



## **Inspire Medical Systems, Inc. Announces FDA Approval of New Sensing Lead**

**MINNEAPOLIS, January 29, 2019** -- 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, announced today that the U.S. Food and Drug Administration (“FDA”) has approved for use in the U.S. Inspire’s new sensing lead. Inspire intends to introduce the new sensing lead to its U.S. medical center customers in March 2019.

The sensing lead monitors a patient’s respiratory pattern as the implanted Inspire system delivers stimulation to the upper airway in order to prevent obstructions during sleep. The new sensing lead has a significantly smaller profile, including a reduction in diameter of 49 percent, as compared to the prior design. This smaller profile is intended to improve the patient’s comfort. The new design also incorporates several features to enable easier implanting and potentially reduce surgical time for an ENT surgeon.

“We are pleased to receive FDA approval of the new sensing lead for Inspire therapy,” said Tim Herbert, President and Chief Executive Officer of Inspire Medical Systems. “The improved features of the sensing lead have led to more reliable and simpler implant procedures, as demonstrated by our recent European experience with the new sensing lead since its introduction in Europe in October 2018. We believe that the product enhancements with this next generation sensing lead will continue to have a positive impact on the commercial opportunity for Inspire therapy.”

### **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’s 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 within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including, without limitation, statements regarding the timing for Inspire’s introduction of its new sensing lead, the potential for improved patient comfort and easier implanting with this new sensing lead and a positive impact on the commercial opportunity for Inspire therapy. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “future,” “outlook,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “continue,” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

These forward-looking statements are based on management's current expectations and involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others: estimates regarding the annual total addressable market for our Inspire therapy in the U.S. and our market opportunity outside the U.S., 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; 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 U.S.; our ability to increase the number of active medical centers implanting Inspire therapy; 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 U.S. and international markets; and our ability to establish and maintain intellectual property protection for our Inspire therapy and system or avoid claims of infringement. Other important factors that could cause actual results, performance or achievements to differ materially from those contemplated in this press release can be found under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our final prospectus filed under Rule 424(b) on December 7, 2018, as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at [www.sec.gov](http://www.sec.gov). These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, unless required by applicable law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Thus, one should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

**Investor and Media Contact:**

Bob Yedid

LifeSci Advisors

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

646-597-6989