Axonics® Receives FDA Approval for Third-Generation Implantable Neurostimulator

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IRVINE, Calif.--(BUSINESS WIRE)--Feb. 16, 2021-- 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, has received PMA supplement approval from the U.S. Food & Drug Administration (FDA) for its third-generation implantable neurostimulator (INS).

This marks the sixth FDA approval Axonics has received for a significant product innovation since the company's U.S. commercial launch in November 2019. The FDA previously approved Axonics' second-generation rechargeable INS in April 2020, which extended the recharge interval to one hour each month.

The third-generation INS upgrades the embedded software in the INS and the functionality of the patient remote control. These modifications give patients the ability to make broader stimulation parameter adjustments at home, including selecting a second therapy program that was set post-operatively based on interoperative findings. These enhancements provide an appropriate level of flexibility to maximize symptom relief as patients settle into their everyday lives. This is accomplished while patients continue to benefit from an intuitive, easy to use therapy experience.

Axonics expects to begin shipping the third-generation INS and patient remote control on March 1, 2021.

Raymond W. Cohen, CEO of Axonics, said, “This is another significant upgrade we have made to the Axonics System, underscoring our commitment to continuous innovation that enhances the patient experience. While our long-lived INS device is as close to a 'set it and forget it' therapy, the new features will benefit physician practices in which patients have to travel long distances should they require therapy adjustments. We are confident that continuing to ensure excellent patient experiences will drive significant market expansion in the years ahead and result in SNM therapy becoming the preferred solution for urinary and bowel dysfunction.”

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. Axonics SNM therapy, which has been clinically proven to reduce symptoms and restore pelvic floor function, is now being offered at hundreds of medical centers across the U.S. and in dozens of select hospitals in Western Europe. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. 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 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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Axonics contact:
Neil Bhalodkar
949-336-5293
IR@axonics.com

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