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Meril presents successful LANDMARK RCT one-year results at prestigious EuroPCR 2025

23 May 2025 | News

First-of-its-kind head-to-head TAVI trial reinforces the performance and safety of the Next Gen Myval THV series

Myval THV series



Myval Octacor



Myval

More to Life

Meril Life Sciences announced one-year results from **LANDMARK** trial, presented during the prestigious Late-Breaking Trial session at EuroPCR 2025, one of the world's premier cardiology conferences held annually in Paris, France.

The **LANDMARK** trial is the first randomized non-inferiority trial comparing the balloon-expandable Myval THV series with other contemporary balloon-expandable Sapien THV series and self-expandable Evolut THV series in patients with symptomatic severe aorti stenosis.

The Myval THV series demonstrated non-inferiority to contemporary THVs in terms of 1-year clinical efficacy composite endpoint (Myval THV Series: 13% vs. Contemporary THV: 13.1%, difference: -0.1%, one-sided 95% CI: 3.9%, Pnoninferiority < 0.0001).

Additionally, in the composite endpoint of clinical efficacy combined with QoL, outcomes were comparable (Myval THV Series: 19.5% vs. Contemporary THVs: 22.7%, difference: -3.2%, 95% CI: -9.2 to 2.9, P=0.33). Hemodynamic parameters including effective orifice area (EOA), mean pressure gradient (PG), and incidence of moderate or greater aortic regurgitation remained stable and similar across all treatment arms.

Survival rates were nearly identical (Myval THV Series: 92.8% vs. Contemporary THVs: 92.9%), and QoL improvements were comparable, reinforcing the overall safety and durability of the Myval THV series in everyday clinical use.

Professor Patrick Serruys, *Chairman and Study Director of the* ***LANDMARK*** *trial*, said: "This trial reflects a new era in comparative valve research. The meticulous design and adherence to VARC-3 standards, including QoL endpoints, mark it as a pivotal study. The results of the **LANDMARK** trial represent a meaningful advancement for the global structural heart community—and most importantly, for patients receiving TAVI. The data not only validate the safety and efficacy of the Myval THV series, but also spotlight its adaptability to complex anatomies. This versatility is exactly what clinicians need to deliver precision care across a broad spectrum of patients."

Professor Andreas Baumbach, *Global Principal Investigator*, said: "The **LANDMARK** trial represents a significant step forward in TAVI research. For the first time, we've benchmarked Myval against both balloon-expandable and self-expanding platforms in a rigorous randomized setting. The one-year results demonstrates that the new generation Myval THV series can match global standards in safety and efficacy."

Mr. Sanjeev Bhatt, *Senior Vice President – Corporate Strategy at Meril*, said: "The **LANDMARK** trial represents a significant milestone not just for Meril, but for the global TAVI community. The strong one-year results affirm the Myval THV series as a next-generation solution that delivers consistent safety, clinical efficacy, and improved quality of life across geographies. As the only head-to-head trial of its kind to include both balloon-expandable and self-expanding valves, it reinforces Myval THV series's versatility and real-world relevance for diverse patient anatomies and healthcare systems. At Meril, we are proud to contribute innovative, evidence-based technologies that are reshaping patient care and expanding access to advanced structural heart therapies worldwide."

The trial is designed to follow patients for a period of 10 years, aiming to generate long-term insights into clinical and echocardiographic outcomes, with a focus on valve durability and sustained performance.

About THE LANDMARK TRIAL:

The **LANDMARK** trial is the first randomized non-inferiority trial comparing the balloon-expandable Myval THV series with other contemporary balloon-expandable Sapien THV series and self-expandable Evolut THV series in patients with symptomatic severe aortic stenosis. The **LANDMARK** trial was a prospective, randomized, multicenter, open-label, non-inferiority trial involving 768 patients who underwent Transcatheter Aortic Valve Implantation (TAVI) for the treatment of aortic stenosis. The first patient was enrolled in the **LANDMARK** trial on 6 January 2021 and the last patient was enrolled on 5 December 2023. The trial included a total of 768 patients at 31 sites across 16 countries (Brazil, New Zealand, and some countries of Europe). The 30-day primary composite endpoints highlighting the safety and efficacy outcomes of the **LANDMARK** trial have been successfully published in *The Lancet* and *EuroIntervention*, two of the most prestigious peer-reviewed medical journals.

About Meril Life Sciences:

Meril is a global medical device company based in India, committed to advancing healthcare through innovation. With a strong focus on research and development, Meril delivers cutting-edge medtech solutions across more than 135 countries and has a robust presence through subsidiaries in the USA, Brazil, Europe, Asia, Africa, and Australia. Through partnerships, precision technology, and adherence to international quality standards, Meril is helping reshape the future of healthcare.

For More Information , Please contact:**media@merillife.com**