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

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IRVINE, Calif.--(BUSINESS WIRE)--Jan. 2, 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 interim clinical data from the ARTISAN-SNM pivotal clinical study to the U.S. Food & Drug Administration ("FDA").

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 [1] for urinary dysfunction.

This interim clinical data was submitted as a supplement to the Company's previously filed "literature-based" premarket approval application ("PMA"). The interim analysis was conducted in accordance with a revised statistical analysis plan using an Intent to Treat ("ITT") analysis of a partial cohort of all implanted subjects that have reached their six-month post-implant time point. The clinical study report, filed with FDA, provides safety and efficacy results from an early-look analysis in 60 implanted subjects, including 59 patients that have reached the six-month primary endpoint and one explanted patient.

Enrollment for the ARTISAN-SNM study was completed in June 2018 and all patients have now reached their six-month, post-implant primary endpoint.

Raymond W. Cohen, CEO of Axonics, commented, "On December 7, 2018, the FDA authorized an interim analysis of a partial ITT cohort from our ARTISAN-SNM pivotal study. Given that, we determined it was advantageous to enrich our current literature-based PMA currently under review by the FDA. We are in the process of analyzing the full ARTISAN-SNM cohort of patients and maintain the option to submit a traditional PMA in Q1 2019. Our strategy is intended to obtain PMA approval of our r-SNM System through the most expeditious route."

Axonics filed the literature-based PMA on December 3, 2018. As is the case with a traditional PMA, the FDA has at least 180 days to review and decide whether or not to approve the PMA. Axonics anticipates that the FDA will complete a substantive review by early March 2019. Once management responds to any questions that may arise, the FDA will then have another 90 days to complete its review and issue a decision letter.

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 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. The r-SNM System offers a temporary disposable external trial system, a miniaturized and rechargeable long-lived stimulator that is qualified to function for at least 15 years. Also included is a tined lead, as well as patient-friendly accessories such as a charging system optimized for minimal charge time without overheating, a small, easy to use patient remote control and an intuitive clinician programmer that facilitates lead placement and programming. 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 an investigational medical device

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