



## **Inspire Medical Systems Reaches Milestones with its Sleep Apnea Therapy**

*STAR pivotal trial actively recruiting and implanting patients at 9 US sites; Feasibility study data shows therapy may significantly reduce severity of sleep apnea in well selected patients*

**Minneapolis – June 9, 2011** – [Inspire Medical Systems](#), the leading developer of neurostimulation therapies for the treatment of obstructive sleep apnea (OSA), announced today [The STAR trial](#) (Stimulation Therapy for Apnea Reduction), evaluating both the safety and effectiveness of [Inspire™ Upper Airway Stimulation \(UAS\) therapy](#), is currently underway at 9 leading medical centers across the United States and at 4 sites in Europe. In addition, several OSA patients have already been implanted with Inspire therapy in The STAR trial.

Sleep Medicine Associates of Texas, under the leadership of Dr. Andrew Jamieson, completed their first implant of Inspire therapy in The STAR trial this spring. “Untreated OSA can become a life-altering condition, causing life-threatening burdens such as cardiovascular disease, high blood pressure and stroke. Inspire therapy is designed to work with the patient’s physiology to reduce the burden of OSA. The implant procedure for Inspire therapy is very straightforward and requires just three small incisions. We are looking forward to conducting additional implants to help contribute to this important clinical study.”

The company also recently presented the latest data from two Inspire feasibility studies conducted in 2009 and 2010, at the American Thoracic Society (ATS) 2011 meeting in May. The data will also be featured at this week’s [National Sleep Meeting](#) taking place June 11-15, 2011, in Minneapolis (Booth #935).

“Data from these feasibility studies suggests that Inspire therapy can significantly reduce the burden of OSA in well selected patients,” commented Tim Herbert, CEO of Inspire Medical Systems. “Inspire’s STAR trial pivotal study protocol was developed based on the information generated from these feasibility studies.”

### **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 OSA, Inspire therapy does not require removing or permanently altering a 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 OSA. To be eligible for screening and inclusion in the STAR trial, patients must have failed or not tolerated CPAP (Continuous Positive Air Pressure), have moderate to severe sleep apnea, and have a body mass index of less than 32. For more information on The STAR trial, visit [www.thestartrial.com](http://www.thestartrial.com) or call 1-888-844-4811.

## **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 (OSA). 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 OSA. 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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