

## New Data Shows Reductions in Obstructive Sleep Apnea (OSA) Severity and Improvement of Quality of Life with Inspire Therapy

Latest research presented at 2014 American Academy of Otolaryngology Meeting in Orlando Sept. 19-23

MINNEAPOLIS and ORLANDO, Fla., Sept. 19, 2014 /PRNewswire/ -- The body of published data supporting Inspire therapy continues to grow, with the publication of two papers this past week. The first paper published on-line in *Otolaryngology – Head and Neck Surgery*, finds that withholding Inspire therapy causes a worsening of both objective and subjective measures of sleep disordered breathing, leading the paper's authors to directly attribute Inspire therapy for the reduction in obstructive sleep apnea severity and improvement of quality of life for patients.

Inspire therapy is an FDA approved treatment for a subset of people with moderate to severe OSA who are unable to use Continuous Positive Airway Pressure (CPAP) and meet the patient selection criteria. The fully implanted system delivers mild stimulation to keep a patient's airway open during sleep and does not require a mask.

The researchers conducted a randomized controlled therapy withdrawal study to assess the efficacy and durability of upper airway stimulation to treat OSA. Participants were randomized to either a therapy maintenance ("ON") group or a therapy withdrawal ("OFF") group. Short-term withdrawal effect as well as therapy durability at 18 months were assessed.

Both groups demonstrated significant improvements at 12 months compared to study baseline. In the randomized assessment, the therapy withdrawal group experienced a return of their OSA, while the therapy maintenance group remained effectively treated. At 18 months with Inspire therapy ON in all patients, both groups showed sustained improvements similar to 12 months.

In addition, a second paper was published on-line by the *European Respiratory Journal*, reports on research to define the mechanism on how Inspire therapy works to relieve systems of OSA. The research demonstrated that Inspire therapy increases the airway at multiple levels including near the back of the tongue as well as at the level of the soft palate. The researchers of the two papers will present their findings at the 75th annual scientific meeting of the American Academy of Otolaryngology (AAO), taking place September 19-23 in Orlando.

"Upper Airway Stimulation for Obstructive Sleep Apnea has been researched for over 20 years," reports Dr. B. Tucker Woodson from the Medical College of Wisconsin in Milwaukee. "The therapy is approved in the United States, and there is strong evidence to support the use of the therapy in select patients who are unable to use CPAP."

"OSA is a prevalent disorder affecting millions of adults in the U.S. and our Inspire therapy technology is helping to fill a tremendous unmet need for innovative, easy to use therapies. This growing body of data supports the use of Inspire therapy for patients who are unable to find relief from front line treatments for OSA such as CPAP," said Tim Herbert, Inspire Medical Systems President and CEO. "Since receiving FDA approval in April, there has been strong interest from both patients and physicians. Inspire therapy is now available at leading medical centers in the United States and Europe."

AAO attendees in Orlando can learn more about Inspire therapy during the conference at three presentations by the researchers:

- Seminar titled: "Hypoglossal Nerve Stimulation Therapy for OSA," Tuesday, September 23, at 10:30 a.m.
- "Randomized Treatment Withdrawal of Hypoglossal Nerve Stimulation for Obstructive Sleep Apnea," Sunday, September 21, at10:30 a.m.
- "The Influence of Drug-Induced Sleep Endoscopy on Determining Candidacy for Upper Airway Stimulation (UAS) Therapy," Monday, September 22, at 9:30 a.m.

Clinicians and scientists attending the meeting and interested in joining these sessions can visit Inspire Medical Systems at booth #1534 to learn more.

## **About Inspire therapy**

Inspire® Upper Airway Stimulation (UAS) is an FDA approved treatment for a subset of people with moderate to severe OSA who are unable to use CPAP. 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, a small handheld Inspire sleep remote, is 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. Patients implanted with Inspire therapy who participated in the 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 Quality of Life. These results were published in the January 9, 2014, issue of the *New England Journal of Medicine*. For more information visit: http://www.multivu.com/mnr/7169651-fda-approves-inspire-upper-airway-stimulation-therapy-sleep-apnea

## **About Inspire Medical Systems**

Inspire Medical Systems, based in Minneapolis, Minn., was formed in 2007 when the technology and a significant intellectual property portfolio was spun-out of Medtronic (NYSE: MDT). Inspire Medical Systems has developed the FDA approved system for the treatment of Obstructive Sleep Apnea (OSA). Privately held, investors include Aperture Venture Partners, GDN Holdings, Johnson & Johnson Development Corporation, Kleiner Perkins Caufield & Byers, Medtronic, OrbiMed Advisors, Synergy Life Science Partners, TGap Ventures and US Venture Partners.

Visit Inspire Medical Systems on the web at www.inspiresleep.com.

## Media contacts:

Helen Shik or Courtney Conery MSLGROUP Boston 781-684-0770 InspireMedical@mslgroup.com