

BlueWind Medical Announces CE-Mark for the BlueWind VIVENDI™ Miniature Implanted Wireless Stimulator to Treat Peripheral Pain

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BlueWind Medical

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HERZLIYA, Israel, September 7, 2016 /PRNewswire/ --

BlueWind Medical, developer of a miniature wireless neurostimulation platform to treat multiple clinical indications, announced today that the company has received CE-Mark for the BlueWind's VIVENDI miniature wireless neurostimulator to treat Peripheral Neuropathic Pain (PNP). This is the second product BlueWind has received CE-Mark based on its advanced neurostimulation platform, after obtaining few months ago CE-Mark for treatment of an Over Active Bladder.

An estimated 8 million people in Europe and 6 million in the USA, suffer from PNP, including about 14% of all people with diabetes. PNP is a debilitating pain that impairs patient's quality of life, daily functioning, sleeps, work productivity and more. The most common treatment for PNP is pharmacological, including intensive use of Opioids, and PNP is one of the key contributors to the Opioid epidemic in the US.

The BlueWind VIVENDI System is a wireless, battery-less neurostimulator which is 90% smaller than typical neurostimulators in the market. The miniature device is implanted in close proximity to the Tibial nerve and by applying electrical stimulation to the nerve, helps to ease or mask the pain sensation. The device is implanted in a minimally invasive simple procedure lasting only about 30 minutes, and is powered wirelessly by an external control unit, conveniently worn as needed by the patient on the ankle.

Patients self-administer the treatment using the wearable device as often and for as long as they need, and up to 8 hours a day. The reduction in pain is typically immediate and lasts between 30 minutes to a few hours post stimulation. In a multi-center clinical study

performed in leading pain centers in Europe with 13 implanted patients, 83% of patients have reported more than 50% reduction in VAS pain scores over 6-month follow-up period.

"This new treatment paradigm, transforms the way patients are treated today, relieves them from the need for Opioid or other pharmacological treatments and allows them to control their own healing process," said Guri Oron BlueWind's CEO. "Until today, it was not possible to locally treat chronic peripheral pain with neurostimulators due to the size and complexity of existing neurostimulators. BlueWind's miniature and wireless neurostimulators are significantly smaller, allow for a simple implant procedure, precise targeting of the pain location, and are easier for patients to use at home."

"The BlueWind Vivendi system provides a solution to many patients that have no other relief," said Prof. Jean-Pierre Van Buyten, Chairman of the Multidisciplinary Pain Centre AZ Nikolaas in Belgium. "The small implant was very easy to implant, and very easy for the patients to activate and use. Patients can use it whenever they have pain and it provides immediate and sustainable pain relief."

"BlueWind VIVNEDI is our second product approved this year and it shows the power of the platform to expand to multiple indications and separate markets," said Efi Cohen Arazi, CEO of Rainbow Medical and Chairman of the Board of BlueWind Medical. "The company now have regulatory approval for two products and will continue to invest to further extend the usage of its platform."

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 (<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.

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