Axonics® Submits Pivotal Clinical Data to U.S. Food & Drug Administration for its Sacral Neuromodulation System

February 26, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Feb. 26, 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 submission of pivotal clinical data from the ARTISAN-SNM pivotal clinical study designed to gain marketing approval from the U.S. Food & Drug Administration ("FDA") for the Axonics r-SNM® System [1].

The ARTISAN-SNM study is a 129-patient single-arm, prospective, multi-center, unblinded pivotal clinical study approved under an FDA Investigational Device Exemption ("IDE") 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 5 centers in Western Europe. All patients reached their six-month, post-implant primary endpoint in January 2019.

As the Company announced on February 19, 2019, the clinical study demonstrated that patients implanted with the Axonics r-SNM System received clinically meaningful and statistically significant improvements in Urinary Urgency Incontinence ("UUI") symptoms and quality of life. Additionally, the study met all primary and secondary endpoints. No serious device-related adverse events have been reported.

The Clinical Study Report ("CSR") was submitted to the FDA on February 21, 2019 as an amendment to the Company's premarket approval ("PMA") application. The CSR provides safety and efficacy results and a detailed analysis of the full cohort of all implanted patients at the six-month post-implant endpoint.

Raymond W. Cohen, CEO of Axonics, commented, "The six-month clinical results from our ARTISAN-SNM pivotal study add to the significant body of evidence that we have submitted and is currently under review at the FDA. Based on ongoing dialogue with the agency, we determined it was advantageous to continue to enrich the current PMA. Our filing strategy is consistent with our primary objective which is to obtain U.S. FDA approval of our r-SNM System in the most efficient and expeditious manner."

ARTISAN-SNM Top-Line Results

All patients diagnosed with UUI and meeting study criteria were implanted with a tined lead and the Axonics neurostimulator. Efficacy data was collected using a 3-day bladder diary, a validated quality of life questionnaire (ICIQ-OABqol), and a satisfaction questionnaire. Therapy responders were identified as patients with at least 50% reduction in urgency incontinence episodes at follow-up visits as compared to baseline. An as-treated analysis was performed for all 129 implanted patients. At six months, 90% of all implanted patients were therapy responders including 80% of therapy responders with a ≥75% reduction in urgency incontinence episodes of which 34% were completely dry. Across all patients, urgency incontinence episodes per day reduced from 5.6 ± 0.3 (mean ± standard error) at baseline to 1.3 ± 0.2 at six months ($p<0.0001$). Patients averaged statistically and clinically significant improvement on the composite ICIQ-OABqol score (34 points) at six months as compared to baseline and 93% of all implanted patients were satisfied with their r-SNM therapy.

Premarket Approval (PMA) Status with the U.S. FDA

Axonics filed a PMA application with the FDA in early December 2018 and interim clinical data from the ARTISAN-SNM study the same month. The ARTISAN-SNM CSR was submitted on February 21, 2019. The clinical data disclosed herein has not yet been reviewed by the FDA. Axonics does not anticipate that the filing of the full cohort of six-month clinical data will significantly impact the FDA's standard 180-day PMA review timeline required to complete its review and issue a decision letter.

Conference Call and Webcast

As previously announced, the Company will host a conference call with the investment community to discuss 2018 fourth quarter and full-year financial results and recent business developments, including clinical data from the ARTISAN-SNM study, on Tuesday, March 5, 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 3386378.

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 urgency 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 and the first SNM system to gain CE mark for full-body MRI conditional labeling. PMA approval for the r-SNM System is currently pending with the U.S. FDA. 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 designated as an investigational medical device in the U.S.

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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