



FOR IMMEDIATE RELEASE

FDA Approves Inspire® Upper Airway Stimulation (UAS) Therapy for Obstructive Sleep Apnea

Fully Implanted Device Represents New Treatment Option for Patients Unable to Use CPAP

Minneapolis, Minn. – May 1, 2014 – Inspire Medical Systems, Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved Inspire Upper Airway Stimulation (UAS) therapy for use in a subset of patients with moderate to severe Obstructive Sleep Apnea (OSA) who are unable to use Continuous Positive Airway Pressure (CPAP). Inspire therapy is a fully implanted neurostimulation device, the first of its kind for sleep apnea, that provides an alternative treatment that is proven, convenient and easy to use.

Obstructive Sleep Apnea is a prevalent health issue affecting about 18 million Americans, according to the National Sleep Foundation. Research shows that an individual with poorly managed OSA is at increased risk for heart attack, stroke, weight gain, high blood pressure, heart failure and falling asleep while driving. Sleep apnea can also be disruptive to one's everyday activities causing depression, spousal issues, irritability and daytime fatigue.

Current treatments for OSA include weight loss, CPAP, oral appliances and anatomy altering surgeries. CPAP is the current standard of care for OSA management. It is often successful but recent studies have shown that roughly half of all patients that start CPAP do not continue to consistently use it.

Inspire therapy is a fully implanted system consisting of three components: a small generator, a sensing lead and a stimulation lead. The single external component is a small handheld Inspire sleep remote used to turn the therapy on before bed and off upon waking. When activated, Inspire therapy senses breathing patterns and delivers mild stimulation to key airway muscles, which keeps the airway open during sleep. In contrast to other surgical options to treat sleep apnea, Inspire therapy does not require removal or permanent alteration of facial or airway anatomy. As such, the procedure is less invasive and should result in a shorter recovery time.

"The FDA approval of Inspire therapy represents a new era of choice for a subset of patients with moderate to severe Obstructive Sleep Apnea who are unable to use CPAP," said Tim Herbert, Inspire Medical Systems president and CEO. "All of us at Inspire Medical Systems are committed to improving the health and quality of life for these individuals with OSA, and we are excited to make this innovative and much needed treatment available to patients and physicians."

"This therapy represents a major advance in sleep apnea treatment for some patients who are unable to use or tolerate CPAP therapy," said Meir Kryger, MD, professor, Yale School of Medicine. "Patients with moderate to severe OSA who are not on effective treatment are at an increased risk for cardiovascular

disease, accidents and death. There is a significant need for safe, effective and well-tolerated new treatments in the sleep medicine field.”

Patients implanted with Inspire therapy who participated in the company’s STAR (Stimulation Therapy for Apnea Reduction) pivotal clinical trial experienced a 68 percent reduction in apnea events, a 70 percent reduction in oxygen desaturation events, and significant improvements in daytime functioning as measured by two validated questionnaires. These results were published in the January 9, 2014 issue of the *New England Journal of Medicine*.

Inspire therapy will be commercially available to patients in the United States in the second half of 2014.

About Inspire Medical Systems

[Inspire Medical Systems](http://www.inspiresleep.com), based in Minneapolis, Minn., has developed the world’s first fully implanted and FDA-approved neurostimulation system for the treatment of Obstructive Sleep Apnea (OSA). The Inspire system uses well established neurostimulation technologies and incorporates a proprietary algorithm which stimulates key airway muscles based on a patient’s unique breathing patterns. 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 reduce OSA severity and improve quality of life for patients living with this challenging condition. Visit Inspire Medical Systems on the web at www.inspiresleep.com.

Safety information for Inspire therapy is provided at www.inspiresleep.com. Inspire therapy is not for everyone. Information at this site should not be used as a substitute for patients talking with their doctor. Patients are encouraged to review this safety information and talk with their doctor about diagnosis and treatment options.

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