

BlueWind Medical Announces the Publication of Breakthrough Results for BLUEWIND-RENOVA™ Implantable Tibial Nerve Neuromodulator

Results from 6-Month OPTIMIST Study show BlueWind Renova™ is a safe, minimally invasive system that offers significant improvements for Over Active Bladder patients.

NEWS PROVIDED BY

BlueWind Medical

Jan 04, 2018, 08:00 EST

SHARE THIS ARTICLE

HERZLIYA, Israel, January 4, 2018 /PRNewswire/ --

BlueWind Medical, developer of a miniature wireless neurostimulation platform for the treatment of multiple clinical indications, announced today the publication of clinical results of OPTIMIST Study. The multi-center prospective study, tested BlueWind's innovative leadless, miniature implantable Tibial Nerve Neuromodulation System for the management of overactive bladder (OAB) complaints. An estimated 66 million people in the European Union and 43 million in the USA suffer from OAB, a disease that adversely affects patient's quality of life.

The scientific publication was published in the September issue of the Neuromodulation and Urodynamics journal.

The study was conducted in four prominent clinical centers in the UK and the Netherlands. Thirty six patients suffering from OAB were enrolled in the study and followed for 6-months to evaluate the long term performance and safety of the BlueWind RENOVA™ implantable tibial nerve neuromodulator for OAB management. The study results demonstrate that the RENOVA™ system has a low-risk safety profile and may be considered an effective treatment option for OAB management.

Of the 34 subjects who completed the study, 71% experienced at least 50% reduction in OAB symptoms at 6 months. Specifically, patients experienced reduction in the number of urine leaks per day, and a significant reduction in the severity of leaks. Patients that frequently need to use pads for protection against unexpected leaks have experienced a reduction in the need to change pads. Most impressively, 27.6% of patients suffering from urge incontinence became "dry", meaning they had stopped experiencing any leaking episodes.

The study also demonstrated that the BlueWind RENOVA system improved all quality of life aspects of the patients, including coping with symptoms, symptom concern, sleep disturbances and problems with social interactions. The research concluded that the BlueWind implantable tibial nerve stimulator is a safe, minimally invasive system that affords OAB patients significant improvements.

"The results of the trial prove once again that BlueWind's miniature implant is a breakthrough in the medical world and could lead many patients suffering from the side effects of the old technology to a different, safer and more accessible reality," said Yossi Gross, inventor of the BlueWind technology and founder of Rainbow Medical investment group, who founded BlueWind Medical and is its main investor. According to Gross, Rainbow Medical will continue to support leading medical breakthroughs such as BlueWind Medical.

"The BlueWind RENOVA device small size and implant location provides important safety benefits as compared to existing devices" said Dr. Suzy Elneil, a Consultant Urogynaecologist and Uro-neurologist at University College Hospital in London. She added that, "patients found the system easy to use and were satisfied with their ability to control the therapy."

Gori Oron, CEO of BlueWind Medical, added: "We are very excited by the positive results of the trial and this prestigious publication. BlueWind has taken upon itself a mission to transform Neuromodulation, eliminating the need for complex and invasive surgeries by offering advanced miniature devices. As our devices will enable a safer and easier procedure, more patients will have the opportunity to benefit from this advanced therapy."

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 creating a versatile and effective platform that will transform Neurostimulation 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, 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.

For more information, contact:

Meital Levi Tal, meital@xmind.co.il

SOURCE BlueWind Medical