For Immediate Release

First U.S. Patient Treated in OASIS Clinical Trial of RENOVA iStim System for Overactive Bladder

OASIS Study Sites Across the U.S. Now Recruiting Participants in Trial of Novel Minimally Invasive, Home-based Treatment for OAB

PARK CITY, Utah and OMAHA, Neb.—October 8, 2020 — Clinical investigators in the OverActive Bladder Stimulation System Study (OASIS) of the RENOVA iStim™ system, Drs. Becky McCrery and Emily Kean at Adult Pediatric Urology & Urogynecology in Omaha implanted the first U.S. patient in this international clinical study. The RENOVA iStim system is an investigational device designed to reduce urinary urge leakage and improve OAB symptoms.

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.

"Overactive bladder can be debilitating and stressful. Many patients tell me that they will limit how far or frequently they venture from home—and that the first thing they do when arriving at a restaurant or a store, is to locate the restroom. While current treatments work for some OAB sufferers, there is a need for more effective, discreet and minimally invasive treatment options

for women who do not benefit from medications and don't want more invasive surgery," said Dr. McCrery, the OASIS Study site Principal Investigator.

"I'm pleased to say that our first implant procedure went smoothly. The RENOVA iStim 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. Dr. McCrery and I are excited to be investigators in the OASIS clinical trial and we look forward to enrolling several women who meet the trial qualifications at our site to advance this important research," said Dr. Kean, OASIS Study Co-Investigator.

About the RENOVA iStim System:

The RENOVA iStim system, developed by BlueWind Medical, is an investigation 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 21 to 80, with a six month or more diagnosis of urinary urgency incontinence. To determine if you might qualify, visit: https://oasisoabstudy.com/

About BlueWind Medical

BlueWind Medical was founded in 2010 by Rainbow Medical. The company is developing a platform technology of miniature, wireless neurostimulators that can be injected or implanted in a minimally invasive procedure to treat multiple indications. The CE Marked RENOVA™ system is an investigational device and not cleared for marketing in the United States.

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

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