



Axonics® Announces Publication of Fecal Incontinence Study Results for Patients Treated with r-SNM® System

November 10, 2020

Patients experienced significant clinical benefits and satisfaction with recharging and therapy

Clinical outcomes consistent with dual incontinence patients from ARSTISAN pivotal study

IRVINE, Calif.--(BUSINESS WIRE)--Nov. 10, 2020-- Axonics Modulation Technologies, Inc. (NASDAQ: AXNX), a medical technology company that has developed and is commercializing novel implantable sacral neuromodulation (SNM) devices for the treatment of urinary and bowel dysfunction, today announced the publication of fecal incontinence study results for patients treated with the Axonics r-SNM System.

The study results were [published](#) in the peer-reviewed journal *Neuromodulation*, the official journal of the International Neuromodulation Society.

This investigator-initiated study, led by Prof. Stefan De Wachter, M.D., Ph.D., Antwerp University Hospital in Edegem, Belgium and Katleen Jottard, M.D., Brugmann University Hospital in Brussels, consisted of 15 fecal incontinence (FI) patients that were implanted with the Axonics r-SNM System in a single-stage procedure (i.e., no external trial prior to implant).

Key findings of the study include:

- At four weeks, 13 patients (87%) of all implanted patients were therapy responders based on a >50% reduction in FI episodes as documented in their bowel diary.
- Of the 13 responders, 92% were therapy responders at six months post-implant.
- Weekly FI episodes decreased from a median of 8 at baseline to a median of 1.5 at six months, corresponding to a 79% reduction in weekly FI episodes.
- Patients experienced significant clinical benefits and were satisfied with their recharging and overall therapy experience. At six months, 93% of patients indicated that charging was both "easy" and "acceptable."
- There were no unanticipated device or procedure-related adverse events.

Karen Noblett, M.D., a board-certified urogynecologist and chief medical officer of Axonics, said, "Fecal incontinence is a physically and psychologically debilitating condition for patients who often suffer in silence due to embarrassment. The strong outcomes of this study are consistent with Axonics' pivotal study, ARTISAN, in which urinary incontinence patients who also had fecal incontinence experienced significant reductions in FI symptoms and meaningful improvements in quality of life. Axonics congratulates and thanks the study investigators for continuing to expand the body of clinical evidence for bowel dysfunction."

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.

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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Source: Axonics Modulation Technologies, Inc.