



**FOR IMMEDIATE RELEASE**

## **Inspire Medical Systems, Inc. Announces Regulatory Approval of Inspire Therapy for Treatment of Moderate to Severe Obstructive Sleep Apnea in Japan**

**MINNEAPOLIS, Minnesota – June 27, 2018** – Inspire Medical Systems, Inc. (NYSE: INSP) ("Inspire"), a medical technology company focused on the development and commercialization of innovative and minimally invasive solutions for patients with obstructive sleep apnea (OSA), today announced that Japan's Ministry of Health, Labour and Welfare has approved its Inspire therapy to treat moderate to severe OSA.

Inspire therapy is an innovative, closed-loop, minimally invasive solution that provides comfort and convenience, resulting in high compliance for patients with moderate to severe OSA. The safety and efficacy of Inspire therapy is supported by a significant body of clinical data, which includes a publication in the *New England Journal of Medicine* and more than 50 peer-reviewed publications. Inspire obtained CE Mark for its Inspire therapy in 2010 and U.S. Food and Drug Administration approval in 2014. To date, physicians have treated more than 3,000 patients worldwide with Inspire therapy.

"With this approval for our Inspire therapy, we are able to provide patients and physicians in Japan with a new alternative for the treatment of moderate to severe OSA," said Tim Herbert, President and Chief Executive Officer of Inspire Medical Systems. "Our Inspire therapy is supported by a strong body of evidence with more than five years of clinical experience demonstrating the efficacy and safety of our therapy for patients and physicians. We look forward to commercializing our Inspire therapy in Japan."

Recent published data estimates that 9% of Japanese men and nearly 3% of Japanese women are diagnosed with OSA. Further reports indicate that approximately 9 million Japanese have an Apnea Hypopnea Index (AHI) greater than 15, which qualifies them at least as moderate OSA patients. Inspire will now seek reimbursement coverage for its therapy in Japan. The reimbursement process will require significant time and interactions with the authorities in Japan. As a result, along with the planned organizational development and physician training, Inspire intends to launch its therapy in Japan in the second half of 2019.

Inspire will be discussing the clinical outcomes and patient experiences with Japanese physicians at the Japanese Society of Sleep Research and the Asian Sleep Research Society (ASRS) meetings, which will be jointly held in Sapporo, Japan, on July 11–13, 2018.

"We would like to thank Cobridge Co., Ltd., a leading regulatory affairs consulting firm that provides comprehensive product registration services for medical products in Japan, for their outstanding efforts and expertise in assisting us to gain approval in Japan," continued Mr. Herbert.

**About Inspire Medical Systems**

Inspire is a medical technology company focused on the development and commercialization of innovative and minimally invasive solutions for patients with obstructive sleep apnea. Inspire Medical Systems' proprietary Inspire therapy is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe obstructive sleep apnea.

For additional information about Inspire, please visit [www.inspiresleep.com](http://www.inspiresleep.com)

### **Forward Looking Statements**

This press release contains forward-looking statements. All statements other than statements of historical facts contained in this press release are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning: our expected commercial launch of Inspire therapy in Japan; estimates regarding the annual total addressable market for our Inspire therapy in the United States and our market opportunity outside the United States, future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing; commercial success and market acceptance of our Inspire therapy, including in Japan; our ability to achieve and maintain adequate levels of coverage or reimbursement for our Inspire system or any future products we may seek to commercialize; competitive companies and technologies in our industry; our ability to expand our indications and develop and commercialize additional products and enhancements to our Inspire system; our business model and strategic plans for our products, technologies and business, including our implementation thereof; our ability to accurately forecast customer demand for our Inspire system and manage our inventory; our ability to expand, manage and maintain our direct sales and marketing organization, and to market and sell our Inspire system in markets outside of the United States, including in Japan; our ability to hire and retain our senior management and other highly qualified personnel; our ability to commercialize or obtain regulatory approvals for our Inspire therapy and system, or the effect of delays in commercializing or obtaining regulatory approvals; FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States and international markets; the timing or likelihood of regulatory filings and approvals; our ability to establish and maintain intellectual property protection for our Inspire therapy and system or avoid claims of infringement; and our expectations about market trends.

### **Investor and Media Contact:**

Bob Yedid

LifeSci Advisors

[bob@lifesciadvisors.com](mailto:bob@lifesciadvisors.com)

646-597-6989