (UUI) episodes:** declined from an average of 5.6 per day at baseline to 1.0 per day at 2-years.
 - 80% of therapy responders had $\geq 75\%$ reduction in their UUI episodes.
 - 37% of therapy responders were dry, having experienced a 100% reduction in their UUI episodes.
- **Quality of life:** participants experienced a clinically meaningful improvement in quality of life as indicated by a 36-point improvement in their ICIQ-OABqol score.
 - 93% of participants reported being “satisfied” with their r-SNM therapy.
 - 93% of participants responded that they would undergo the procedure again to gain the benefit of the therapy.
- **Recharging experience:** all participants reported successful device recharging throughout the 2-year study.
 - 94% of participants reported charging frequency and duration as “acceptable.”
 - 91% of participants reported charging as “easy.”
- **Safety:** there were no serious device-related adverse events.

Detailed study results were presented via webinar by principal investigators Felicia Lane, M.D., FPMRS of University of California, Irvine and Andrea Pezzella, M.D., FPMRS, FACOG of Southern Urogynecology in West Columbia, South Carolina. Interested parties may access the webinar by visiting axonicswebinars.com.

Karen Noblett, M.D., FPMRS, chief medical officer of Axonics, said, “The 2-year responder rate from the ARTISAN-SNM pivotal study is the highest ever reported in SNM clinical literature. The clinically significant and durable symptom relief, ease of recharging, and high degree of satisfaction reported by study participants is being replicated every day in the real world, with over 4,000 patients having been treated with the Axonics System since its introduction into the U.S. market in November 2019. We remain committed to partnering with physicians to increase the awareness and adoption of sacral neuromodulation, which has the potential to significantly improve quality of life for millions of patients suffering from bladder and bowel dysfunction.”

The completion of 2-year follow-ups concludes the ARTISAN-SNM study.

Axonics will continue to add to its growing body of clinical data with the fourth quarter 2020 launch of a multi-center registry study in the United States. The registry will collect additional real-world clinical evidence on performance, safety and patient experience with the Axonics System across all approved clinical indications to advance physician knowledge and patient access to rechargeable sacral neuromodulation therapy.

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 (no external trials) procedure. Pre- and post-implant efficacy data was collected using a 3-day bladder diary, a validated quality of life questionnaire (ICIQ-OABqol), and a 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. Any patient that did not meet the reduction criteria or who dropped out of the study were counted as non-responders. A total of 121 participants completed the 2-year follow-up visit, which 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. 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 www.axonics.com.

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