



Axonics® Announces U.S. Food & Drug Administration Approval of Wireless Patient Remote Control with SmartMRI Technology

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IRVINE, Calif.--(BUSINESS WIRE)--Jun. 3, 2020-- Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing novel implantable Sacral Neuromodulation (SNM) devices for the treatment of urinary and bowel dysfunction, today announced U.S. Food & Drug Administration (FDA) approval of its new wireless patient Remote Control with *SmartMRI*™ technology for the Axonics r-SNM® System under a premarket approval (PMA) supplement.

The new Remote Control simplifies the process by which patients can receive a full-body MRI. An MRI technician can perform a simple check using a patient's Remote Control immediately prior to an MRI, avoiding the need for the patient to visit their implanting physician's office or involving personnel from Axonics. The new patient Remote Control with *SmartMRI* technology will be included in all new orders of the Axonics r-SNM System in the United States beginning this month.

The Axonics r-SNM System is approved for 1.5T full-body MRI scans in the United States and both 1.5T and 3.0T full-body MRI scans in Canada and Europe. In April 2020, Axonics submitted a PMA supplement to the FDA for the purpose of gaining full-body MRI conditional labeling for 3.0T MR scanners in the United States. The FDA review of this expansion of labeling is expected to be completed in early Q4 2020.

Raymond W. Cohen, CEO of Axonics commented, "Delivering a superior experience to patients, physicians and their staff has been the key focus of our product development initiatives since Axonics' founding. The introduction of this new patient Remote Control provides for significant convenience and reduces the burden on physician practices. This FDA approval follows the recent approval of both our next generation implantable neurostimulator and programmer and is part of a cadence of product enhancements that we are committed to pursuing."

About Axonics Modulation Technologies, Inc.

Axonics, based in Irvine, Calif., has developed and is commercializing novel implantable SNM devices for patients with urinary and bowel dysfunction. These conditions are caused by a miscommunication between the bladder and the brain and significantly impact quality of life. Overactive bladder affects an estimated 87 million adults in the U.S. and Europe. Another estimated 40 million adults are reported to suffer from fecal incontinence/accidental bowel leakage. SNM therapy has been employed to reduce symptoms and restore pelvic floor function for the past two decades. Reimbursement coverage is well established in the U.S. and Europe. The Axonics System is the first long-lived rechargeable SNM system approved for sale in the world, and the first to gain full-body MRI conditional labeling. For more information, visit the Company's website at www.axonics.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.

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Neil Bhalodkar
Investor Relations
949-336-5293
ir@axonics.com

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