Axonics® Announces Agreement to Supply its Sacral Neuromodulation System to The University of Tennessee Medical Center

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IRVINE, Calif. & KNOXVILLE, Tenn.--(BUSINESS WIRE)--Nov. 21, 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 that it has entered into an agreement to supply the Axonics r-SNM® System to The University of Tennessee Medical Center (UTMC) in Knoxville, Tennessee.

UTMC has been implanting SNM devices for more than a decade and is among the first hospitals in the United States implanting the Axonics r-SNM® System for its patients.

The Axonics r-SNM System was recently approved by the U.S. Food & Drug Administration ("FDA") for overactive bladder as well as urinary retention and fecal incontinence. The Axonics long-lived rechargeable implantable device is full-body MRI compatible and provides relief for patients suffering from bladder and bowel function and control issues.

C. Bryce Bowling, MD, FACOG, FACS, a Urogynecologist at UTMC/UT Urogynecology and Division Director of Female Pelvic Medicine & Reconstructive Surgery, said, "UT Medical Center is committed to assisting women who are suffering from pelvic floor disorders. It is unfortunate that this population is suffering and for the most part, unaware there are numerous treatments available to help alleviate symptoms and correct anatomic and neurologic related conditions. We believe that offering the latest technology in sacral neuromodulation is important for our patients. We are impressed with the efficacy results from the ARTISAN-SNM clinical trial and the tangible and significant features of the Axonics r-SNM System, including the long life of the implant and MRI compatibility. Both the urogynecology and urology departments at the medical center are currently implanting the Axonics system. We look forward to working with Axonics for years to come."

ARTISAN-SNM pivotal study

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. No serious device-related adverse events were reported.

About The University of Tennessee Medical Center

The mission of The University of Tennessee Medical Center, the region's only hospital to achieve status as a Magnet® recognized organization, is to serve through healing, education and discovery. UT Medical Center, a 685-bed, not-for-profit academic medical center, serves as a referral center for Eastern Tennessee, Southeast Kentucky and Western North Carolina. The medical center, the region's only Level I Trauma Center, is one of the largest employers in Knoxville. For more information about The University of Tennessee Medical Center, visit online at www.utmedicalcenter.org.

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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