



Axonics Receives FDA Approval for Fourth-Generation Rechargeable Sacral Neuromodulation System

January 31, 2023

IRVINE, Calif.--(BUSINESS WIRE)--Jan. 31, 2023-- Axonics, Inc. (Nasdaq: AXNX), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, today announced that the U.S. Food and Drug Administration has approved the company's fourth-generation rechargeable sacral neuromodulation system.

The newly approved Axonics R20™ neurostimulator is labeled for a functional life in the body of at least 20 years and reduces how frequently a patient needs to recharge their implanted device to just once every 6 to 10 months for only one hour. This compares to the third-generation's recharge interval of once a month for one hour. The Axonics R20 neurostimulator utilizes the same small 5cc form factor as the Axonics R15™ and is paired with the same timed lead and intuitive patient remote control. Axonics plans to commercially launch the product in the United States in March.

"Delivering a superior patient experience has been at the forefront of our sacral neuromodulation development efforts," said John Woock, Ph.D., executive vice president, chief marketing and strategy officer of Axonics. "Patients with overactive bladder tell us that first and foremost, they value efficacy and a long-lived solution to address their chronic condition. The Axonics R20, which requires recharging just twice per year, represents another significant breakthrough for rechargeable neuromodulation devices and underscores our commitment to continuous innovation. We are confident that Axonics' keen focus on the incontinence patient population and increasing public [awareness](#) of sacral neuromodulation has the potential to drive significant market expansion in the years ahead."

About Axonics®

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 2022 [Financial Times](#) ranking of the 500 fastest growing companies in the Americas and No. 4 on the 2022 [Deloitte](#) Technology Fast 500™ following its No. 1 ranking in 2021.

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 "plans," "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.

View source version on businesswire.com: <https://www.businesswire.com/news/home/20230131005339/en/>

Axonics contact:

Neil Bhalodkar
949-336-5293
ir@axonics.com

Source: Axonics, Inc.