Axonics® Receives FDA Approval Further Expanding MRI Labeling

May 20, 2021

IRVINE, Calif.--(BUSINESS WIRE)--May 20, 2021-- Axonics, Inc. (Nasdaq: AXNX), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, has received FDA approval allowing the use of detachable extremity coils for patients undergoing 1.5T and 3.0T MRI scans.

The FDA previously approved 1.5T and 3.0T MRI conditional labeling for using head and full-body transmit coils for the implantable components of the Axonics r-SNM® system.

Extremity scans account for approximately 24% of all MRI scans performed today[1]. The expanded labeling now includes extremity scans using "Detachable Upper and Lower Extremity Transmit/Receive Coils." The expanded labeling is applicable to all previously implanted Axonics devices.

"These additional conditions provide Axonics with the widest range of FDA approved MRI conditions in sacral neuromodulation," said Guangqiang Jiang, Ph.D., chief technology officer of Axonics. "The benefits of this labeling expansion include better image quality for extremity scans and increased scanning setup flexibility; broader MRI access for patients; and the avoidance of RF exposure of the entire body, which is important to patients who are frail, elderly, diabetic, obese, or pregnant as they are less tolerant to thermal stress from RF exposure. This approval further demonstrates Axonics' commitment to continuous innovation for the benefit of patients and clinicians."

About Axonics

Based in Irvine, Calif., Axonics is a global medical technology company that is developing and commercializing novel products for patients with bladder and bowel dysfunction. The company's rechargeable sacral neuromodulation (SNM) system provides patients suffering from overactive bladder and/or fecal incontinence with long-lived, easy to use, safe, clinically effective therapy. In addition, Axonics' best-in-class urethral bulking agent, Bulkamid®, provides women suffering from stress urinary incontinence (SUI) with safe and durable symptom relief. Overactive bladder affects an estimated 87 million adults in the U.S. and Europe, with an additional 40 million adults estimated to suffer from fecal incontinence. SUI affects an estimated 20 million women in the U.S. alone. Axonics' clinically proven products are offered at hundreds of medical centers across the U.S. and abroad. Reimbursement coverage is well established in the U.S. and is a covered service in most European countries. For more information, visit www.axonics.com.

[1] IMV Benchmark Report MR 2018.

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Source: Axonics, Inc.