Axonics® Announces ARTISAN-SNM Pivotal Study Results Presented at the American Urological Association Annual Meeting

May 6, 2019

IRVINE, Calif.--(BUSINESS WIRE)--May 6, 2019-- Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company focused on the development and commercialization of novel implantable Sacral Neuromodulation ("SNM") devices for the treatment of urinary and bowel dysfunction, announced the presentation of positive results from the ARTISAN-SNM pivotal study, designed to gain market approval from the U.S. Food & Drug Administration (FDA) for the Axonics r-SNM® System[1].

ARTISAN-SNM study results were presented on May 5 at the 2019 American Urological Association (AUA) Annual Meeting in Chicago by Professor Howard Goldman, M.D., of the Cleveland Clinic.

The presentation, entitled *"Treatment of urinary urgency incontinence using a novel rechargeable SNM system: 6-month results of the ARTISAN-SNM study,"* summarized the clinical study 6-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 is being conducted in 14 centers in the U.S. and five centers in Western Europe.

Key results at 6-months included:

- 90% of the treated patients were therapy responders, defined as a ≥50% reduction in urgency incontinence episodes compared to their baseline
- Urgency incontinence episodes across all patients reduced from an average of 5.6 per day at baseline to 1.3 per day at 6 months
- 80% of the therapy responders had ≥75% reduction in their urgency incontinence episodes, and 34% 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
- There were no serious device-related adverse events

"The ARTISAN-SNM study has demonstrated that the Axonics r-SNM System is providing clinically significant symptom relief to patients," said Karen Noblett, M.D., Chief Medical Officer of Axonics. "The high levels of patient success and satisfaction exceed historical clinical results for Sacral Neuromodulation. The Axonics r-SNM System, designed to last a minimum of 15-years in the body, is a game-changing solution for physicians and patients as it significantly reduces the need for device replacement surgeries associated with the legacy non-rechargeable implant which has historically been the only SNM system available."

Conference Call and Webcast
As previously announced, the Company will host a conference call with the investment community to discuss 2019 first quarter financial results and recent business developments on Wednesday, May 8, 2019, at 4:30 p.m. Eastern Time.

Interested parties may access the live call via telephone by dialing (866) 687-5771 (U.S.) or (409) 217-8725 (International) and using passcode 7475517. A live webcast of the call may be accessed by visiting the Events & Presentations page of the investors section of the Company's website at ir.axonicsmodulation.com. A replay of the webcast will be available shortly after the conclusion of the call and will be archived on the Company's website for 90 days.

About Overactive Bladder and Sacral Neuromodulation
Overactive bladder (OAB) includes urinary urge incontinence and urinary frequency and affects an estimated 85 million adults in the U.S. and Europe. OAB is caused by a miscommunication between the bladder and the brain and significantly impacts quality of life. SNM therapy is a well-established treatment that has been widely employed to reduce symptoms and restore bladder function and is also employed to treat urinary retention and fecal incontinence. Reimbursement for SNM is well established in the United States and is a covered service in Europe, Canada and Australia.

About Axonics Modulation Technologies, Inc.
Axonics, based in Irvine, CA, is focused on the development and commercialization of a novel implantable SNM system for patients with urinary and bowel dysfunction. The Axonics r-SNM® System is the first rechargeable Sacral Neuromodulation system approved for sale in Europe, Canada and Australia. Premarket approval for the r-SNM System is currently pending with the U.S. Food & Drug Administration. 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.

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[1] The Axonics r-SNM System is currently designated as an investigational medical device

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