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Medtronic enrolls first patient in ENDURANCE post approval study of the Altaviva™ tibial neuromodulation device

First procedure performed at Axia Women's Health by Dr. Vincent R. Lucente

Medtronic announced that the first patient has been enrolled in the ENDURANCE Post-Approval Study (PAS) evaluating the Altaviva™ implantable tibial neuromodulation (ITNM) device for the treatment of urge urinary incontinence. The first study procedure was successfully performed by Vincent R. Lucente, MD, MBA, FACOG, FPMRS at Axia Women's Health in Allentown, Pennsylvania.

The ENDURANCE study, formally titled *Post Approval Effectiveness and Durability Evaluation of the Altaviva™ Tibial System*, is a prospective, multicenter study designed to evaluate real-world outcomes of the Altaviva™ device in a broad patient population, supporting a deeper understanding of long-term safety and clinical performance.

"It is well documented that patients with urge urinary incontinence may go years without meaningful symptom improvement, sometimes only seeking advanced therapies after standard treatments have failed to provide durable relief," said Dr. Lucente. "The ENDURANCE study addresses this unmet need by generating additional data, which I believe will help to advance access to neuromodulation. Enrolling the first patient at Axia Women's Health marks an important step forward for both clinicians and patients."

The Altaviva™ device is implanted near the ankle, just under the skin and above the fascia. It sends electrical impulses to the tibial nerve, helping to restore communication between the bladder and brain to regulate bladder control. Approximately half the length of a stick of chewing gum, the Altaviva™ device is implanted during a minimally invasive procedure that requires neither sedation nor imaging. Patients return home with therapy activated, a first among implantable tibial devices for this condition.

With a 15-year battery lifespan under expected settings, the Altaviva™ device requires no daily intervention or manual adjustments from the patient. Patients with an Altaviva™ device can receive future MRI scans anywhere on the body, provided they follow device labeling. The Altaviva™ device was approved by the U.S. Food and Drug Administration (FDA) in September 2025 for the treatment of urge urinary incontinence.

"Our goal is to make Altaviva an established part of the urge urinary incontinence care pathway," said Emily Elswick, president of

Medtronic Pelvic Health in the Neuroscience Portfolio. “By providing the long-term evidence needed to expand coverage and support informed reimbursement decisions, the ENDURANCE trial will help remove hurdles that currently keep many appropriate patients from accessing the Altaviva device.”

The primary endpoint of ENDURANCE is the urge urinary incontinence episodes responder rate, defined as the proportion of patients who achieve at least a 50% reduction from baseline in average, daily urge urinary incontinence episodes. ENDURANCE will evaluate 170 patients implanted at up to 30 centers in the U.S. over five years.

Bladder control problems affect an estimated 43 million – or one in six – U.S. adults. Nearly 16 million people have urge urinary incontinence, a common symptom of overactive bladder (OAB) characterized by a sudden, intense urge to urinate, often followed by involuntary leaks before reaching the bathroom.

For additional information about the ENDURANCE post-approval study, visit **ClinicalTrials.gov** and search for **NCT07456865**.

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