

# BlueWind Medical Announces Positive Long-Term Results of the BLUEWIND-RENOVA™ Implantable Tibial Nerve Neuromodulator

Results from 36-month OPTIMIST Follow-Up study show BlueWind Renova™ is a safe, minimally invasive system that offers durable and significant improvements for Over Active Bladder patients

---

NEWS PROVIDED BY

**BlueWind Medical**

Aug 30, 2018, 08:30 ET

HERZLIYA, Israel, August 30, 2018 /PRNewswire/ --

**BlueWind Medical**, developer of the RENOVA iStim™, an innovative, leadless, miniature, wireless neurostimulation platform, for the treatment of multiple clinical indications, announced today the publication of long-term clinical results of OPTIMIST follow-up study. BlueWind Medical is the only company today with long-term positive clinical data for implantable tibial stimulation for the treatment of overactive bladder (OAB). An estimated 66 million people in the EU and 43 million in the US suffer from OAB, a disease that adversely affects patients' quality of life.

The prospective study was conducted in four leading clinical centers in the UK and the Netherlands that evaluated the long-term performance and safety of the RENOVA iStim™ for the management of OverActive Bladder (OAB), including Urinary Urge Incontinence (UUI) and symptoms of Urgency Frequency (UF).

The OPTIMIST Follow-Up study is an extension of the previously published OPTIMIST six-month pilot study and included 20 of the 36 pilot study patients. The 20 patients that were available for long-term follow-up well represent the original pilot cohort based both on demographics and on clinical response.

The study demonstrated a sustained high responder rate over a 36-month follow-up period, comparable with response rates typical to sacral neuromodulation. Three years after implantation of the RENOVA iStim™ device, 75% of patients experienced at least a 50% long-term reduction in OAB symptoms. Patients experienced durable, long-term, effect of

UUI relief in "leaks" (50% of patients) and in "large leaks" (80% of patients). No severe adverse events (SAE's) were reported throughout the follow-up study.

"We are very encouraged by the sustained long-term results of the RENOVA system", said Dr. John Heesakkers, the primary investigator of the study. "The study provides assurance that BlueWind's RENOVA iStim stimulation of the tibial nerve can lead to meaningful symptoms improvement, without the clinical risks associated with sacral device implantation".

The study also demonstrated that the RENOVA iStim™ system provided long-term improvement in all health-related quality of life aspects of patients, with 70% of the patients showing a meaningful improvement as assessed by OAB quality of life questionnaire.

"The 36-month study results confirm that the RENOVA iStim™ system provides robust and effective long-term performance, that could help millions of patients in the management of OAB", commented Efi Cohen Arazi, CEO of Rainbow Medical and Chairman of the Board of BlueWind Medical. "We believe BlueWind has highly differentiated wireless neuromodulation, and this data provides strong evidence of the potential for this technology in OAB and other indications".

### **About BlueWind Medical**

BlueWind Medical (<http://www.bluewindmedical.com>) 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. By putting patients' needs first, BlueWind Medical's team of experienced and dedicated engineers and researchers are 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, addressing significant unmet market needs in a diverse range of medical fields.

For more information, contact:

Ms. Meital Levi Tal, [meital@xmind.co.il](mailto:meital@xmind.co.il)

SOURCE BlueWind Medical