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To whom it may concern,

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Announcement on FDA Approval for Next Generation of Endoscopic Laser Ablation System

Japan Lifeline Co.,Ltd. (“JLL” or “the Company”) is pleased to announce that HeartLight X3, the next generation of the endoscopic laser ablation system HeartLight currently exclusively marketed by the Company in Japan, has been approved by the Food and Drug Administration (FDA) by the manufacturer, CardioFocus, Inc. (USA).

HeartLight is an unique ablation system in the market that utilizes titratable laser energy and an endoscope in pulmonary vein isolation for the ablation treatment of atrial fibrillation. With this device, physicians can view direct images of the heart tissues through the endoscope and perform linear lesions with appropriate energy dosage at each site. Therefore, physicians can effectively block the abnormal electrical circuit and achieve a safer pulmonary vein isolation.

In addition to the combination of the fundamental features of endoscope and laser energy, HeartLight X3, the next generation just approved in the United States, is now equipped with an innovative technology to attain a significant reduction in the procedure times, which has remained as an issue with the product today. With a precise motor control system built into the handle, this function allows for an automatic uninterrupted continuous laser ablation under the control of the operator. It has been successful to reduce the procedure time to an average of 73.7 minutes, while the conventional product takes an average of 206 minutes.

In addition, another new feature, the implementation of a flexible material for balloon is highly beneficial. This compliant balloon not only enables to provide treatment to more cases with various anatomical characteristics, but also eliminates the need for preoperative computerized tomography. Therefore, radiation exposure is expected to be reduced. Further, the balloon sizes can be inflated larger so that it is expected to expand the isolation area.

Since the introduction of HeartLight in 2018 as the marketing authorization holder in Japan, JLL has strived to expand the usage of the endoscopic laser ablation technology throughout Japanese hospitals that perform advanced arrhythmia treatments. Following the regulatory approval in the United States, the Company is expecting to bring HeartLight X3 to the market in Japan in the second quarter of the fiscal year ending March 31, 2022. The Company is eager to provide this advanced technology in Japan as early as possible.