Neurostimulation Established as a Treatment Option for Sleep Apnea Patients Who Do Not Tolerate CPAP

New Results of Landmark Long-Term Sleep Apnea Study Published: Inspire Upper Airway Stimulation Therapy Shows Significant and Sustained Reductions in Sleep Apnea Severity, Improvements in Quality of Life and High Adherence Rates at Three Years

MINNEAPOLIS (November 19, 2015) — Inspire Medical Systems, Inc., announced today the results of a landmark long-term clinical study for its Inspire Upper Airway Stimulation (UAS) System, the first FDA-approved implantable neurostimulation treatment for people diagnosed with Obstructive Sleep Apnea (OSA). OSA affects more than 18 million Americans and can have devastating effects on heart and brain health, impair quality of life and increase accident risk.

Inspire therapy is for some people diagnosed with moderate to severe OSA who are unable to tolerate or get relief from Continuous Positive Airway Pressure (CPAP). In contrast to CPAP, Inspire therapy works inside the body and with a patient’s natural breathing process. Controlled by the patient sleep remote, the system includes a breathing sensor and a stimulation lead powered by a small battery. During sleep, the system senses breathing patterns and delivers mild stimulation to the tongue and other soft tissues of the throat to keep the airway open. Inspire therapy is currently available at more than 60 leading medical centers across the United States and Europe.

The Stimulation Therapy for Apnea Reduction (STAR) trial was conducted at 22 leading sleep medicine centers across the United States and Europe. One-year STAR trial outcome measures, published in the January 9, 2014 edition of the New England Journal of Medicine, showed that sleep apnea patients receiving Inspire therapy experienced significant reductions in sleep apnea events and significant improvements in quality of life measures. The new long-term study outcomes showed that the improvements observed at one-year were sustained at the three-year follow up mark. The outcomes include:

- A 78 percent reduction in apnea-hypopnea index (AHI) from baseline
- An 80 percent reduction in oxygen desaturation events from baseline
- 80 percent of bed partners reported soft or no snoring as compared to 17 percent of bed partners at baseline
- Quality of life measures, including daytime sleepiness and functioning, showed clinically meaningful improvements and a return to normal levels over baseline

The results were published this week in the online issue of *Otolaryngology – Head and Neck Surgery*, the official peer-reviewed publication of the American Academy of Otolaryngology – Head and Neck Surgery Foundation.

The biggest challenge for OSA patients is that many are unable to tolerate or get relief from CPAP. Published studies show that CPAP adherence rates are less than 50 percent. In contrast, the new data from the STAR Trial demonstrate that more than 80 percent of the patients with Inspire therapy report nightly use after three years of being prescribed the therapy.

The data was recently presented at the annual American Academy of Otolaryngology – Head and Neck Surgery Foundation meeting in Dallas by B. Tucker Woodson, MD, Chief, Division of Sleep Medicine at Froedtert Hospital and the Medical College of Wisconsin. Dr. Woodson is the lead author of the 36-month manuscript. “The data confirms that Inspire Upper Airway Stimulation therapy is safe and effective and that the results are consistent over the long term,” said Dr. Woodson. “We also observed high therapy adherence rates throughout the three-year STAR trial follow-up period. It is exciting to have an effective treatment to help those sleep apnea patients who are not able to tolerate or achieve consistent benefit from CPAP.”

“The three-year study outcomes are significant as they demonstrate that improvements in both objective respiratory and subjective quality of life measures are maintained,” says Tim Herbert, Chief Executive Officer of Inspire Medical Systems. “We thank and congratulate both the STAR trial investigator group and the author team for completing the long-term follow up and publishing these important outcomes.”

**About Inspire Therapy**

Untreated Obstructive Sleep Apnea (OSA) can have devastating effects on heart and brain health, impair quality of life, and increase accident risk. [Inspire Upper Airway Stimulation (UAS)](https://www.inspiremedicalsystems.com/upper-airway-stimulation/) therapy is an FDA-approved treatment for some people with moderate to severe OSA who are unable to tolerate or get relief from CPAP. In contrast to CPAP, Inspire therapy is implanted inside the body and works with a patient’s natural breathing process. Controlled by the patient sleep remote, the system includes a breathing sensor and a stimulation lead powered by a small battery. During sleep, the system senses breathing patterns and delivers mild stimulation to the tongue and other soft tissues of the throat to keep the airway open.
Inspire therapy is currently available at more than 60 leading medical centers across the United States and Europe.

**About Inspire Medical Systems, Inc.**

Inspire Medical Systems, Inc., based in Minneapolis, Minn., was incorporated in 2007 with the sole purpose of developing a safe, effective and well-accepted therapy to help those OSA patients who are unable to tolerate or get relief from CPAP. Inspire therapy is the world’s first implantable FDA-approved neurostimulation system for the treatment of OSA. The Company is privately held and investors include Aperture Venture Partners, GDN Holdings, Johnson & Johnson, Kleiner Perkins Caufield & Byers, Medtronic, OrbiMed Advisors, Synergy Life Science Partners, TGap Ventures and US Venture Partners.

For more information, visit [www.InspireSleep.com](http://www.InspireSleep.com).