FOR IMMEDIATE RELEASE

First Patient in Florida Treated in Tampa in the OASIS Clinical Trial of the RENOVA iStim System for Overactive Bladder

Florida Urology Partners Is Recruiting Additional Women to Participate in Study of a Novel, Minimally Invasive Home-based Treatment for OAB

TAMPA, Fla.—October 20, 2020 — Overactive bladder or OAB, affects millions of women of all ages, and can negatively impact nearly every aspect of daily life—from work performance to family life, to social interactions. OAB symptoms can vary, but typically include abnormal or a sudden need to pass urine, accidental leakage and frequent urination of 8 or more times in a day.

There are approximately 40 million adults in the U.S. who experience OAB. Current treatment options, such as sacral nerve stimulation devices, require extensive surgery, general anesthesia and battery replacement. Other treatments require weekly visits to the doctor's office. RENOVA is a tiny, battery-less and lead-less neurostimulation implant that provides a patient-centric, home-based alternative therapy option for women with OAB.

Dr. Osvaldo Padron at Florida Urology Partners in Tampa is a clinical investigator in the OASIS Clinical trial of the RENOVA iStim™ system. He has treated the first Florida patient in Tampa and is recruiting additional study participants who meet the study criteria. The RENOVA iStim system is an investigational device designed to reduce urinary urge leakage and improve OAB symptoms.

"Overactive bladder can be debilitating and stressful. Sufferers constantly worry about accidental leakages so they limit how far or frequently they venture out to go to the gym or shop or dine in a restaurant. While current treatments work for some OAB sufferers, there's need for additional discreet and minimally invasive treatment options for women who do not benefit from medications and don't want more invasive surgery," said Dr. Padron, the OASIS Study site

Principal Investigator. “We’ve now treated the first patient with the RENOVA iStim. The small implant was placed during an outpatient procedure and treatment will now be done at the patient’s home. Especially now during a pandemic, having an option that does not require frequent doctor visits, and allows women to manage their treatment at home on their schedule, may be of interest to many women with OAB. Our site is actively recruiting additional qualifying participants to help advance this important research.”

About the RENOVA iStim System:

The RENOVA iStim system, developed by BlueWind Medical, is an investigational device designed to reduce urinary urge leakage and improve OAB symptoms. The RENOVA iStim uses a miniature implant that is placed during an outpatient procedure under local anesthesia. The implant is placed just above the ankle, near the tibial nerve. The implant stimulates the tibial nerve that communicates with nerves in the low back that control bladder function. A comfortable, wearable cuff powers the implant and is worn for just 30 to 120 minutes per day.

About the OASIS Clinical Trial:

The OverActive Bladder Stimulation System Study (OASIS), a prospective, interventional, multi-center study, will evaluate the safety and efficacy of RENOVA to improve urinary urgency incontinence (UUI) episodes. The OASIS study will enroll approximately 200 subjects at 20-25 study sites in Europe and the U.S. Results of this pivotal clinical trial will be the basis of a submission to the U. S. Food and Drug Administration. The study is recruiting women, ages 18 to 80, with a six month or more diagnosis of urinary urgency incontinence. To determine if you might qualify, visit: https://oasisoabstudy.com/ or contact Linda Seibert BS, CCRC Study Coordinator 239-223-4488

CAUTION—Investigational device. Limited by Federal (or United States) law to investigational use.

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