Axonics® Announces U.S. Food & Drug Administration Approval of Next Generation Implantable Neurostimulator

April 14, 2020

New Implantable Neurostimulator Decreases Recharge Interval to Only Once a Month

IRVINE, Calif.--(BUSINESS WIRE)--Apr. 14, 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 U.S. Food & Drug Administration ("FDA") approval of its next generation rechargeable implantable neurostimulator ("INS") for its r-SNM® System under a premarket approval ("PMA") supplement.

This next generation INS decreases how frequently a patient needs to recharge their implanted device to once a month for about one hour[1]. This compares to the current recharging interval which is one hour every two weeks. This new feature will also give patients the option to customize their charging experience, for example, choosing to charge for only 15 minutes once a week or only one hour every two months for those patients at lower stimulation intensity levels. In addition to extending the recharging interval, the enhanced INS will experience virtually no battery degradation over the 15+ year life of the INS due to the reduced charging burden.

The FDA approved the long-lived, rechargeable, full-body MRI compatible Axonics r-SNM System in late 2019, with the first commercial sales occurring in November 2019. The next generation Axonics INS is expected to begin shipping to customers in the U.S. during the third quarter of 2020.

Raymond W. Cohen, CEO of Axonics, commented, "This FDA approval is another example of our commitment to innovation and to creating awareness, particularly among middle-aged women, that sacral neuromodulation is a safe and efficacious treatment for bladder and bowel dysfunction. From our inception, delivering a superior patient experience has been at the forefront of our development efforts. With this objective in mind, we developed a bespoke SNM device that is intuitive, fuss-free, long-lived, MRI full-body compatible, safe and clinically effective. The response by the SNM implanting community and their patients has been exceptional. This is evidenced by the fact that in just five months in the U.S. market, approximately one-third of centers offering SNM therapy are now implanting the Axonics System. We will continue to innovate by adding new embodiments and capabilities to our SNM product offering as well as working with the FDA to expand clinical indications."

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.

[1] Under standard operating conditions.

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Source: Axonics Modulation Technologies, Inc.