

BlueWind Medical Announces CE-Mark for BlueWind RENOVA™, the first in the world miniature wireless neurostimulator to treat Overactive Bladder

Herzliya, Israel, June 15, 2016 – Bluewind Medical, developer of a miniature wireless neurostimulation platform to treat multiple clinical indications, announced today that the company has received CE-Mark for its BlueWind RENOVA System, the first in the world miniature wireless neurostimulator to treat Overactive Bladder (OAB).

An estimated 66 million people in the European Union and 43 million in the USA, suffer from OAB, a disease that adversely affects quality of life and social life of patients. So far, neurostimulation treatment for OAB, while effective, requires an invasive surgical procedure to implant a stimulation lead and a neurostimulator in the pelvic area.

The Bluewind RENOVA system is a wireless, battery-less neurostimulator which is 90% smaller than typical neurostimulators in the market. The miniature device will allow physicians to treat OAB with a minimally invasive simple procedure lasting only 30 minutes, placing it near the tibial nerve, in the lower leg. The device electrically stimulates the tibial nerve, which influences urinary function, and is powered wirelessly by an external control unit, conveniently worn by the patient. Patients wear the external control unit for only 30 minutes, and can use it while performing their daily tasks without interruption. Since the implantable neurostimulator is battery-less, it does not require invasive replacement like conventional devices. This new treatment paradigm, transforms the way patients are treated today, relieves them from the need for frequent clinic visits, and allows them to control their own healing process.

"Today, neurostimulators that treat OAB are large, bulky, and require complex and expensive surgery," said Guri Oron Bluewind Medical's CEO. "BlueWind's implantable microstimulators are significantly smaller, allow for a simple implant procedure and are easier for patients to use at home. This is the first product out of many in our pipeline that will transform Neurostimulation and by that, will enable the treatment of millions of additional patients", he added.

Earlier this year, BlueWind Medical successfully completed a thirty-six patients clinical study in four medical centers in the Netherlands and United Kingdom to study the safety and performance of the RENOVA miniature implanted stimulator. The company plans to present the complete results of this OAB study, in the International UroGynecological Association (IUGA) conference in Cape Town, South Africa in August and in the International Continence Society (ICS) conference in Tokyo, Japan in September.

"The device was easy to implant, activate and use," said Dr. S Elneil, UCL and NHNN hospitals, London, UK. "European participants in the study liked the idea of such a small implant and a very short procedure; They were very favorable to having the flexibility and sense of control by treating themselves at home," added Dr. Elneil. "The patients were also relieved from the burden of logistics associated with therapy in the clinic."

"We are very pleased with BlueWind Medical's achievement of CE Mark for OAB" said Efi Cohen Arazi, CEO of Rainbow Medical and Chairman of the Board of BlueWind Medical. "This achievement is a testament for the team dedication, high quality of work and ingenuity. We plan to make these products available for physicians and patients in the near future."

About BlueWind Medical:

BlueWind Medical was founded in 2010 by the premier Israeli innovation and investment company Rainbow Medical. The company is developing a platform technology of miniature wireless neurostimulators that can be placed in a minimally invasive procedure and treat multiple indications. BlueWind Medical is led by a team of experienced and dedicated engineers and researchers that strive for the highest quality products and most advanced engineering processes. By putting the patients' needs first, Bluewind is able to create a versatile and effective platform that will transform Neurostimulation as we know it.

About Rainbow Medical

Rainbow Medical (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, in a diverse range of medical fields. By addressing significant unmet market needs, Rainbow Medical seeks to improve people's lives and generate exceptional returns for its shareholders.

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