Axonics® Announces Publication of ARTISAN Clinical Study Results in the Journal of Urology

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IRVINE, Calif.--(BUSINESS WIRE)--Jul. 29, 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, today announced the results from its ARTISAN-SNM study were published online in the peer-reviewed *Journal of Urology (https://doi.org/10.1097/JU.0000000000000458)*.

This is the first journal publication to detail outcomes for patients in the United States treated with a rechargeable sacral neuromodulation system. The study, conducted under a U.S. Food & Drug Administration (FDA) Investigational Device Exemption ("IDE"), found that 90% of all implanted patients with the Axonics r-SNM® System had successful therapy outcomes.

Rebecca McCrery, M.D., an ARTISAN-SNM study investigator and urogynecologist at Adult Pediatric Urology & Urogynecology in Omaha, NE, commented, "The ARTISAN-SNM results provide the highest response rate for Sacral Neuromodulation seen in the clinical literature. These results are reflective of the benefits of the Axonics miniaturized rechargeable system and recent improvements in Sacral Neuromodulation techniques. Publication of the results in the *Journal of Urology* underscores the quality of the study and the interest among the physician community in innovative treatment options for patients suffering from urinary incontinence and bowel dysfunction."

The ARTISAN-SNM study evaluated the safety and efficacy of the Axonics r-SNM System in 129 patients suffering from Urinary Urgency Incontinence. The article details the 6-month study results including:

- 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 *Journal of Urology* is the official journal of the American Urological Association and is widely read and cited," said Raymond W. Cohen, CEO of Axonics. "Publication in this peer-reviewed journal means the ARTISAN-SNM results are now available to current SNM implanters and the urology community at large. As we anticipate FDA approval in the United States in the coming months, this publication will be an aid in helping us reach our target clinical audience regarding the performance of the Axonics r-SNM System."

About Overactive Bladder and Sacral Neuromodulation

Overactive bladder (OAB) includes urinary urge incontinence and urinary frequency and affects an estimated 87 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 and the first SNM system to gain full-body MRI conditional labeling in Europe. 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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