



ImThera Medical to Begin European Clinical Trials in Belgium

Also receives ISO 13485 certification

San Diego, CA., – September 29, 2009 – ImThera Medical, Inc. has received Ethics Committee clearance to begin human clinical trials in Belgium. The trials will include ImThera’s Targeted Hypoglossal Neurostimulation (THN) Sleep Therapy to treat Obstructive Sleep Apnea (OSA). Along with the clinical trial approvals, ImThera has received ISO 13485 certification of its quality system as a pre-requisite for the future CE mark application for European commercialization of medical products.

ImThera’s European clinical trial, a pilot study involving ImThera’s THN sleep therapy system, is expected to publish its first results in the first quarter of 2010. “We are excited to be involved in the clinical trial of ImThera’s innovative THN Sleep Therapy,” said Professor Dr. Daniel Rodenstein of the Catholic University of Louvain, Belgium, and principal investigator of the European study.

While Continuous Positive Airway Pressure (CPAP) remains the established therapy for treating OSA, studies show that up to 50% of patients do not comply with the therapy. ImThera’s THN Sleep Therapy was developed as a surgical option to CPAP delivering neurostimulation to the hypoglossal nerve to control certain muscles of the tongue. Using a multi-contact electrode and a programmable implantable pulse generator (IPG), the system delivers muscle tone to key tongue muscles to prevent the tongue from collapsing into the upper airway.

“This technology has the potential to help a very large number of patients who cannot or will not comply with CPAP,” said Dr. Terence M. Davidson, Professor of Head and Neck Surgery at UCSD, and head of ImThera’s Medical Advisory Board.

“Our mission is to help moderate-to-severe OSA patients enjoy better lives while substantially reducing health care costs related to serious complications associated with Obstructive Sleep Apnea,” said Marcelo G. Lima, Chairman, President and CEO of ImThera Medical, Inc. “The ISO 13485 certification and launch of the pilot study are critical steps in our path to provide a safe and efficacious treatment.”

CAUTION: ImThera’s device is not for sale in the U.S.A.

About ImThera Medical, Inc (www.imtheramedical.com)

Based in San Diego, ImThera Medical is a privately funded, early-stage company developing a patent-pending, neurostimulation medical device for the treatment of Obstructive Sleep Apnea (OSA).

ImThera Medical's Targeted Hypoglossal Neurostimulation (THN) Sleep Therapy delivers neurostimulation to the hypoglossal nerve to control certain muscles of the tongue. Using a multi-contact electrode and a programmable implantable pulse generator (IPG), the system delivers muscle tone to key tongue muscles to prevent the tongue from collapsing into the upper airway. This innovative technology is designed to increase airway flow, permitting normal and restful sleep for OSA patients.

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