

June 26, 2019

To whom it may concern,

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**Announcement on Extension of Term of the Exclusive Distribution Agreement  
For Orsiro® Sirolimus Eluting Coronary Stent System**

Japan Lifeline Co., Ltd. (“JLL”) has announced today that JLL and BIOTRONIK AG and BIOTRONIK JAPAN, INC. have agreed with the two years’ extension of the term of the exclusive distribution agreement concluded on February 10, 2017 concerning the Orsiro® Sirolimus Eluting Coronary Stent System (“Orsiro®”) manufactured by BIOTRONIK AG. JLL has been selling Orsiro® since March 2018 and will continue up to the end of March 2023.

Orsiro® is a new-generation of drug-eluting stent with hybrid coatings consisting of BIOlute coating and proBIO coating; BIOlute coating is the upper layer that is bioabsorbable after elution of the limus-family drug which effectively suppresses restenosis, and proBIO coating is the lower layer which suppresses inflammations between the metallic surfaces of the stent and the surrounding vascular tissue. The platform of nitinol stents has the Ultrathin\*1-strut and its unique design made it possible to achieve a high degree of flexibility and deliverability without compromising its durability and capability to support the blood vessel as a scaffold. Consequently, it is expected to improve patient’s long-term prognosis by minimizing damage on the vessel wall.

The clinical efficacy and safety of Orsiro® have been demonstrated in numerous clinical trials and studies, which have been conducted in many countries and have enrolled more than 50,500 cases. In the results of the BIOFLOW-V joint international trial that were presented at the ESC\*2 Congress 2017, it was reported that Orsiro® demonstrated a statistically significant outcomes in 12-month target lesion failure (TLF) in comparison to the market leading competing products for the first time. Also, it was reported at the TCT\*3 Conference 2018 that its excellent clinical performance has been maintained at 24 months after implantation. Furthermore, the results of BIOSTEMI trial designed to assess the clinical superiority of Orsiro® are expected to be reported at the ESC Congress scheduled at the end of August this year.

Since the launch of Orsiro® in Japan, JLL has promoted its penetration into the medical field. In order to show excellent clinical results in Japan as well, CASTLE Study\*4 was started in March this year. The expectation is high that accumulating clinical data on 1,440 cases will support the excellent clinical performance of Orsiro®.

In response to this contract extension, JLL intends to further focus on raising awareness of the excellent clinical efficacy and safety of Orsiro® and to accumulate clinical data. As a result, JLL aims to further gain market share by increasing Orsiro®’s credibility in the medical field and also enhance competitiveness in the interventional field with a full range of devices required for PCI\*5 treatment, including other existing products such as the self-manufactured balloon catheters and guide wires, and intravascular imaging devices planned to be launched in the near future.

\*1 thickness of 60µm (stent diameter 3mm or under)

\*2 European Society of Cardiology

\*3 Transcatheter Cardiovascular Therapeutics

\*4 Randomized Comparison “All-Comers” Study of Ultrathin-Strut and Thin Strut Drug-Eluting Stents

\*5 Percutaneous Coronary Intervention

### **About BIOTRONIK**

A global leader in cardio- and endovascular medical technology, BIOTRONIK is headquartered in Berlin, Germany, and represented in over 100 countries or regions. Several million patients have received BIOTRONIK implants designed to save and improve the quality of their lives, or have been treated with BIOTRONIK coronary and peripheral vascular intervention products. Since its development of the first German pacemaker in 1963, BIOTRONIK has engineered many innovations, including Home Monitoring® and the world's first implantable cardioverter defibrillators and heart failure therapy devices with ProMRI® technology.