Inspire Medical Systems Completes First Implant of the Inspire II System to Treat Obstructive Sleep Apnea

Second generation implantable device utilizes electrical stimulation to prevent airway closure during sleep

Minneapolis, MN – February 26, 2009 – Inspire Medical Systems, Inc., a private medical device company, today announced it has completed the first human implant of its Inspire II system designed to treat Obstructive Sleep Apnea (OSA).

It is estimated that one in fifteen adults has moderate to severe OSA[1]. People with OSA experience recurrent blockage of their upper airway during sleep, resulting in frequent arousals from sleep and reduced oxygen levels in the blood. This happens in patients with OSA because the muscles that normally hold the airway open during wakefulness relax during sleep and allow the airway to collapse. When the airway is partially closed and/or the muscles relax too much, trying to inhale will completely close the airway, resulting in an obstructive sleep apnea event. Depending on the degree of severity, OSA is a potentially life-threatening condition. According to a recent report[2] from the National Center on Sleep Disorders Research and the National Institute of Health, someone who has undiagnosed or is non-compliant to treatment of their sleep apnea is significantly more likely to have a heart attack, a stroke, cardiac arrest during sleep, or a harmful accident.

The Inspire II system is an implantable device that delivers electrical stimulation to prevent the closure of the upper airway that can stop airflow in patients with OSA. The device is a unique closed-loop system that is able to sense respiratory effort and deliver stimulation to keep the airway open and breathing normal.

Inspire Medical Systems collaborated with Paul Van de Heyning, M.D., professor of Otorhinolaryngology and Head and Neck surgery and Wilfried De Backer, M.D., professor of Respiratory Medicine both at the University Hospital in Antwerp, Belgium for the first patient implant as part of the Inspire II clinical study. The company has also received approval from the U.S. Food and Drug Administration (FDA) and is expected to begin implants in the U.S. next month.

“Compliance with current sleep apnea therapies continues to be an issue for patients with moderate to severe OSA. Previous clinical studies of the first generation Inspire I system demonstrated the value of electrical stimulation of the hypoglossal nerve to prevent closure of the upper airway during sleep. Based on these results and the improvements to the Inspire II system, we believe that the implantable device could be the answer to helping patients with OSA,” said Professor Van de Heyning.

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[1] (Caples et al, *Ann Intern Med.* 2005;142:187-197)

[2] (Quan et al, Circulation, 2004;109:951-957)

Inspire Medical Systems was formed when the Inspire intellectual property and technology was licensed and spun out from Medtronic in 2007. Previous development efforts at Medtronic included conducting an eight-patient human feasibility trial from 1998-2001. Professor Van de Heyning implanted four of the eight patients in the initial trial.

"We have been able to build significant momentum with the Inspire system development program since licensing the technology from Medtronic, and our efforts have coincided nicely with the further identification and visibility of OSA as a significant global health problem," said Timothy Herbert, President and CEO of Inspire Medical Systems. "The results of the first feasibility trial provided good indicators of therapeutic response, but we believe the next generation device, the Inspire II, now incorporates improved features that will aid in implantation and optimize long-term results for the patients."

"The physiologic mechanisms associated with OSA lend themselves well to the application of the advanced neurostimulation and sensing technology provided by the Inspire system," added Dr. Glen Nelson, Chairman for Inspire Medical Systems. Dr. Nelson was formerly Vice-Chairman at Medtronic and recently retired as Chairman of MinuteClinic after its sale to CVS Caremark.

About the Inspire II System

The Inspire II system consists of an implantable pulse generator, a respiration pressure sensor and a stimulation lead that delivers the electrical impulses to the patient's hypoglossal nerve. The hypoglossal nerve is the twelfth cranial nerve that is located along the side of the neck and leads to the tongue. The unique closed-loop design of the Inspire II system senses a patient's respiratory effort during sleep and provides hypoglossal nerve stimulation to maintain an open airway synchronous with respiration. Patients have a programming device that is used to turn the device on at bedtime and to turn the unit off during non-sleep periods. The stimulation delivered is sufficient enough to evoke a response from the nerve but at a low enough level to not disturb the patient's sleep. A physician controller unit, used during visits to the patient's treating physician, is used to monitor the therapy and make adjustments to the device as needed for the patient's unique physiology.

About Inspire Medical Systems: www.inspiremedicalsystems.com

Inspire Medical Systems, Inc., based in Minneapolis, Minnesota, was created to be the world's leading provider of innovative and cost-effective implantable therapeutic devices for the treatment of Obstructive Sleep Apnea. The focus for the company is developing and commercially releasing the Inspire system for the treatment of Obstructive Sleep Apnea (OSA). The company was formed when the intellectual property for the Inspire System was licensed and spun out from Medtronic in 2007 through financing provide by blue-chip venture investors Kleiner Perkins Caufield & Byers, U.S. Venture Partners and Glen D. Nelson, M.D., through GDN Holdings. Medtronic also invested in the company, maintains a minority ownership position and provides important contract manufacturing to the company. The leadership team of Inspire Medical Systems oversaw the development of the technology at Medtronic and managed the successful spin-out of the program as an independent enterprise.