



## **Axonics® Receives Health Canada Approval of Next Generation Implantable Neurostimulator**

September 21, 2020

IRVINE, Calif.--(BUSINESS WIRE)--Sep. 21, 2020-- Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing novel implantable sacral neuromodulation devices for the treatment of urinary and bowel dysfunction, today announced that Health Canada has approved its next generation rechargeable implantable neurostimulator (INS) for the Axonics r-SNM® System.

The next generation INS approved by Health Canada reduces how frequently a patient needs to recharge their implanted device to once a month for about one hour. Axonics received U.S. FDA approval for this version of its INS in April 2020. Health Canada previously approved the first generation Axonics r-SNM System in January 2017. Axonics is currently the only rechargeable SNM system available in Canada.

"This approval is welcome news for patients in Western Canada suffering from bladder and bowel dysfunction, and reinforces the notion that Axonics is committed to providing the latest technology to all of its customers," said Gary J. Gray, M.D., FRCS, a urologist and clinical professor at the Kipnes Urology Centre in the Department of Surgery at the University of Alberta. "We have implanted over 85 Axonics SNM devices in our center prior to the pandemic and have achieved clinical results that have exceeded our expectations. There is significant unmet need for sacral neuromodulation therapy in Western Canada and we have barely scratched the surface of fulfilling this demand. We look forward to continuing our relationship with Axonics for many years to come."

Raymond W. Cohen, CEO of Axonics, said, "Physician and patient response to our next generation INS has been exceptional since it began shipping to U.S. customers in August. This approval from Health Canada demonstrates our commitment to support Canadian patients who can now benefit from the latest SNM technology. Axonics will continue to invest in innovation and enhancing the patient experience, and given the exceptional clinical results being generated, we are confident our efforts will accrue to SNM becoming the preferred therapy for overactive bladder and bowel dysfunction patients in North America."

### **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. Axonics SNM therapy, which has been clinically proven to reduce symptoms and restore pelvic floor function, is now being offered at hundreds of medical centers across the U.S. and in dozens of select hospitals in Western Europe. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. 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 [www.axonics.com](http://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](http://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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Source: Axonics Modulation Technologies, Inc.