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

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ST. PAUL, Minn., Aug. 2, 2011 /PRNewswire/ -- 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®) 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.

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