



**New Data Support Effectiveness of Ventus Medical's PROVENT® Therapy  
In Treating Obstructive Sleep Apnea**

***- Data Presented at SLEEP 2009 Conference -***

***- Discreet, Nightly-Use Prescription Device for the Treatment of Obstructive Sleep Apnea -***

BELMONT, CA (June 9th, 2009) – Ventus Medical, a privately-held medical device company focused on improving the lives of patients with sleep-disordered breathing, today announced that clinical data from three poster presentations presented at the SLEEP 2009 23<sup>rd</sup> Annual Meeting of the Associated Professional Sleep Societies further confirm PROVENT® Sleep Apnea Therapy's clinical utility in treating mild, moderate and severe obstructive sleep apnea (OSA). SLEEP 2009 is being held June 8-11 in Seattle, WA.

OSA occurs when the upper airway (near the back of the mouth) collapses during sleep, obstructing the airway and preventing air from entering the lungs. Pauses in breathing result and are associated with a decrease in oxygenation of the blood.

The reported data also suggest that positive end-expiratory pressure is the mechanism of action by which PROVENT Therapy helps patients with sleep-disordered breathing.<sup>1</sup>

"An estimated 50 million people in the U.S. suffer from obstructive sleep apnea, yet there are few treatment options that meet all patients' needs. PROVENT Therapy offers a new alternative that is discreet, easy to use, disposable and comfortable to use throughout the night, regardless of a patient's sleep position," explained Philip Westbrook, MD, Emeritus Professor of Medicine at UCLA and Ventus Medical's Chief Medical Officer. "These new data offer additional evidence that PROVENT Therapy is clinically-proven and truly designed with the patient's needs in mind."

"We welcome innovation and additional treatment options for our patients with sleep breathing disorders," said Meir Kryger, MD, Director of Sleep Medicine Research and Education at Gaylord Hospital in Wallingford, CT. "These results are very promising, and Ventus is clearly taking the appropriate steps to establish this treatment through rigorous clinical testing."

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<sup>1</sup>Hwang D, Patel A, Chen G, Ayappa I, Rapoport DM. Nasal EPAP – Physiologic Mechanism of Action, June 9, 2009, poster presentation at SLEEP 2009, the 23<sup>rd</sup> Annual Meeting of the Associated Professional Sleep Societies. Abstract 0591.

## Three Poster Presentations:

### 1. Mechanism of Action Study

A physiologic mechanism of action study (abstract 0591), by Dennis Hwang, MD, and colleagues, including David Rapoport, MD, Associate Professor of Medicine, New York University School of Medicine, found that PROVENT Therapy produced marked improvement in sleep-disordered breathing in 8 of 11 treated patients with some residual sleep-disordered breathing during REM sleep.<sup>1</sup> Of the 8 patients, 5 demonstrated a complete response and 3 a partial response.

"These positive efficacy findings were associated with positive and prolonged intranasal pressure when the patient exhales," said Dr. Rapoport. "We believe it is this pressure, known as autoPEEP (positive end-expiratory pressure), that keeps the airway open until the patient inhales, may increase the end-expiratory lung volume, and thus creates a pull on the trachea and upper airway. This is how PROVENT Therapy prevents apneic episodes and helps patients with sleep-disordered breathing."

In the 8 responsive PROVENT Therapy patients, end-expiratory intranasal pressure increased to a range between 11 and 26 cmH<sub>2</sub>O during periods of complete success, whereas the non-responders' intranasal pressure ranged from 3 to 10 cmH<sub>2</sub>O, with lowest pressures at the time of failure of treatment. This suggests that the increased pressure could have been the mechanism of action that keeps the airway open until the patient inhales.<sup>1</sup>

### 2. Modeling the Effectiveness of PROVENT Therapy Compared to CPAP

A model (abstract 0599) comparing the efficacy and compliance of current PROVENT Therapy data to continuous positive airway pressure (CPAP) data from the literature suggests that PROVENT Therapy may prevent a similar or greater number of apnea/hypopnea events as compared to CPAP when the therapies' respective adherence rates are taken into account.<sup>2</sup>

This model analysis by Anne Abreu, Director of Reimbursement and Business Development at Ventus Medical, and colleagues, compared the effectiveness of PROVENT Therapy versus CPAP taking into consideration both apneas and hypopneas prevented during hours of use and those not prevented due to lack of use.

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<sup>2</sup> Abreu A, Doshi R, Loomas B, Westbrook P. Modeling the Effectiveness of Treatments for Obstructive Sleep Apnea/Hypopnea, June 09, 2009, poster presentation at SLEEP 2009, the 23<sup>rd</sup> Annual Meeting of the Associated Professional Sleep Societies. Abstract 0599.

Results showed that PROVENT Therapy may prevent a similar or greater number of abnormal breathing events as compared to CPAP, based on the modeling scenarios. "This model demonstrates the importance of factoring in compliance rates when choosing a therapy for treating obstructive sleep apnea," said Ms. Abreu.

### 3. PROVENT Therapy Pooled Data Analysis

A new analysis of pooled data from prior PROVENT Therapy studies (abstract 0570) by Philip Westbrook, MD, Emeritus Professor of Medicine at UCLA and Ventus Medical's Chief Medical Officer, and colleagues, showed success rates and a significant change in Apnea-Hypopnea Index (AHI) in 58 patients that demonstrate the viability of PROVENT Therapy via expiratory resistive loading in the treatment of OSA.<sup>3</sup>

"These success rates are comparable to alternative therapies, such as mandibular advancement devices and surgical approaches, and PROVENT had fewer adverse events," explained Dr. Westbrook. "Given PROVENT Therapy is much easier to try than these other therapies, it could be an early consideration for the treatment of OSA."

Results demonstrated that PROVENT Therapy reduced AHI from  $26.6 \pm 24.8$  to  $13.7 \pm 20.1$ , a 49% reduction ( $p < 0.001$ ). During the treatment night, 72% of subjects met either the AHI < 10 or AHI improved by at least 50% criteria; 36% met the success criteria of AHI < 5; 59% met AHI < 10; and 66% had an AHI < 50% of their baseline value. Further, 50% of subjects met both the AHI < 10 and AHI improved by at least 50% criteria.<sup>3</sup>

#### **About PROVENT Therapy**

PROVENT Therapy is a prescription device indicated for the treatment of obstructive sleep apnea (OSA). It is easy to use, disposable, and comfortable prescription treatment that works across mild, moderate, and severe OSA. The treatment utilizes nasal expiratory positive airway pressure (EPAP) and has been clinically shown to reduce sleep apnea. It incorporates a novel MicroValve design that is placed over the nostrils and secured with hypoallergenic adhesive. During inhalation, the valve opens allowing nearly unobstructed airflow, and during exhalation, the valve closes, limiting airflow through two small openings, which increases expiratory pressure.

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<sup>3</sup> Westbrook P, Doshi R, Loomas B. Success Rates of Nasal Expiratory Positive Airway Pressure (nEPAP) Via Expiratory Resistive Load for the Treatment of Obstructive Sleep Apnea, June 9, 2009, poster presentation at SLEEP 2009, the 23<sup>rd</sup> Annual Meeting of the Associated Professional Sleep Societies. Abstract 0570.

Currently, PROVENT Therapy is only available in limited locations in the United States with the assistance and support of professional sleep physicians. For more information, please visit [www.ProventTherapy.com](http://www.ProventTherapy.com).

### **Sleep-Disordered Breathing**

Sleep-disordered breathing broadly refers to a group of disorders characterized by abnormalities of breathing pattern (such as stopping breathing) or the abnormal reduction in the volume of breaths while sleeping. OSA is the most common type of sleep-disordered breathing. An estimated 50 million people in the United States suffer from OSA, which occurs when the upper airway (near the back of the mouth) collapses during sleep, obstructing the airway and preventing air from entering the lungs. OSA is caused by multiple factors, including sleep-induced relaxation of the throat muscles and tongue, enlarged tonsils and adenoids, an abnormally small airway diameter in the back of the mouth and throat, and extra soft tissue in and around the throat due to being overweight.

### **About Ventus Medical**

Ventus Medical is a medical device company focused on improving the lives of patients with sleep-disordered breathing. Located in Belmont, California, Ventus Medical has developed and markets PROVENT Therapy, an innovative, clinically-proven treatment for OSA. Existing OSA solutions do not always meet patients' needs. Through truly innovative technology, solid clinical evidence, and a focus on the patient, Ventus Medical seeks to deliver consumer-preferred, physician-recommended solutions. The company is privately-held and funded by De Novo Ventures, Mohr Davidow Ventures, and Johnson & Johnson Development Corporation.

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