Axonics® Announces U.S. Food & Drug Administration Approves Use of Full-Body MRI for Pivotal Study Patients

June 18, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Jun. 18, 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 U.S. Food & Drug Administration (“FDA”) approved the use of full-body magnetic resonance imaging (“MRI”) using 1.5 Tesla MRI scanners for clinical study patients implanted with the Axonics System.

The approval was a result of a supplement filed by Axonics with the FDA under the Investigational Device Exemption (“IDE”) regarding the Company’s ARTISAN-SNM 129-patient pivotal clinical study. The FDA concluded that Axonics provided sufficient data to support full-body MRIs.

Raymond W. Cohen, CEO of Axonics, commented, “Allowing full-body MRI scans for our clinical study patients means that none will have to undergo an explant of their neurostimulator device should they require an MRI. We view this as a very positive step by the FDA that underscores the quality of data that Axonics has submitted to the agency. Given this approval, we are confident that this capability will be included as part of the Axonics SNM System premarket approval (“PMA”) approval, which is anticipated in the second half of 2019.”

The Axonics System[1] is the first rechargeable SNM system approved for sale in Europe, Canada and Australia and is currently under PMA review by the FDA. Axonics offers a long-lived miniaturized neurostimulator that is approximately the size of a USB stick and is qualified to last at least 15 years in the body, as compared to the only competitive device on the market from Medtronic, which requires replacement every 3 to 5 years. The Axonics System also features many other differentiating attributes, including a patented tined lead, a wireless charging system optimized for infrequent charging, a key fob size easy-to-use patient remote control and an intuitive clinician programmer that facilitates lead placement and stimulation programming.

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 the development and commercialization of a novel implantable SNM system for patients with urinary and bowel dysfunction. The Axonics 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 and is designated as an investigational medical device

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