



PUBLICATION IN *SLEEP* JOURNAL DEMONSTRATES POSITIVE RESULTS OF LARGE MULTI-CENTER CLINICAL TRIAL FOR PROVENT® SLEEP APNEA THERAPY

-- 19 Center, 250 Patient Study Shows Non-Invasive Provent Therapy Significantly Improves Sleep Apnea with High Patient Compliance --

BELMONT, CA (April 4, 2011) – Ventus Medical, Inc. today reported positive results from a 19 center clinical trial using its FDA-cleared Provent® Sleep Apnea Therapy device to treat obstructive sleep apnea. Provent Therapy uses the patient’s own breathing to create expiratory positive airway pressure (EPAP) to keep the airway open during sleep. The full results of this three month study were published in the April 2011 issue of the peer-reviewed medical journal *SLEEP*, an official publication of the American Academy of Sleep Medicine.

“This randomized, sham-controlled study demonstrates that Provent Therapy significantly improves the apnea hypopnea index (AHI), a scale to measure the number of breathing interruptions or stoppages per hour of sleep, as well as subjective sleepiness, as measured by the Epworth Sleepiness Scale (ESS) in patients with obstructive sleep apnea,” said study author Richard B. Berry, M.D., professor of medicine at the University of Florida College of Medicine, medical director of the University of Florida and Shands Sleep Disorders Center, and former president of the American Sleep Medicine Foundation. “Importantly, self-reported patient adherence on Provent Therapy was almost 90 percent.”

The prospective, double-blind, sham-controlled clinical study enrolled 250 patients diagnosed with obstructive sleep apnea at 19 academic and private sleep centers in the United States. The primary endpoint of the study was the reduction in AHI. In-laboratory polysomnography, a method of monitoring breathing disruptions during sleep, was performed at the start of the study and after three months of treatment.

Results at the start of the study showed that AHI was reduced by 52.7 percent in the Provent Therapy group compared to a 7.3 percent reduction in the sham group, representing a highly significant treatment effect ($p < 0.0001$). A highly significant improvement in AHI was also demonstrated at the conclusion of the study. Using the Epworth Sleepiness Scale to evaluate daytime sleepiness, patients using Provent Therapy showed improved alertness, reducing sleepiness from 9.9 ± 4.7 to 7.2 ± 4.2 compared to the sham group of 9.6 ± 8.3 to 8.3 ± 5.1 , a statistically significant improvement compared to the sham group ($p = 0.04$). Importantly, self-reported patient adherence was excellent, with the Provent Therapy device worn all night for 88.2 percent of nights in the study.

“CPAP is the gold standard in the treatment for obstructive sleep apnea, but unfortunately many patients who are prescribed CPAP cannot get used to it, or use it less often than they should,” stated study author Meir Kryger, M.D., director of sleep medicine research and education at Gaylord Hospital in Wallingford, Connecticut and former president of the American Academy of Sleep Medicine. “This large trial provides solid clinical data validating Provent Therapy as an important treatment alternative for obstructive sleep apnea.”



About Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is the most common type of sleep-disordered breathing. It is estimated that 40 million people in the United States suffer from sleep apnea. In people with OSA, the airway collapses during sleep when the muscles, that hold the airway open, relax. People with this disorder can stop breathing while sleeping---in some cases hundreds of times each night---usually for periods of ten seconds or longer. Importantly, many recent studies have shown that people with OSA experience higher rates of car accidents as well as serious health problems including high blood pressure, heart attack, stroke and diabetes.

Unfortunately, OSA often goes undiagnosed and therefore untreated. Of the patients that do receive treatment, most are prescribed a CPAP machine. CPAP is extremely effective at treating OSA if worn as directed. However, more than half of all patients stop treatment with CPAP due to its cumbersome nature. Provent Therapy was developed to help patients who do not use CPAP regularly and who can benefit from a non-invasive and clinically effective treatment alternative.

About Provent Sleep Apnea Therapy

Provent Therapy is a prescription device indicated for the treatment of obstructive sleep apnea. It is an easy-to-use, disposable treatment that works across mild, moderate and severe OSA. Provent Therapy is cleared by the U.S. Food and Drug Administration (FDA) and numerous peer-reviewed published studies have demonstrated that Provent Therapy improves sleep apnea and oxygenation. The device works through Ventus Medical's proprietary MicroValve technology that uses the patient's own breathing to create expiratory positive airway pressure (EPAP) to keep the airway open during sleep. For more information, please visit www.proventtherapy.com.

About Ventus Medical

Ventus Medical is a privately-held medical device company dedicated to providing non-invasive medical solutions for people with sleep-disordered breathing. Based on its innovative MicroValve technology and patented designs, Ventus Medical has developed a unique line of clinically-proven medical devices to address the continuum of sleep disorders from severe obstructive sleep apnea to snoring. Ventus Medical devices work by creating expiratory positive airway pressure (EPAP). The company markets FDA-cleared, prescription-only Provent Therapy, a discreet, easy-to-use nasal device, for the treatment of obstructive sleep apnea and is developing an over-the-counter device for snoring.

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