Axonics® Announces 1-Year Top-Line Clinical Results from its ARTISAN-SNM Pivotal Study

August 1, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Aug. 1, 2019-- Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing a novel implantable Sacral Neuromodulation ("SNM") device for the treatment of urinary and bowel dysfunction, today announced completion of 1-year follow-ups and top-line clinical results from its ARTISAN-SNM pivotal clinical study conducted under an U.S. Food & Drug Administration ("FDA") Investigational Device Exemption ("IDE") designed to evaluate the safety and efficacy of the Axonics r-SNM® System[1].

The study results at 1-year 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 1-year, 89% of all implanted subjects were therapy responders, consistent with the 90% therapy responder rate reported at 6-months. There were no serious adverse device related events or unanticipated device related events. The results at 1-year show consistent symptom decrease, quality of life improvement, and patient satisfaction as the previously reported 6-month study results.

Karen Noblett, M.D., Chief Medical Officer of Axonics said, "The responder rate from the ARTISAN-SNM study is the highest success rate reported in SNM literature and confirms sustained efficacy. Analyzing all implanted subjects is the most rigorous form of data analysis and makes the results that much more impressive."

Detailed study results are planned to be presented at the American Urogynecologic Society (AUGS), International Urogynecological Association (IUGA) congress being held from September 24 - 28, 2019 in Nashville.

ARTISAN-SNM: 1-Year Responder Rate

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. An as-treated analysis was performed for all patients. At 1-year, 89% of all implanted subjects were therapy responders.

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 novel implantable SNM devices 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.

[1] The Axonics r-SNM System is currently under PMA review by the FDA and designated as an investigational medical device

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