Axonics® Submits Full Body MRI Data to U.S. Food & Drug Administration for its Sacral Neuromodulation System

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IRVINE, Calif.--(BUSINESS WIRE)--Feb. 12, 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 complete test data to the U.S. Food & Drug Administration ("FDA") for the purpose of gaining Conditional Full Body Magnetic Resonance Imaging ("MRI") labeling approval for the Axonics r-SNM® System [1] for urinary and bowel dysfunction. This data was submitted as an amendment to the Company's previously filed premarket approval application ("PMA").

Raymond W. Cohen, CEO of Axonics, commented, "Without this Full Body labeling, any patient requiring an MRI scan on any body part below the head must have their neurostimulator and lead surgically explanted prior to the MRI scan, resulting in loss of an effective treatment, another surgery for the patient and additional cost to the patient and healthcare system. Our robust testing and analyses conclude that Full Body MRI scans can be safely performed on patients with an implanted Axonics r-SNM system."

The Axonics r-SNM System is already approved for head and neck MR scans in Europe, Canada and Australia. CE Mark approval of Full Body MRI conditional labeling for the Axonics r-SNM System is currently pending.

Cohen continued, "We met with the FDA in January 2019 and determined it was advantageous to file an amendment to the current literature-based PMA. The FDA now has all of our MRI test data for both head and full body and we believe that, once PMA approved, our r-SNM System will include conditional labeling for 1.5T MRI scans."

Axonics has performed all the required tests to support Full Body conditional labeling on 1.5T MR scanners for the implantable components of its r-SNM System.

What is MRI Conditional Labeling

MRI is short for Magnetic Resonance Imaging. MR scanners come in different magnet field strengths measured in Tesla or "T", usually between 0.5T and 3.0T. They also come in varying sizes including open and wide-bore. Simplistically, an MR scanner is a very large, strong magnet into which a patient lies. A radio wave is used to send signals to the body of the patient. The returning signals are received and converted into images by a computer attached to the MR scanner. The image quality of an MRI depends on signal and field strength. MRI Conditional Labeling means a product has been tested and demonstrated to pose no known hazards to the patient in a specified MRI environment with specified conditions of use and the results of testing are sufficient to characterize the behavior of the product in the MRI environment. Testing for devices that may be placed in the MRI environment should address magnetically induced displacement force and torque, unintended stimulation, and thermal injury. Other possible safety issues include but are not limited to, image artifact, device vibration, interaction among devices, the safe functioning of the device and the safe operation of the MRI system. Any parameter that affects the safety of the device should be listed and any condition that is known to produce an unsafe consequence must be described.

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 a proven therapy to treat urinary retention and fecal incontinence. Reimbursement for SNM is well established and available in the United States, 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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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