PRESS RELEASE***PRESS RELEASE

Bluewind Medical™ Ltd. Completes OASIS Study Patient Enrollment

Park City, Utah, and Herzliya, Israel—November 16, 2021 – Bluewind Medical™, Ltd., developer of the innovative RENOVA™ iStim implantable neuromodulation device for treatment of urinary urgency incontinence, today announced the successful completion of patient enrollment in the OASIS pivotal clinical study that will be the basis by which the company will seek US-FDA (Food & Drug Administration) marketing clearance in the United States.

OASIS is a 150-patient prospective clinical study designed to demonstrate the safety and efficacy of Bluewind Medical's RENOVA iStim System to reduce symptoms of urgency incontinence, including urinary urgency and urinary frequency. Patients were screened and implanted at 23 centers in the United States, United Kingdom, The Netherlands, and Belgium.

"We are thrilled that enrollment has been completed in the OASIS study" said Dan Lemaitre, Chief Executive Officer of Bluewind Medical. "I am proud of our courageous field team that traveled throughout the pandemic, who along with our R&D colleagues in Israel, collaborated to ensure investigative sites and patients had optimal support during the study's enrollment period."

"What sets the RENOVA iStim apart from other available devices is our patient-centric approach to managing the symptoms of urgency incontinence," said Dr. Roger R. Dmochowski, MD, Bluewind Medical's Chief Medical Officer and renowned leader in the fields of urology, OAB and incontinence. "RENOVA can be adjusted to meet the individual needs of the patient, meaning that a patient can change stimulation parameters, or wear the control unit for as much or as little as the patient feels they need to improve their symptoms."

BlueWind intends to submit 6-month and 12-month safety and efficacy data to the FDA in 2022. In addition, BlueWind plans to follow OASIS patients for up to 36 months post device activation to demonstrate sustained efficacy. "While too soon to gauge study outcomes, we remain optimistic that the results of the OASIS study will take us closer to a time when RENOVA will help mitigate the debilitating effects of urgency incontinence for the millions of patients that suffer from this affliction." added Lemaitre.

About Overactive Bladder:
According to the American Urological Association, OAB is a chronic, debilitating condition affecting over 33 million Americans.

About Bluewind Medical Ltd.
BlueWind Medical was founded in Israel in 2010 to capitalize on unique neuromodulation technology that has the potential to treat multiple medical conditions. CE Mark for use in the treatment of overactive bladder was obtained in 2016.

For additional information please visit BluewindMedical.com

Press Contact: Daniel Dean @RothIvy
818-665-6188

###