Axonics® Announces CE Mark Approval for Implantable Sacral Neurostimulator that Significantly Extends Recharge Interval

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IRVINE, Calif.--(BUSINESS WIRE)--May 18, 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, today announced European CE Mark approval of its second generation Axonics r-SNM® implantable neurostimulator (INS) and wireless patient remote control with *SmartMRI*™ technology.

Axonics previously received U.S. Food & Drug Administration approval for this INS and remote control during 2020. This version reduces how frequently a patient needs to recharge their sacral neuromodulation device to just once a month for about one hour. The newly approved remote control simplifies the process by which patients can receive a full-body MRI, avoiding the need for the patient to visit their implanting physician's office.

"There has been a significant backlog of pending regulatory submissions in Europe due to Covid-19 and the transition to the new European Union Medical Device Regulation, which will become fully applicable later this month," said Rinda K. Sama, chief operating officer of Axonics. "Despite the delay and investment of Axonics' regulatory resources, we are committed to supporting our customers and delivering a superior therapy experience in all markets worldwide where Axonics has an established presence."

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.

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Axonics contact:
Neil Bhalodkar
949-336-5293
ir@axonics.com

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