Axonics® Granted Expanded CE Mark Label; First and Only Sacral Neuromodulation System Approved for Use with Full-Body MRI Scans

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IRVINE, Calif.--(BUSINESS WIRE)--Feb. 22, 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, announced today that it has received CE mark approval for 1.5T and 3T full-body magnetic resonance imaging ("MRI") conditional labeling for the Axonics r-SNM® System.

The Axonics r-SNM System is the only implantable SNM system that has received full-body MRI conditional labeling for sale in Europe[1].

Raymond W. Cohen, Chief Executive Officer of Axonics, said, "Without this labeling, any patient requiring an MRI scan on any body part below the head must have their neurostimulator surgically explanted prior to the MRI scan, resulting in an additional surgery for the patient and additional costs to patients and the healthcare system. This authorization of full-body MRI scans in Europe is another important milestone for Axonics, differentiating our technology from the competitive system and further demonstrating the foresight of our engineers and our commitment to invest the time and capital to provide the best possible SNM solution for patients, clinicians and the healthcare system. As announced on February 12, Axonics submitted complete test data to the U.S. FDA for the purpose of gaining Conditional Full Body Magnetic Resonance Imaging labeling approval in the U.S."

Full-body MRI labeling is a significant addition to the many differentiating attributes already offered by the Axonics r-SNM product: a miniaturized and long-lived implantable neurostimulator that is one-third the size of the only competitor and is qualified to last at least 15 years in the body. The Axonics r-SNM System also features, among other things, a fast and safe charging capability with an infrequent charging interval, and a patient-friendly wireless remote control.

"This is a game changer," said Karen L. Noblett, M.D., Chief Medical Officer of Axonics. "Full-body MRI labeling is critical to patients who need, or may anticipate needing, magnetic resonance imaging. This new expanded labeling eliminates a major concern for both groups of patients and will allow more patients to choose SNM to treat their urinary and bowel dysfunction without compromising their quality of life."

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 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 approved for sale in Europe, Canada and Australia. It currently is designated as an investigational medical device in

the U.S.

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