



Axonics® Files PMA Supplement with FDA for Fourth Generation Rechargeable Neurostimulator

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IRVINE, Calif.--(BUSINESS WIRE)--May 31, 2022-- Axonics, Inc. (Nasdaq: AXNX), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, has filed a premarket approval supplement with the FDA for its fourth generation rechargeable sacral neuromodulation implantable neurostimulator (INS).

The fourth generation rechargeable INS reduces how frequently a patient needs to recharge their implanted device to only once every six months for one hour.¹ This compares to the current recharging interval of once a month for one hour with the Axonics third generation rechargeable INS. The new INS utilizes the same small 5cc form factor as the Axonics R15™ and is paired with the same tined lead and intuitive, easy to use patient remote control. Axonics expects the new INS to receive FDA labeling for 20 years of useful life in the body.

Axonics anticipates receiving FDA approval for the fourth generation rechargeable INS in the fourth quarter of 2022 and expects to begin shipping the new device to customers in the first quarter of 2023. This filing follows the recent FDA [approval](#) of the Axonics F15™, the company's newly developed, long-lived, recharge-free system, which commenced a comprehensive U.S. commercial launch in [April](#).

"Since Axonics' founding, delivering superior patient experiences has been at the forefront of the company's development efforts," said Raymond W. Cohen, chief executive officer of Axonics. "Our fourth generation INS, which requires recharging just twice per year, represents a significant breakthrough for rechargeable neuromodulation devices and underscores our commitment to continuous innovation for the benefit of patients and clinicians. We are confident that Axonics' keen focus on enhancing the patient experience and increasing public [awareness](#) of sacral neuromodulation has the potential to drive significant market expansion in the years ahead."

About Axonics

Based in Irvine, Calif., Axonics is a global medical technology company that is developing and commercializing novel products for adults with bladder and bowel dysfunction. Axonics recently ranked No. 1 on the 2021 [Deloitte](#) Technology Fast 500™ and the 2022 [Financial Times](#) ranking of the 500 fastest growing companies in the Americas.

Axonics' sacral neuromodulation (SNM) systems provide patients suffering from overactive bladder and/or fecal incontinence with long-lived, easy to use, safe, clinically effective therapy. In addition, the company's best-in-class urethral bulking hydrogel, Bulkamid®, provides safe and durable symptom relief to women with stress urinary incontinence (SUI). Overactive bladder affects an estimated 87 million adults in the U.S. and Europe, with an additional 40 million adults estimated to suffer from fecal incontinence. SUI affects an estimated 29 million women in the U.S. alone. Axonics' clinically proven products are offered at hundreds of medical centers across the U.S. and abroad. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. 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.

¹ Under standard operating conditions.

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