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BlueWind Medical Announces Successful Completion of Patients' Enrolment for Its Overactive Bladder (OAB) Clinical Study Toward a CE Mark

The study evaluates the Bluewind RENOVA™ System*, a miniature wireless leadless neuro-stimulation platform to treat multiple indications

Herzliya, Israel January 11th, 2016 – Bluewind Medical, developer of a wireless neuro-stimulation device to treat multiple clinical indications, such as back pain, peripheral neuropathic pain, incontinence (OAB), epilepsy, and more, announced today the completion of patient enrolment for an Overactive Bladder (OAB) study which is currently being conducted to support CE Mark submission.

Thirty-six patients were successfully enrolled in four medical centres in the Netherlands and The United Kingdom.

About five million people, in the US alone, suffer from OAB and may benefit from emerging solutions such as the BlueWind RENOVA miniature neuro-stimulation device.

The BlueWind RENOVA neuro-stimulator is implanted near the tibial nerve in the lower leg in a minimally invasive procedure under local anaesthesia. The miniature device electrically stimulates the tibial nerve, which is known to influence urinary function. Individual parameter settings are determined by the physician according to user's sensations in order to help achieve normal urinary control relieving the need for frequent clinic visits.

“The implantation of BlueWind Medical's innovative implant was simple and smooth, and it was very easy to activate and use the device. Patients in Europe will benefit from its quality, flexibility and ease of use at home. During the screening phase of the study, we did not encounter any difficulties in enrolling patients, as they were convinced immediately” said Dr. J Heesakkers, a study investigator from Radboud Medical Center, Nijmegen, Netherland. “Mostly they liked the idea to have such a small implant in such a short procedure and then to have the freedom of the option to self-control the treatment at home. The patients were relieved from the burden of logistics associated with clinic therapy.”

“The future of neurostimulation is in miniaturization and patient empowerment,” said Guri Oron, Bluewind Medical's CEO. “Today, neurostimulators that treat OAB are large and require complex and expensive surgery. We believe that in order to treat most patients, devices that are significantly smaller and simpler to implant will be required and Bluewind is currently completing the development of an injectable stimulator for that purpose.”

"This is already the second indication for which we have collected clinical data to support CE mark submission. We are very pleased with the clinical study conductance so far and the performance of the device that can significantly improve the quality of life of patients suffering from OAB and other indications as peripheral neuropathic pain," said Efi Cohen Arazi, CEO of Rainbow Medical and chairman of the board of BlueWind Medical.

Initial clinical results of the study are expected to be announced at the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) conference in New Orleans in February of 2016.

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About Bluewind Medical

Bluewind Medical, based in Herzliya, Israel, is developing a novel wireless neuro-stimulation device for the treatment of multiple potential clinical applications in the human body, including peripheral neuropathic pain (PNP), incontinence (OAB), Deep Brain Stimulation (DBS), and more.

The company was founded in 2010 by Rainbow Medical (www.rainbowmd.com), 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.