Axonics® Files for Premarket Approval with U.S. Food & Drug Administration for its Sacral Neuromodulation System

December 4, 2018

IRVINE, Calif.--(BUSINESS WIRE)--Dec. 4, 2018-- Axonics Modulation Technologies, Inc. (NASDAQ:AXNX), a medical technology company focused on the design, development and commercialization of rechargeable implantable Sacral Neuromodulation ("SNM") solutions for the treatment of urinary and bowel dysfunction, today announced that on December 3, 2018, the Company submitted a premarket approval application ("PMA") to the U.S. Food & Drug Administration ("FDA") for the Axonics r-SNM® System, an investigational medical device.

This PMA filing submitted by Axonics is referred to as a "literature-based PMA". While most PMAs are supported by original clinical investigations, in rare cases, literature-based evidence may be accepted as the sole basis for approval of a PMA to establish reasonable assurance of safety and effectiveness when the literature is sufficient, detailed, objective, and directly applicable to the subject device. In this PMA filing, Axonics has submitted existing literature reporting on InterStim II®, manufactured by Medtronic plc, the only currently approved SNM device.

In addition to the technical specifications, testing data and published literature, Axonics included one-year follow-up data from its 51-patient RELAX-OAB European Post-Market Clinical Follow-up study to support the PMA. This PMA filing incorporates all elements of the Axonics r-SNM implantable system as well as the External Trial System and related accessories.

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 the Company responds to any questions that may arise, the FDA will then have another 90 days to complete its review and issue a decision letter. Therefore, the earliest date a final determination is anticipated is June 2019.

Axonics is currently conducting a 129-patient pivotal clinical study, ARTISAN-SNM, under a U.S. Food & Drug Administration Investigational Device Exemption, for urinary dysfunction. On June 27, 2018, Axonics announced completion of the enrollment and implant phase. Axonics anticipates that substantially all patients will reach their 6-month post-implant endpoint on or about January 4, 2019.

Raymond W. Cohen, CEO of Axonics, commented, "This PMA filing gets Axonics on the review clock with the FDA. We believe the filing is robust and provides substantive responses to requests for additional information made by the FDA in May of this year. This filing also includes 1-year clinical follow up data from our European RELAX-OAB study. Given the FDA authorized an interim analysis of a partial cohort of 6-month post-implant safety and effectiveness data from our ongoing ARTISAN-SNM pivotal study for the same device, we have the option to submit this data to the FDA as part of this PMA. Moreover, we also retain the option to submit a traditional PMA in Q1 2019 once our full ARTISAN-SNM cohort reaches the 6-month primary endpoint. This strategy of filing both a literature-based PMA and conducting a pivotal clinical study in parallel provides Axonics with several pathways to ultimately obtain PMA approval of our r-SNM System."

Axonics originally filed the literature-based PMA in January 2018, which underwent a substantive review by the FDA. On May 9, 2018, the FDA responded and requested that the Company submit additional information. In October of 2018, the Company withdrew the PMA in order to allow sufficient time to prepare a thorough response to the questions. The Company refiled the PMA on December 3, which included all of the information previously submitted, as well as the additional information addressing FDA's questions in its May 9, 2018 correspondence. Axonics already underwent a pre-PMA audit by the FDA during 2018 which was completed without findings. Axonics continues to maintain a good working relationship with the FDA and will work interactively and expeditiously with the FDA during this process.

About Overactive Bladder and Sacral Neuromodulation

Overactive bladder (OAB) affects an estimated 85 million adults in the U.S. and Europe. Another approximately 40 million adults are reported to suffer from fecal incontinence. SNM therapy is well-established treatment that has been widely used and reimbursed in Europe and the U.S. for the past two decades.

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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20181204005264/en/

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