PRESS RELEASE

For immediate release

Meril's CE-marked Myval Transcatheter Heart Valve (THV) demonstrates 100% freedom from device related mortality at one year

- *Data on 30 patients treated with Myval THV for severe symptomatic aortic valve stenosis demonstrate study met its endpoints for safety and effectiveness at 12 months in MyVal-1 clinical trial*
- *Follow-up of patients continue out to five years, with larger studies planned*

6 June 2019 – One-year clinical outcomes from the MyVal-1 study[1] of the Myval – THV System for Transcatheter Aortic Valve Replacement (TAVR) – a product indigenously designed and manufactured in India by Meril Life Sciences – demonstrated 100% acute procedural success and no device-related mortality up to one year follow-up, as reported at EuroPCR 2019 (21-24 May).[1]

Imrankhan Lohani, Head Myval-THV Clinical Research at Meril Life Sciences, commented: "We are excited by these results. Our Myval transcatheter heart valve was granted the CE mark in April of this year. As we get set to launch it across Europe, we believe this valve from the emerging world is going to positively impact care substantially."

The data were presented in a late-breaking trial session by the trial's principal investigator, Dr Ashok Seth, Chairman of Fortis Escorts Heart Institute in New Delhi, India. Dr Seth explained that in addition to the procedural success and zero device-related mortality rate, there were also no new pacemaker implantations, no strokes and no paravalvular leaks observed in the trial patients.[1] Furthermore, echo parameters were maintained at 12-month follow-up and there was a significant improvement in the quality of life of patients as demonstrated by tests including NYHA functional class.[1]

Myval THV System is a balloon expandable transcatheter heart valve, made of Nickel Cobalt alloy frame. It has a unique hybrid honeycomb cell design, with open cells on the upper half to ensure un-jailing of the coronary ostia and closed cells on the lower half for high radial strength. It is equipped with an internal PET sealing cuff for lower profile and puncture resistance and an external PET buffing to minimise paravalvular leaks. Dr Seth also explained that the delivery system of the Myval device is intuitively simple, with an operator friendly rotatory handle that also demonstrates high distal flexion for ease of navigation.

MyVal-1 study is a first-in-human, prospective, multicentre, single-arm, open label study of the Myval transcatheter heart valve for the treatment of severe symptomatic native aortic valve stenosis which enrolled 30 patients and will follow-up out to five years.

At 12-months, the study met its primary endpoint for safety and effectiveness, as there was 100% procedural success and no major adverse events and that there was a marked improvement from baseline to 12 months in quality of life scores as measured by the six-minute walk test and the Kansas City Cardiomyopathy Questionnaire.[1] Furthermore, 80.77% of patients were NYHA class I and the remainder NYHA class II at 12-months, compared to 23.33% class I post-procedure.[1]

"Based on these encouraging first-in-human results, further studies are being planned in a larger population and differing geographies for longer durations of time," Dr Seth added.

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About MyVal-1
MyVal-1 is a first-in-human, prospective, multicentre, single-arm, open label study of the Myval transcatheter heart valve in the treatment of severe symptomatic native aortic valve stenosis which enrolled 30 patients and will follow-up out to five years. The safety endpoint is survival at 30 days, six months and 12 months. Efficacy endpoints are improvement in NYHA class, effective orifice area and six-minute walk test, all at 30 days, six months and 12 months. Additional endpoints are quality of life and evidence of prosthetic valve dysfunction, including haemolysis, infection, thrombosis, severe paravalvular leak or migration.

About Myval
Myval is a next generation TAVR technology amalgamating virtues of novel valve design elements resulting in accurate positioning and orthotropic valve deployment. Myval is designed keeping precision at its heart, ensuring predictable clinical safety and efficacy outcomes.

About Meril Life Sciences
Founded in 2006, Meril is a global medical device company that is dedicated to innovate, design and develop novel, clinically relevant and state-of-the-art devices. Headquartered in Vapi, Gujarat, India with more than 4,000 employees, Meril currently conducts business in more than 100 countries with subsidiaries in India, USA, Germany, Brazil and Turkey.
Meril manufactures wide array of medical solutions from vascular intervention devices, Orthopaedic implants, in-vitro diagnostics, endo-surgery and ENT products. For more information about Meril, please visit https://www.merillife.com/. Follow Meril Life Sciences on LinkedIn here.

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References
1. Seth A. One-year clinical outcomes of India's first indigenously designed and manufactured TAVR system. Presented at EuroPCR 2019