Axonics® Submits PMA Supplement to FDA to Further Expand MRI Labeling

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IRVINE, Calif.--(BUSINESS WIRE)--Oct. 29, 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, has submitted a premarket approval (PMA) supplement to the FDA for the purpose of gaining detachable extremity coil magnetic resonance imaging (MRI) conditional labeling for 1.5T and 3.0T MR scanners.

The FDA previously approved 1.5T and 3.0T MRI conditional labeling with head and full-body transmit coils for the implantable components of the Axonics r-SNM® System. This submission adds the ability to conduct MRI scans with detachable extremity transmit/receive coils. The standard FDA review timeline for labeling expansion PMA supplements is 180 days.

Extremity scans account for approximately 24% of all MRI scans performed today[1]. Axonics' current MRI labeling allows for extremity scans with RF body and specialized extremity coils. The expanded labeling would allow extremity scans using “Detachable Upper and Lower Extremity Transmit/Receive Coils.” The expanded labeling, if approved, would be applicable to all previously implanted Axonics Systems.

Guangqiang “Jay” Jiang, chief technology officer of Axonics, commented, “These additional conditions will provide Axonics with the widest range of MRI conditions in sacral neuromodulation. The benefits of this expansion include (a) better image quality for extremity scans and increased scanning setup flexibility; (b) broader MRI access for patients; and (c) avoiding RF exposure of the entire body, which may be important to patients who are frail, elderly, diabetic, obese, or pregnant as they are less tolerant to thermal stress from RF exposure. This submission further demonstrates Axonics’ commitment to continuous innovation for the benefit of patients, clinicians and the healthcare system.”

[1] IMV Benchmark Report MR 2018

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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