



MEMBERSHIP

October 27, 2023

To whom it may concern,

Company: Japan Lifeline Co. , Ltd.

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**Japan Lifeline Enters into Exclusive Distribution Agreement with Meril Life Sciences
for Myval Octacor Transcatheter Heart Valve in Japan**

Japan Lifeline Co., Ltd. (“Japan Lifeline” or “the Company”) is pleased to announce that it has signed an exclusive 10-year distribution agreement with Meril Life Sciences Pvt. Ltd. (“Meril”) This agreement, signed on October 27, 2023, allows the Company to sell the transcatheter heart valve “Myval Octacor” used in Transcatheter Aortic Valve Replacement / Implantation (TAVR / TAVI) procedures in Japan following its approval of the Ministry of Health, Labor and Welfare. The Company is planning to newly enter the TAVR / TAVI market as part of its cardiovascular business expansion strategy. The Company expects to launch the product within a few years.

TAVR / TAVI is a treatment that replaces a malfunctioning heart valve caused by aortic stenosis with a biological valve through a catheter based interventional procedure. This treatment received the reimbursement coverage in Japan in 2013. While open-heart surgery (SAVR) was the common treatment before, TAVR / TAVI has quickly become widespread because it’s less physically invasive. In 2021, about 12,000 TAVR / TAVI procedures were performed*1, and the Company expects this number to increase by 4-5% annually.

In TAVR / TAVI, it is crucial to place the valve in the correct position to avoid serious complications*2. Meril’s Myval Octacor THV is a next generation, balloon-expandable transcatheter heart valve that has various features to ensure accurate placement. It offers a wider range of sizes than competitors, allowing doctors to choose a size that best fits the patient’s annulus diameter. The “octagonal cell structure” helps reduce positional displacement during the procedure.

Japan Lifeline used to sell heart valves for surgical treatment (SAVR), but the Company withdrew from the business area in 2019 due to the rapid spread of TAVR / TAVI. Japan Lifeline’s President and CEO, Keisuke Suzuki, commented on the exclusive distribution agreement with Meril, saying, “We have been involved in the field of heart valve disease treatment for about 30 years since our founding era. It’s very emotional for us to re-enter the market with a next generation TAVR / TAVI technology that has proven clinical results worldwide.”

Sanjeev Bhatt, Senior Vice President – Corporate Strategy from Meril also provided a comment, saying, “Meril welcomes this distribution agreement as a strategic collaboration in Japan between two serious players in cardiovascular therapy.” He further added, “Meril has a strong history and lineage of R&D, ultra-modern manufacturing, global clinical research, training, and education of health care professionals. Both Meril and Japan Lifeline share similar corporate values. More than 25,000 Meril Heart Valves (both TAVR and SAVR) have been implanted across 75 countries over past 7 years with proven clinical safety, efficacy and supported by 80+ scientific publications”

Japan Lifeline plans to apply for regulatory approval for Myval Octacor THV as a marketing authorization holder, and prepare for a launch within a few years. Japan Lifeline’s spokesperson says that they are eager to expand their product portfolio in the TAVR / TAVI field with the Meril’s distinctive product, and work to realize a healthier society through the latest and most optimal medical device technologies.

*1 Source: The Japanese Registry Of All Cardiac and vascular Diseases (JROAD) 2022 Report (Japanese only)
https://www.j-circ.or.jp/jittai_chosa/media/jittai_chosa2021web.pdf

*2 One of the serious complications is atrioventricular block. This can occur during surgery when there is interference with the conduction system running directly below the placement position (self-valve ring). If this condition develops, it may be necessary to implant a pacemaker.



Transcatheter Heart Valve “Myval Octacor”
manufactured by Meril Life Sciences

About Meril Life Sciences

Founded in 2006, Meril (www.merillife.com) is a fast-growing global medical device company dedicated to the design and development of novel, clinically relevant, state-of-the-art and best-in-the-class devices to alleviate human suffering and improve quality of life.

With over 100 technology platforms, Meril’s businesses span across – Cardio, Peripheral & Neuro Vascular Interventions, Structural Heart Interventions, Orthopedic Implants, Surgical Robotics, Endo-Surgical Solutions, ENT Solutions, In-Vitro Diagnostics – analyzers & reagents (including COVID-19 test portfolio).

HQ at Vapi, Gujarat, India, the company has >6,000 employees with a large footprint in India, direct operations in – USA, Europe, Latin America, Middle East, Russia & CIS, Australia, UK, South Africa, Turkey & South Asia and presence in >100 countries.

Meril has a strong commitment to R&D, high-quality manufacturing, clinical and scientific research as well as training & education of its stakeholders (patients & care providers).

Company Name:	Meril Life Sciences Pvt. Ltd.
Head Office:	Muktanand, Marg, Chala, Vapi, Gujarat. India.
Year of Establishment:	2006
URL:	https://www.merillife.com/
Business descriptions:	Manufacture and sales of medical devices