Axonics® Broadens EU Commercial Footprint with Recommendation for Reimbursement in France and Supply Contract in Norway

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IRVINE, Calif.--(BUSINESS WIRE)--Oct. 7, 2019-- Axonics Modulation Technologies, Inc. (NASDAQ:AXNX), a medical technology company that has developed and is commercializing a novel implantable rechargeable sacral neuromodulation ("SNM") system, today announced it achieved two milestones that expand its commercial reach in France and Norway. Specifically, the French Haute Autorité de Santé ("HAS") published a positive recommendation required to gain reimbursement in France, and in Norway, a contract was awarded to supply the Axonics r-SNM® System to SNM-implanting hospitals in key cities.

The technical and clinical evaluation by HAS concluded that the therapeutic benefit of the Axonics r-SNM System for the treatment of Overactive Bladder is sufficient for registration on the Liste des Produits et Prestations Remboursables ("LPPR"). Registration is anticipated by the end of Q1 2020 following approval by the French Department of Health. HAS noted the advantages of the Axonics r-SNM System compared to InterStim®, in particular the opportunity to reduce the number of surgical procedures related to neurostimulator replacements as a result of the Axonics 15+ years long-lived implant, as well as the ability for patients to undergo full-body MRI scans without the necessity of having the device explanted. Approximately 1,000 patients receive an SNM implant in France every year.

In Norway, Axonics now has the opportunity to supply SNM products to six hospitals that were part of an evaluation process conducted by the national hospital procurement trust, Sykehusinnkjøp HF. The award states that buying decisions will be left up to implanting physicians to determine if the Axonics r-SNM System or that of the incumbent is best suited for individual patients. If a physician deems the systems to be equally suitable for a patient, it is the lifecycle costs that should determine which SNM system is selected. Approximately 500 SNM systems are envisioned to be implanted over the next four years in Norway.

Raymond W. Cohen, CEO of Axonics, commented, "While we are keenly focused on the U.S. commercial launch following our recent FDA approval, we continue parallel efforts to selectively expand our global reach, focusing on countries where reimbursement levels and the volume of implants allow our rechargeable SNM system to benefit more patients. This positive French HAS recommendation is based on an in-depth review of our technical and clinical evidence, and is testament to the technology benefits and quality of work at Axonics."

Cohen continued, "In Norway, we look forward to supplying our product to this network of hospitals. We are confident that given a choice, patients and providers will choose and benefit from Axonics' technology, and the healthcare system will capture the cost savings associated with our long-lived device."

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. The Axonics r-SNM System is the first rechargeable SNM system approved for sale in the United States, Europe, Canada and Australia. 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 also the first SNM system to gain full-body MRI conditional labeling. For more information, visit the Company's website at www.axonicsmodulation.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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