



## Inspire Medical Systems Announces FDA approval for Pivotal Clinical Trial

*Inspire Device for Obstructive Sleep Apnea will be tested at sites in US and Europe*

**Minneapolis – November 30, 2010** – [Inspire Medical Systems](#), a leading developer of neuro-stimulation therapies for the treatment of obstructive sleep apnea (OSA), announced today that the company has received approval from the U.S. Food and Drug Administration (FDA) to begin its STAR pivotal clinical trial. [The STAR trial](#) (Stimulation Therapy for Apnea Reduction), is a multi-center study that will evaluate both the safety and effectiveness of [Inspire™ Upper Airway Stimulation \(UAS\) therapy](#) in patients with moderate to severe obstructive sleep apnea (OSA). The STAR trial will be conducted at leading medical centers across the United States and Europe. The results of this study will be the basis for a Pre-market approval (PMA) application to the FDA.

“OSA is a prevalent disorder affecting over 15 million adults in the U.S. alone. Current front line therapies for OSA, including CPAP, can have a significant impact on the lifestyle and comfort for both the OSA patient and their bed partner. As a result, patient compliance for these front line therapies is sub-optimal. A substantial number of patients suffering from OSA are looking for a new approach to treat this challenging condition,” commented [Tim Herbert](#), President and CEO of Inspire Medical Systems. “Our goal with Inspire therapy is to significantly reduce the burden of sleep apnea and restore restful sleep without the lifestyle tradeoffs that some other therapies require.”

“Patients with untreated sleep apnea are at higher risk of developing hypertension, heart failure and stroke,” said [Dr. Meir Kryger](#), Director of Sleep Medicine Research and Education at Gaylord Hospital in New Haven, Connecticut. “There is a growing need for new treatment options for those patients who are non-compliant with current therapies.”

Inspire also announced today that it has received CE Mark for Inspire™ Upper Airway Stimulation (UAS) therapy. “The receipt of the CE Mark is an important validation of our internal quality system and it authorizes the commercial sale of Inspire therapy in Europe,” commented Mr. Herbert. “The company’s current focus is to conduct a robust pivotal trial. We will begin initial European market development activities in late 2011.”

Leading medical centers in Germany, Belgium and The Netherlands are currently approved to implant patients into the STAR trial. Professor Paul Van de Heyning, Director of Otolaryngology and Head and Neck Surgery at the University of Antwerp in Antwerp Belgium recently implanted the first patient in the STAR trial. “Inspire’s stimulation therapy is well suited to address the root cause of OSA for many patients which is a decrease in airway muscle tone during sleep,” said Professor Van de Heyning. “The Inspire implant procedure is less invasive than most OSA surgical techniques which will likely contribute to faster patient recovery times. The STAR trial will provide valuable information on the potential role of upper airway stimulation therapy.”



The first U.S. implants in the STAR trial are targeted for early 2011. Prior to the approval of the STAR trial, Inspire Medical Systems completed three independent feasibility studies in The United States, Europe and Israel. Clinical data from those studies served as the basis for initiating the STAR trial.

### **About Obstructive Sleep Apnea (OSA)**

OSA is a common sleep disorder that occurs when the tongue and other soft tissues of the throat relax and obstruct the airway during sleep. Apnea events can occur multiple times per hour throughout the night, disrupting normal sleep. People suffering from OSA report significant daytime sleepiness and impaired quality of life. Depending on the degree of severity, OSA can be a potentially dangerous condition. OSA has been linked with increased risks for cardiovascular disease, weight gain and accidents resulting from daytime drowsiness. It is estimated that one in fifteen US adults has moderate to severe OSA.

### **About Inspire™ Upper Airway Stimulation (UAS) Therapy**

Inspire Upper Airway Stimulation (UAS) therapy is a dynamic, implantable therapy that works with the body's natural physiology to prevent airway obstruction during sleep. While the [OSA patient](#) sleeps, Inspire therapy is designed to deliver physiologically timed, mild stimulation to the hypoglossal nerve on each breathing cycle. The stimulation is intended to restore tone to the muscles that control the base of tongue, preventing the tongue from collapsing and obstructing the airway. Patients control when the therapy is turned on and off via a handheld programmer. In contrast to other surgical procedures to treat sleep apnea, Inspire therapy does not require removing or permanently altering an OSA patient's facial or airway anatomy.

### **About The STAR Trial**

The STAR trial is a global, multi-center clinical trial which will assess the safety and effectiveness of Inspire Upper Airway Stimulation (UAS) therapy in patients who suffer from moderate to severe obstructive sleep apnea (OSA). The trial will be conducted at leading medical centers throughout the United States and Europe. For more information on The STAR trial, visit [www.InspireSleep.com](http://www.InspireSleep.com).

### **About Inspire Medical Systems**

Inspire Medical Systems, based in Minneapolis, Minnesota, is the world's leading developer of innovative, implantable neurostimulation technologies to treat Obstructive Sleep Apnea. Utilizing well-established technologies from the fields of cardiac pacing and neurostimulation, Inspire has developed a proprietary Upper Airway Stimulation (UAS) therapy for patients who suffer from obstructive sleep apnea. Inspire was formed in 2007 when the technology and a significant intellectual property portfolio was spun-out of Medtronic (NYSE: MDT). Inspire therapy is designed to significantly reduce the burden of sleep apnea and restore restful sleep to patients suffering from this challenging condition. Inspire is funded by the prestigious medical technology investment firms GDN Holdings LLC, Kleiner, Perkins,



Caufield and Byers, Synergy Life Sciences Partners, US Venture Partners as well as Medtronic. Visit Inspire Medical Systems on the web at [www.InspireSleep.com](http://www.InspireSleep.com).

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