Axonics® Announces FDA Approval of Enhanced Neurostimulator Programmer

January 21, 2020

IRVINE, Calif.--(BUSINESS WIRE)--Jan. 21, 2020-- Axonics Modulation Technologies, Inc. (NASDAQ:AXNX), a medical technology company that has developed and is commercializing novel implantable rechargeable Sacral Neuromodulation (SNM) devices for the treatment of bladder and bowel dysfunction, today announced U.S. Food & Drug Administration ("FDA") approval of an enhanced, second-generation Programmer for its r-SNM ® System under a premarket approval ("PMA") application supplement.

The new Programmer is used to program the Axonics external trial neurostimulator as well as the implantable neurostimulator in both the procedure and post-operative environments.

The Programmer is a custom-made tablet with a color touchscreen and an easy-to-use graphical interface and expands on its user-friendly capabilities by streamlining and simplifying the patient programming process.

The Programmer offers, among other things:

- A predictive programming algorithm that translates intra-operative responses and suggests how to program the patient for optimum therapy thereby reducing the need to adjust therapy post-implant
- A fully wireless system that reduces time during surgery and simplifies post-implant device programming
- Tools that facilitate lead placement and programming
- Exportable reports on SNM therapy performance and device usage for both temporary external trials and permanent implants

Raymond W. Cohen, CEO of Axonics, commented, "Axonics is committed to further enhancing our SNM product offerings to ensure physicians have the latest technology available to treat this underserved patient population and develop what we believe is a multi-billion-dollar market opportunity. These innovations will further enable clinicians using the Axonics r-SNM System to identify optimal lead placement during the implant procedure and personalize therapy for each patient. FDA approval of the second-generation Programmer is part of an anticipated cadence of product enhancements in our robust product pipeline."

The long-lived, rechargeable, full-body MRI-compatible Axonics r-SNM System has obtained U.S. FDA approval, European CE Mark approval, Health Canada approval, and Australian Therapeutic Goods Administration approval for the treatment of overactive bladder, urinary retention and fecal incontinence. Axonics launched commercially in the United States following FDA approval in late 2019.

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 representing a potential $6 billion market opportunity. 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. and the first to gain full-body MRI labeling. For more information, please 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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