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**Inspire Medical Systems Announces FDA Approval of  
Inspire 3028 Neurostimulator for the Treatment of Obstructive Sleep Apnea**

*Next generation technology is 40% smaller & 18% thinner than  
current neurostimulator and includes MRI Conditional labeling*

*Product launched at SLEEP 2017 annual meeting, taking place in Boston June 3-7*

**MINNEAPOLIS (June 5, 2017)** — Inspire Medical Systems, Inc., manufacturer of the only FDA-approved implantable device for obstructive sleep apnea (OSA), has received U.S. Food and Drug Administration (FDA) approval for its next-generation device, the Inspire 3028 implantable pulse generator, which includes magnetic resonance (MR) conditional labeling, allowing patients to undergo magnetic resonance imaging (MRI) safely.

“The continuous positive airway pressure (CPAP) intolerant patients I see want to lead active and engaging lives,” said Alan Kominsky, MD, a practicing ENT-otolaryngologist at the Cleveland Clinic. “With conditional MRI labeling, the new Inspire device provides my OSA patients peace of mind now that MRIs are an option. Similar to approvals in the cardiac and neurological implantable device arenas, this labeling expansion is a welcome addition to the upper airway stimulation therapy.”

In addition to the conditional MRI labeling, the newly approved implantable device provides many OSA patients with a size profile that meets the needs of patients who cannot use or get benefit from CPAP. The Inspire 3028 device is 40% smaller and 18% thinner than the current Inspire neurostimulator which received FDA approval in April 2014.

“We have received consistent feedback from the medical community that providing the ability for patients to have an MRI is very important,” said Tim Herbert, President and CEO of Inspire Medical Systems. “We incorporated features to allow for an MRI and redesigned the device to have both a smaller footprint as well as being significantly thinner without compromising product functionality or device battery life which remains at about 11 years. We believe that the peace of mind and improved patient comfort with this next generation device will have a direct and positive impact on the commercial opportunity for Inspire therapy.”

Inspire therapy is currently being implanted in over 100 leading medical centers across the United States and over 25 centers in Europe. Over 1,700 patients worldwide are

currently using Inspire therapy, and objective and subjective patient outcomes have proven the therapeutic benefit of the technology. Inspire also announced that two key publications have been issued in peer-reviewed medical journals further describing the safety and efficacy of Inspire therapy. First, the four-year long-term follow-up clinical data of patients in the STAR phase III pivotal trial was published in the journal, [\*Otolaryngology–Head and Neck Surgery\*](#), in May 2017. The results of the four-year follow-up showed sustained quality of life improvements in patients who have used the therapy for over four years.

Also published, in the April 2017 of [\*Otolaryngology–Head and Neck Surgery\*](#), was the first multi-center trial conducted to validate the results of the STAR trial. This second trial was conducted in Germany with 60 patients implanted with the Inspire device. The authors concluded that selective upper airway stimulation is a safe and effective therapy for patients with obstructive sleep apnea and represents a powerful option for its surgical treatment.

“Inspire therapy is proving to be a valuable option for patients who are unable to tolerate CPAP,” said Kingman Strohl, MD, Professor of Medicine at Case Western Reserve University School of Medicine and Program Director, Sleep Medicine at UH Cleveland Medical Center. “I remain convinced that we will continue to see outstanding patient outcomes with the Inspire therapy system and am confident this next generation of smaller and thinner device with conditional MRI labeling will be an important therapy for my untreated OSA patients.”

Inspire will be announcing the approval of the Inspire 3028 neurostimulator at SLEEP 2017, the joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, June 3<sup>rd</sup> – 7<sup>th</sup> in Boston. Further, several physicians who have investigated the safety and efficacy of Inspire therapy will present their results during this meeting including the 5-year long-term clinical data from the STAR phase III pivotal as well as additional independent clinical trials and reporting on long-term compliance to the therapy. On Monday, June 5, 2017 at 12:45pm ET, Inspire is sponsoring an Industry Product Theater titled, “Incorporating Inspire Upper Airway Stimulation into Your Practice.”

### **About Inspire Therapy**

Inspire Upper Airway Stimulation therapy is an FDA-approved treatment for some people with moderate to severe Obstructive Sleep Apnea who are unable to use or get consistent benefit from continuous positive airway pressure (CPAP). In contrast to CPAP, Inspire therapy is implanted inside the body and works with a patient's natural breathing process. Controlled by the small handheld sleep remote, the system includes a breathing sensor and a stimulation lead powered by a small battery. During sleep, the system senses breathing patterns and delivers mild stimulation to the tongue and other soft tissues of the throat to keep the airway open. Inspire therapy is currently available at more than 100 leading medical centers across the United States and Europe.

### **About Inspire Medical Systems, Inc.**

Inspire Medical Systems, Inc., based in Minneapolis, Minn., was incorporated with the purpose of developing a safe, effective and well-accepted therapy to help those OSA patients who are unable to tolerate or get relief from CPAP. Inspire therapy is the world's first implantable FDA-approved neurostimulation system for the treatment of OSA. The Company is privately held and investors include Amzak Health, Aperture Venture Partners, GDN Holdings, Johnson & Johnson, Kleiner Perkins Caufield & Byers, Medtronic, OrbiMed Advisors, Synergy Life Science Partners, TGap Ventures and US Venture Partners.

For more information, visit [www.InspireSleep.com](http://www.InspireSleep.com).