Axonics® Submits PMA Supplement to U.S. Food & Drug Administration to Expand Full-Body MRI Labeling for 3T Scans

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IRVINE, Calif.--(BUSINESS WIRE)--Apr. 6, 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 the submission of a premarket approval (“PMA”) supplement to the U.S. Food & Drug Administration (“FDA”) for the purpose of gaining full-body magnetic resonance imaging (“MRI”) conditional labeling for 3.0T MRI scans.

In September 2019, the FDA approved the Axonics r-SNM® System with full-body conditional labeling for 1.5T MR scanners. Axonics has since performed all the required tests to support a PMA supplement for full-body conditional labeling on 3.0T MR scanners for the implantable components of its r-SNM System. The FDA review timeline for labeling expansion PMA supplements is 180 days.

Raymond W. Cohen, Axonics CEO commented, “The Axonics r-SNM System is already approved for 1.5T and 3.0T full-body MRI scans in Europe. While only approximately 15% of MRI scanners operating in the U.S. are 3.0T, we believe it was a worthwhile investment to conduct the testing and analyses required for this filing and we are confident our PMA supplement will meet all criteria for FDA approval. This submission further demonstrates Axonics’ commitment to continuous innovation for the benefit of patients, clinicians and the healthcare system.”

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 impacts 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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