Axonics® Files PMA Supplement with the FDA for Non-Rechargeable Implantable Sacral Neurostimulator

June 24, 2021

IRVINE, Calif.--(BUSINESS WIRE)--Jun. 24, 2021-- 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 (PMA) supplement with the FDA for its newly developed, long-lived, non-rechargeable sacral neuromodulation (SNM) implantable neurostimulator (INS).

Axonics has designed its new non-rechargeable SNM system to replicate key features of its currently marketed, FDA-approved rechargeable SNM system, which provides patients with clinically significant, durable symptom relief and high levels of satisfaction.

Once approved, the Axonics non-rechargeable system will be the first fully recharge-free SNM system and have the following attributes:

- **INS type and longevity:** primary cell battery with an expected life of at least 10 years with standard stimulation parameters
- **INS size:** 11 cubic centimeters
- **Stimulation:** constant current
- **MRI compatibility:** full-body with 1.5T and 3.0T scanners
- **Patient remote control:** intuitive, recharge-free key fob featuring *SmartMRI* ™technology
- **Programming:** utilizes proprietary algorithm to recommend the best program

Raymond W. Cohen, chief executive officer of Axonics, commented, “Since the company’s founding, we have focused on developing best-in-class, patient-centric SNM solutions. Our rechargeable system introduced innovations to the SNM category that clinicians and patients had been requesting for years – longevity in the body, MRI compatibility, a miniaturized implant and a fuss-free patient remote control that is easy for patients to use. Our new non-rechargeable system is similarly groundbreaking – a relatively small and thin INS with an expected life in the body that is more than double the competitor’s non-rechargeable device. We are confident that the introduction of our non-rechargeable device will continue to drive market expansion and advance Axonics on its path to SNM market leadership.”

Axonics expects to begin shipping the new non-rechargeable SNM system to customers upon FDA approval, which it anticipates receiving during the first half of 2022.

Karen Noblett, M.D., FPMRS, chief medical officer of Axonics, commented, “The clinical benefits of the product features and technology enhancements Axonics has brought to SNM were demonstrated in our FDA pivotal study, which achieved the highest efficacy ever reported in SNM clinical literature. We anticipate the 10-year life of our non-rechargeable INS will be a very attractive therapy proposition for patients, who will also benefit from the advantages of constant current stimulation and the convenience of an easy to use, recharge-free remote control.”

About Axonics

Based in Irvine, Calif., Axonics is a global medical technology company that is developing and commercializing novel products for patients with bladder and bowel dysfunction. The company’s rechargeable sacral neuromodulation (SNM) system provides patients suffering from overactive bladder and/or fecal incontinence with long-lived, easy to use, safe, clinically effective therapy. In addition, Axonics’ best-in-class urethral bulking agent, Bulkamid®, provides women suffering from stress urinary incontinence (SUI) with safe and durable symptom relief.

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 20 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.

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