BlueWind Medical Reaches 100th Patient for the OASIS Study of the RENOVA™ iStim System

BlueWind Medical announces its 100th patient implant in their pivotal study for treating overactive bladder symptoms using an innovative medical device the RENOVA™ iStim. The milestone marks an important step towards FDA clearance for the device.

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PARK CITY, Utah and HERZLIYA, Israel, July 6, 2021 /PRNewswire/ -- BlueWind Medical, Ltd. a leading innovator of neuromodulation medical devices for the treatment for overactive bladder (OAB), announced that the 100th patient has been enrolled in the OASIS clinical pivotal study. The Overactive Bladder Stimulation System Study (OASIS) clinical pivotal study is designed to test the safety and efficacy of the RENOVA™ iStim System in providing tibial neuromodulation (TNM) therapy.

The 100th patient was enrolled at St. Mary's Hospital in London, UK by Dr. Alex Digesu, Consultant Obstetrician & Gynecologist. "I had the privilege of taking part both to the pilot and pivotal trials of the RENOVA iStim System" said Dr. Digesu. "I find the RENOVA iStim a device easy to implant for a surgeon and easy to operate for a patient."

OASIS is a prospective, single arm, multi-site, international study. The study is enrolling female patients suffering from urinary incontinence and is testing the safety of the device, as well as the ability of TNM therapy to reduce and even eliminate incontinence episodes. At the conclusion of the study, BlueWind intends to submit the device for FDA clearance.

The RENOVA iStim System is composed of two parts: a miniature implanted stimulator and a mobile, wearable device. Patients undergo a simple procedure under local anesthesia implanting the stimulator, a tiny device just over an inch in length and the width of a matchstick. The procedure typically lasts half an hour or less and can be performed by the patient's urologist or urogynecologist. After implantation, patients wear the wearable device on their ankle, which communicates wirelessly with the stimulator to perform Tibial Nerve Modulation (TNM) treatment. Treatments are performed twice a day for half an hour. Patients can opt to be mobile when wearing the device or therapy can be administered with the patient stationary, in the comfort of their own home, at a convenient time. "Several advantages (battery-less, leadless, miniature, closed loop stimulation) make RENOVA iStim innovative neuromodulation system an interesting option for patients with overactive bladder symptoms who do not respond to, or cannot tolerate, conventional medical therapy," added Dr. Digesu.

Results from BlueWind's previously performed pilot clinical study have been optimistic, showing that over 70% of patients receiving treatment were responders as measured by composite OAB symptoms, with 28% of patients becoming fully "dry."

"The 100th patient is an important milestone for BlueWind since the pace of enrollment is indicative of a large unmet clinical need that our RENOVA system will address," said Dan Lemaitre, Chairman and CEO of BlueWind Medical. "The company will receive $20 million in funding as a result of hitting this milestone which provides the capital needed to complete enrollment in the OASIS study this year and to prepare for a commercial launch in 2023."

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

About BlueWind Medical
BlueWind Medical, founded in 2010, is developing the RENOVA™ iStim, a miniature, wireless neurostimulator to treat Overactive Bladder (OAB). The CE Marked RENOVA™ system is an investigational device and not cleared for marketing in the United States. For more information on the company, visit: BlueWindMedical.com.

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