FOR IMMEDIATE RELEASE

BlueWind Initiates U.S. Enrollment in Clinical Trial of the RENOVA iStim to Treat Overactive Bladder

Company Expands Leadership Team Adding Two MedTech Veterans

PARK CITY, Utah and HERZLIYA, Israel—August 11, 2020 — BlueWind Medical

announced today that enrollment has commenced at U. S. sites in the Pivotal Clinical Trial of the RENOVA iStim™ implantable tibial neuromodulation System (RENOVA) for the treatment of Overactive Bladder (OAB) following conditional Investigative Device Exemption (IDE) approval by the U.S. Food and Drug Administration (FDA).

There are approximately 40 million adults in the U.S. alone who experience OAB. OAB affects women of all ages, and can impact quality of life including work performance, family life and social interactions. OAB symptoms include sudden and frequent bladder voiding. Current treatment options, such as sacral nerve stimulation devices, require extensive surgery, general anesthesia and battery replacement. 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.

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 15 study sites in the U.S. and sites in Europe.

BlueWind's RENOVA tibial nerve stimulation involves the minimally invasive implantation of a miniature implant in the ankle placed under local anesthesia. A comfortable, wearable cuff powers the system and is worn for just 30 to 60 minutes per day.

“Only a small percentage of patients with overactive bladder are treated with current devices due to the complexity, invasiveness, complications, cost and need for reintervention of current therapies. The RENOVA System has the potential to address the unmet need for a minimally invasive, home-based treatment option. Especially now, COVID-19 has exposed the benefits of wearables and treatments that do not require multiple visits to the physician’s office," said Roger R. Dmochowski, M.D., a practicing urologist

“We are pleased to announce two strategic appointments to the BlueWind leadership team who will play important roles as we advance our neuromodulation platform technology. We welcome Roni Diaz, VP of Clinical Affairs and Grant Palmer, VP of Quality and Regulatory Affairs, whose extensive experience taking innovative medical devices from clinical development to commercialization will be invaluable as we build the requisite infrastructure to support the pivotal study of the RENOVA System,” said Dan Lemaitre, Chairman and CEO of BlueWind Medical.

Roni Diaz has 26 years of experience in medical device clinical trial management. Prior to joining BlueWind Medical, Roni was Director of Clinical Research at Insightec where she led worldwide studies of a Class III medical device for the treatment of prostate cancer and various neurological disorders. Before Insightec, Roni was Global Director of Clinical Affairs for 13 years at Abbott Neuromodulation (formerly St. Jude Medical) where she oversaw studies for the global chronic pain portfolio. Roni holds a B.Sc. in Health Sciences from San Jose State University.

Grant Palmer has 30 years of experience in Research & Development, Field Clinical Engineering, Clinical and Regulatory affairs as well as Quality Assurance in Class II and II medical device products. Prior to joining BlueWind, Grant was Vice President of Quality, Regulatory and Clinical for Bruin Biometrics, LLC. Previously, he led the Quality and Regulatory departments at Sparton Aubrey Group, a medical device contract design and manufacturing company. Grant holds a Bachelors of Electrics Engineering (Hons) and a Bachelor of Science in Physics & Computer Science from the University of Sydney.

Information regarding the OASIS Clinical Trial may be found at www.clinicaltrials.gov/ct2/show/NCT03596671.

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.

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