April 26, 2021

To whom it may concern,

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Japan Lifeline Closes Exclusive Distribution Agreement for Implantable Treatment Device for Obstructive Sleep Apnea Syndrome

Japan Lifeline Co., Ltd. is pleased to announce that it has concluded a 10-year exclusive distribution agreement with Inspire Medical Systems, Inc. (Minnesota, USA) for Inspire Upper Airway Stimulation (Inspire UAS), the first domestic implantable treatment device for obstructive sleep apnea (OSA). The Inspire UAS obtained regulatory approval in 2019 and will be approved for coverage under the National Health Insurance in June of this year. Market launch is to follow thereafter.

Sleep apnea syndrome is a disease that causes apnea or hypopnea during sleep, resulting in hypoxia. The main symptoms are excessive daytime sleepiness, general fatigue, and a decreased ability to concentrate. In a more severe state, sleep apnea syndrome leads to hypertension and sympathetic nerve hyperactivity. This may cause serious complications such as heart disease and stroke. There are about 4 million potential patients in Japan and approximately 90% of them is diagnosed as OSA. Currently, the most common therapy for OSA is continuous positive airway pressure (CPAP) therapy, and the number of CPAP patients is about 400,000 in Japan.

In CPAP therapy, patients wear special masks at bedtime and air is constantly blown from the device to open the airways to prevent sleep apnea. However, approximately 20 to 30% of patients find CPAP therapy cumbersome or uncomfortable and give up on the therapy. The Inspire UAS is indicated for such patients. When the two-lead system connected to the implanted pulse generator senses breathing, the generator delivers a weak stimulation to the hypoglossal nerve, which causes the tongue to slightly move forward, securing the airway. Clinical trials in the United States showed a 79% reduction in the apnea/hypopnea event index and a 71% improvement in the oxygen desaturation index after treatment with Inspire compared to pretreatment. Inspire UAS will provide a new treatment option for patients who gave up on CPAP therapy.

In recent years, a strong relationship between heart disease and sleep apnea has been identified, and the number of heart failure patients are estimated to sharply increase in the near future. Under such circumstances, Japan Lifeline finds it a meaningful initiative to newly enter into the field of sleep disordered breathing treatment. The company believes that the Inspire UAS will have a high synergy with the company's existing products in the arrhythmia business, and thus aims to penetrate the market at an early stage.



Inspire Upper Airway System (UAS)
the pulse generator

About Inspire Medical Systems

Inspire Medical Systems, based in Minneapolis, Minnesota, USA, was founded in 2007 as a spin-out from Medtronic. The company has developed a standard treatment for obstructive sleep apnea syndrome (OSA) and aims to improve the quality of life for all patients suffering from OSA. The company's one-and-only implantable device in the world, Inspire, received FDA approval in 2014 as the first FDA approved OSA treatment device. Commercial sales began in the United States and Europe in 2015, and a cumulative total of more than 12,500 units have been implanted to date. The company is listed on the New York Stock Exchange. (Securities code: INSP) For details, please refer to the website below. https://www.inspiresleep.com/