BlueWind Medical Receives FDA Approval for Pivotal Trial Design of RENOVA iStim™ Implantable Tibial Nerve Neuromodulator for Overactive Bladder

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HERZLIYA, Israel, June 14, 2018 /PRNewswire/ --

BlueWind Medical, a developer of a miniature wireless neurostimulation platform, for the treatment of multiple clinical indications, announced today that the US Food and Drug Administration (FDA) has approved the company's pivotal study design for its RENOVA iStim™ system to support its marketing application in the US.

RENOVA iStim™ is an innovative, battery-less, leadless, miniature, implantable Tibial Nerve Neuromodulation System, for the management of overactive bladder (OAB), including urinary urge incontinence and symptoms of urgency-frequency. An estimated 66 million people in the EU and 43 million in the US suffer from OAB, a disease that adversely affects patient's quality of life.

The **OASIS** pivotal trial (**O**ver**A**ctive bladder **S**t**I**mulation **S**ystem study) is designed to evaluate the safety and effectiveness of BlueWind's RENOVA iStim™ Tibial Stimulation System for the treatment of urinary urgency incontinence in patients who have failed or could not tolerate more conservative treatments. The endpoints of the OASIS pivotal study are similar to those published in clinical literature for urinary dysfunction. Study analysis will be focused, among other things, on the proportion of responders to tibial therapy at six months post-implant based on reduction in urinary urgency incontinence episodes from the patient's baseline diary. Safety and durability of the effect will be assessed 12 months post implantation.

BlueWind Medical expects patient enrollment to commence in early 2019, with an overall target of 250 patients to be implanted with RENOVA iStim™ at up to 25 medical centers, in several European countries, including the UK, Netherlands, Belgium and Germany.

On June 15 2016, a CE Mark was granted to BlueWind's RENOVA iStim™ system for the treatment of OAB. In a pilot clinical study conducted in Europe, BlueWind Medical demonstrated the safety and performance of the RENOVA iStim™. Of the overall patient cohort, 70.6% of patients had ≥50% reduction in their symptoms or a return to normal voiding at the 6-month follow-up; this high rate of responders coincides with significant improvement in all aspects of OAB health related quality of life. At the 1-month follow-up after activation, a significant therapeutic impact was observed, with more than 50% of subjects reporting ≥50% symptoms relief.

About BlueWind Medical

BlueWind Medical was founded in 2010 by the premier Israeli innovation and investment company Rainbow Medical. BlueWind is developing a platform technology of miniature wireless neurostimulators that can be placed in minimally invasive procedures and treat multiple indications. By putting patients' needs first, BlueWind is creating a versatile and effective platform that will transform Neuromodulation as we know it.

About Rainbow Medical

Rainbow Medical (http://www.rainbowmd.com) is a unique private operational investment company that seeds and grows start-up companies developing breakthrough medical devices invented by Yossi Gross, for diverse unmet medical conditions.

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