Axonics® Provides Full One-Year Results from ARTISAN-SNM Pivotal Study at AUGS/IUGA Joint Scientific Meeting

October 3, 2019

Durable Outcomes Highlighted in Plenary Session Presentation; Expanding on Positive Topline Data Released in August
More than 350 Physicians Attended a Symposium Highlighting Hands-on Physician Experience with the Recently FDA-Approved Axonics r-SNM® System[1]

IRVINE, Calif.--(BUSINESS WIRE)--Oct. 3, 2019-- Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing novel implantable Sacral Neuromodulation ("SNM") devices, today announced the presentation of detailed one-year results from its ARTISAN-SNM pivotal study at a plenary session at the joint scientific meeting of the American Urogynecologic Society (AUGS) and the International Urogynecological Association (IUGA). The presentation of positive data, as well as numerous launch activities, highlighted Axonics' first scientific meeting following the FDA clearance of the Axonics r-SNM® System[1] in September 2019.

During the meeting, more than 350 physicians of the approximate 2,000 at the Conference, attended a one-hour symposium at which experienced physician implanters from the ARTISAN-SNM pivotal study discussed their first-hand impressions of the Axonics r-SNM System and post-implant patient feedback. In addition, more than 550 urologists and urogynecologists from the U.S. and abroad, visited Axonics' exhibit and requested follow-up contact from the Company.

ARTISAN-SNM study results were presented on September 28 at a plenary session by Felicia Lane, M.D., Vice Chair, Clinical Affairs, OBGYN, School of Medicine at the University of California, Irvine. The presentation, entitled *"Treatment of urinary urgency incontinence with the Axonics® miniaturized, rechargeable SNM system: Clinical outcomes of the ARTISAN-SNM pivotal study,"* summarized the clinical study 12-month outcomes demonstrating that patients implanted with the Axonics r-SNM System received clinically meaningful and statistically significant improvements in urinary urgency incontinence symptoms and quality of life.

The ARTISAN-SNM study is a 129-patient single-arm, prospective, multi-center, unblinded pivotal clinical study approved under an FDA Investigational Device Exemption to evaluate the safety and efficacy of the Axonics r-SNM System for urinary dysfunction. The study was conducted in 14 centers in the U.S. and five centers in Western Europe. Top-line data was previously released in August 2019.

Key results at 12 months included:

- 89% of the treated patients were therapy responders, defined as a ≥50% reduction in urgency incontinence episodes compared to their baseline. These results are consistent with the six-month results.
- Urgency incontinence episodes across all patients reduced from an average of 5.6 per day at baseline to 1.3 per day at six months
- 77% of the therapy responders had ≥75% reduction in their urgency incontinence episodes, and approximately 30% were dry, having experienced a 100% reduction
- Patients experienced a clinically meaningful improvement in quality of life as indicated by a 34-point improvement in their ICIQ-OABqol score
- 93% of treated patients were satisfied with their r-SNM therapy and 98% said their charging experience was acceptable
- 124 of the 129 patients remained in the study at one-year post-implant
- There were no serious device-related adverse events

"AUGS/IUGA was the first major medical conference at which our U.S. commercial team was on hand to present our system and meet physicians who are experienced at implanting SNM devices – a key milestone and a truly successful event for Axonics," said Raymond W. Cohen, Chief Executive Officer. "We accomplished our objective of establishing broad exposure of the Axonics brand and generating significant interest in our product among top SNM implanters. We were particularly pleased with the attendance at the sponsored symposium which exceeded our expectations. In addition, the

presentation of comprehensive one-year clinical results, which highlighted clinically significant symptom relief to patients, was also well received by the audience of health care providers."

About Axonics Modulation Technologies, Inc. and Sacral Neuromodulation

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. SNM therapy has been employed to reduce symptoms and restore pelvic floor function for the past two decades. Reimbursement coverage is well established in the U.S. and Europe. The Axonics System is the first 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.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

[1] *The Axonics SNM System received FDA approval for the treatment of fecal incontinence on September 9, 2019. Clinical indications for urinary dysfunction are currently under PMA review with the FDA.*

View source version on businesswire.com: https://www.businesswire.com/news/home/20191003005284/en/

Source: Axonics Modulation Technologies, Inc.

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