



## **Apnex Medical, Inc. Receives FDA Approval for Pivotal Clinical Study for Obstructive Sleep Apnea**

**ST. PAUL, Minn., August 2, 2011** - Apnex Medical, Inc., received investigational device exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) to begin a clinical study to evaluate the safety and effectiveness of its Hypoglossal Nerve Stimulation (HGNS<sup>®</sup>) System to treat obstructive sleep apnea (OSA). Data from this clinical study are intended to support the Pre-Market Approval (PMA) application for the HGNS System to the FDA.

“Many patients who suffer from OSA are unable to tolerate existing therapies such as continuous positive airway pressure (CPAP). The HGNS System provides a fundamentally new approach to the treatment of OSA. This study will help us further understand the potential role this device will have in treating the millions of people who suffer from OSA,” said the study’s co-principal investigator, Dr. Atul Malhotra, Clinical Chief, Division of Sleep Medicine, Brigham and Women’s Hospital.

Sponsored by Apnex Medical, the Apnex Clinical Study is a prospective, randomized, multi-center clinical trial. It is being conducted in leading medical centers in the United States, Europe and Australia. The trial is designed to demonstrate the safety and effectiveness of the HGNS therapy in treating patients with moderate to severe OSA. To be enrolled in the study patients must not have received lasting benefit from CPAP or other OSA treatments.

“We have seen very encouraging results from the HGNS feasibility studies. Results recently presented at the international SLEEP meeting showed that most patients treated with the HGNS System experienced significant improvements in their sleep apnea, sleepiness, and quality of life. This study will help us determine if these results can be demonstrated in a second larger patient population,” said the study’s co-principal investigator, Dr. Eric Kezirian, Department of Otolaryngology – Head and Neck Surgery, University of California, San Francisco.

### **About Apnex Medical, Inc. and HGNS System**

Apnex Medical was founded in 2006 with a mission to pioneer medical innovations to improve the health of people with sleep disordered breathing. The company has developed a proprietary medical device for the treatment of OSA.

The Apnex HGNS System is an implantable therapy that is intended to work by activating the muscles in the upper airway to ensure that the airway remains open during sleep. The system detects the patient’s breathing and delivers mild stimulation to the hypoglossal nerve, the nerve that controls the muscles of the tongue, to keep the airway open. The stimulation is timed to a patient’s own breathing pattern. The HGNS System is designed to work only when the patient is asleep through a handheld controller.

### **About OSA**

According to the World Health Organization approximately 100 million people worldwide have OSA. It occurs because of blockage of breathing during sleep. This can deprive OSA sufferers of deep restful sleep and lead to sleepiness and fatigue. OSA sufferers are also at an increased risk for a variety of

health conditions, including high blood pressure, coronary artery disease, diabetes and stroke. Untreated OSA is also associated with an increased risk of death. Current OSA treatments are not always successful or well tolerated. The Apnex device is designed to provide an alternative treatment for OSA that addresses these problems.

**More information on the Apnex Clinical Study can be found at [www.SleepApneaTrial.com](http://www.SleepApneaTrial.com). To learn if you might qualify for the study go to this website or call 1-888-975-3370.**

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**CAUTION:** The Apnex HGNS System is an investigational device and is limited by Federal Law to investigational use.

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