

Health Canada Approves Full-Body MRI Labeling for the Axonics® Sacral Neuromodulation System

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IRVINE, Calif.--(BUSINESS WIRE)--Dec. 2, 2019-- Axonics Modulation Technologies, Inc. (NASDAQ:AXNX), a medical technology company that has developed and is commercializing novel implantable rechargeable sacral neuromodulation ("r-SNM®") devices for the treatment of bladder and bowel dysfunction, today announced Health Canada (Homologation d'un instrument medical) approved the use of full-body magnetic resonance imaging ("MRI") using 1.5 and 3 Tesla MRI scanners for patients implanted with the Axonics r-SNM System.

Axonics previously received Health Canada approval for its complete r-SNM System and related system components in January 2017 and has been marketing in Canada since 2018. The U.S. Food & Drug Administration approved the Axonics r-SNM System for full-body MRI scans for 1.5 Tesla MRI scans in September 2019.

Raymond W. Cohen, CEO of Axonics, commented, "Allowing full-body MRI scans for Canadian patients means that none will have to undergo an explant of their neurostimulator device should they require an MRI. This approval underscores the commitment of Axonics to all patients in North America."

About Axonics Modulation Technologies, Inc. and Sacral Neuromodulation

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. SNM therapy has been employed to reduce symptoms and restore pelvic floor function for the past two decades. Reimbursement coverage is well established in the U.S. and Europe. The Axonics System is the first rechargeable SNM system approved for sale in the U.S., Canada and Europe and the first to gain full-body MRI conditional labeling. For more information, visit the Company's website at 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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