To whom it may concern,

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Announcement of the Regulatory Approval
For “HeartLight Endoscopic Ablation System”

Japan Lifeline Co., Ltd. ("JLL") received regulatory approval for the HeartLight, Endoscopic Ablation System, manufactured by CardioFocus Inc. (USA) on July 28th. The launch of the HeartLight System is scheduled to be in the fourth quarter of the current fiscal year.

HeartLight is the first system in Japan that uses laser energy and endoscope technology for pulmonary vein isolation of atrial fibrillation. The system consists of a balloon catheter that delivers laser energy, deflectable sheath to guide the balloon catheter to the target sites, endoscope to confirm the ablation sites, and console to control the laser energy and balloon catheter, as well as display the endoscopic images.

The treatment method of the HeartLight is simply performed by positioning the balloon catheter at the pulmonary vein ostium, and delivering laser energy to the tissue from the center of the catheter. The laser energy is accurately applied circumferentially around the vein by monitoring the positioning inside the heart using an endoscope, which allows an effective achievement of the pulmonary vein isolation. Additionally, since it is capable of titrating the energy dosage at each target site, it is expected to be associated with fewer complications such as pulmonary vein stenosis and phrenic nerve palsy, thus contributing to enhancing the safety of pulmonary vein isolation procedures.

Thus far, regarding medical devices associated with atrial fibrillation, JLL has been striving to promote diagnostic systems and supplementary products for ablation devices, ranging from a cardioversion system, an exclusive product in the atrial fibrillation market, to radiofrequency transspetal puncture and esophageal temperature monitoring systems. On this occasion of receiving the regulatory approval for HeartLight, further preparation towards the launch will take place, and JLL will seek to strengthen the product portfolio of their therapeutic devices.

JLL is committed to bringing latest innovations manufactured by foreign companies to Japan, along with the timely and accurate development of its own products by reflecting the needs in clinical practice. The company aims to offer quality products needed in clinical practice and by the patients.
About CardioFocus, Inc.
CardioFocus, Inc. is headquartered in the United States (Marlborough, Massachusetts), and it is a company dedicated to researching and developing advanced treatments for arrhythmias such as atrial fibrillation. The HeartLight Endoscopic Ablation System is a groundbreaking medical device for ablation therapy of atrial fibrillation, and it has already been used in Europe and the United States with a clinical track record of over 4,500 procedures.

Ablation treatment for atrial fibrillation
Atrial fibrillation is a type of arrhythmia, and it is a condition which the heart goes into spasms when irregular electrical stimulation within the atria occurs frequently. In addition to symptoms such as palpitations, shortness of breathing, and light headedness, it is likely for blood to become stationary, which could result in clot formation, and blood clots may clog the vessels and increase the risk of strokes. Furthermore, age, hypertension, cardiac disease, and alcohol are considered to be responsible for the cause of atrial fibrillation.

The immediate cause of atrial fibrillation mainly originates from the electrical stimulation in the pulmonary veins located in the left atrium. In recent years, the establishment of pulmonary vein isolation, which is a treatment method that creates an electrical block by delivering radiofrequency energy around the pulmonary veins using an ablation catheter, has contributed to the continued increasing trend in the amount of procedures. Taking also into account the number of potential patients, it is widely considered that the number of patients with atrial fibrillation in Japan is going to exceed one million patients, and the company estimates that the number of ablation procedures performed in 2016 accounted for approximately 50,000 procedures.