Axonics® Announces U.S. Food & Drug Administration Approval for its Sacral Neuromodulation System for Urinary Clinical Indications

November 14, 2019

IRVINE, Calif.--(BUSINESS WIRE)--Nov. 14, 2019--

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 the approval of the Axonics r-SNM® System by the United States Food & Drug Administration ("FDA") for the clinical indications of overactive bladder ("OAB") and urinary retention.

The FDA premarket approval ("PMA") grants Axonics the right to market its product in the United States for the clinical indications of OAB (urinary urge incontinence and urinary urge frequency) as well as urinary retention, representing the largest segment of the market for SNM devices. The FDA approval follows the Company's September approval for the clinical indication of fecal incontinence, which, according to published clinical studies, is a co-morbidity reported by as many as a third of patients presenting with urinary urge incontinence.

The FDA approval was supported by the results of a detailed review of technical data and the positive results of the Axonics ARTISAN-SNM 129-patient pivotal clinical study that met all primary and secondary endpoints and demonstrated 90% efficacy for all implanted urinary incontinence patients at six months, as well as published clinical literature.

The Axonics r-SNM System is the first rechargeable SNM system approved for sale in the U.S., Europe, Canada and Australia. It is also the only SNM device approved for patients to undergo full-body MRI scan without the necessity of having the device explanted. The FDA approval includes the claim of a 15-year functional life, which is in contrast to the incumbent company's legacy device which requires replacement on average every four years. In addition to many other differentiating attributes, the system includes a patented tined lead, user-friendly accessories, such as a wireless charging system optimized for infrequent charging, a small easy-to-use key-fob patient remote control and an intuitive clinician programmer that facilitates lead placement and stimulation programming. The long-lived miniaturized neurostimulator is approximately the size of a USB stick.

"If we consider the millions of women who have tried and discontinued OAB pharmaceuticals, the market opportunity for Axonics goes well beyond the approximate $700 million of revenue that is currently being generated by the incumbent's non-rechargeable SNM device," said Raymond W. Cohen, CEO of Axonics. "Based on feedback from U.S. physicians, we believe the SNM market is poised to dramatically expand over the next few years given our fuss-free, highly efficacious, long-lived, full-body MRI compatible device. Our U.S. commercial team of 146 territory managers, clinical support specialists and sales managers rivals the size of the incumbent's field staff, and is focused on calling on the top 1,000 urologists, urogynecologists and colorectal surgeons who account for approximately 80% of the SNM implants in the U.S."

As previously announced, Axonics is hosting a conference call with the investment community today, Thursday, November 14, 2019, at 4:30 p.m. Eastern Time to discuss 2019 third quarter financial results and recent business developments.

Interested parties may access the live call via telephone by dialing (866) 687-5771 (U.S.) or (409) 217-8725 (International) and using passcode 4373989. A live webcast of the call may be accessed by visiting the Events & Presentations page of the investors section of the Company's website at ir.axonicsmodulation.com.

ARTISAN-SNM pivotal study and the PMA approval process with the U.S. FDA

ARTISAN-SNM was conducted at 14 centers in the U.S. and five centers in Western Europe. The study met all primary and secondary endpoints and demonstrated that implanted patients received clinically meaningful and statistically significant improvements in urinary incontinence symptoms and quality of life. At the study endpoint of six months post-implant, 90% of all 129 implanted patients were therapy responders. At one year, the efficacy remained consistent with an 89% responder rate. The vast majority of implanted patients experienced a significant reduction in urgency incontinence episodes and approximately one third were completely dry. No serious device-related adverse events were reported.

After the initial filing in December 2018, the Company filed a number of amendments, including complete test data to support full-body MRI labeling for the implantable components of the Axonics r-SNM System and the full six-month data set from its pivotal study. The FDA conducted two detailed PMA audits of the Axonics quality system and manufacturing during the review period. The audits were completed without any negative observations.

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 world, 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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