GENESIS-II Study Reveals Promising 30-Day Results for the Hydra Self-Expanding Transcatheter Aortic Valve

Study Synopsis

- GENESIS-II Study Unveils Breakthrough Results: Dr. Nagendra Boopathy Senguttuvan presented pioneering findings from the GENESIS-II study, showcasing the Hydra THV's remarkable performance during EuroPCR 2024.
- Exceptional Safety and Efficacy Demonstrated: Key findings reveal the Hydra THV's outstanding safety and efficacy, with a low cardiovascular mortality rate of 2.5% and a high device success rate of 95% at 30 days post-intervention.

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SMT (Sahajanand Medical Technologies), a leading innovator in cardiovascular medical device technology announces significant findings from the GENESIS-II study evaluating the Hydra self-expanding transcatheter aortic valve (THV). Dr. Nagendra Boopathy Senguttuvan of Sri Ramachandra Hospital, Chennai, Tamil Nadu, showcased the study's 30-day results during the TAVI Hotline session at EuroPCR 2024.

“GENESIS II demonstrated impressive safety and efficacy results for the Hydra THV, with low mortality, significant reductions in valve gradients, and minimal paravalvular leak at 30 days. We look forward to the longer-term results from this trial, an important addition to available data on this promising TAVI technology from India.,” says Dr John Jose, Study lead & Principal investigator on the trial.

Spanning 19 sites throughout India and involving a cohort of 40 patients diagnosed with severe aortic stenosis and classified as high surgical risk, the GENESIS-II study was designed to evaluate the continuous safety and performance of the Hydra THV. The study, a prospective, multicenter, non-randomized investigational endeavor, enrolled patients from November 01, 2021, to November 10, 2023.

Key findings from the study reveal that at 30 days post-intervention, the Hydra THV demonstrated a cardiovascular mortality rate of 2.5% and a new permanent pacemaker implantation incidence of 7.9%. Notably, no clinical events related to secondary endpoints were observed, and the device success rate stood impressively at 95%. Furthermore, significant improvements were noted in parameters such as effective orifice area and mean aortic valve gradient, along with favorable enhancements in New York Heart Association (NYHA) functional class.

Elaborating on the results, prominent TAVR specialist Dr Anmol Sonawane from Breach Candy Hospital, who played a pivotal role as principal proctor in this study, remarked, “The modification of the Hydra delivery system with a novel active release mechanism has significantly eased device deployment. Clinical outcomes have notably improved, with lower 30-day mortality compared to the earlier GENESIS trial, and acceptable complication rates. The Hydra THV represents a promising new technology in patients with severe aortic stenosis.”

Adding to his views, chief medical officer in SMT Dr Krishna Sudheer ascertains, “At 30-day follow up, the GENESIS II trial showed excellent clinical outcomes for the Hydra THV, now with a novel active release mechanism for deploying the valve. These results add to earlier data from the GENESIS and the CE Mark trials, confirming the safety and performance of SMT’s TAVI device in the treatment of severe aortic stenosis in patients at high surgical risk.”

In conclusion, the GENESIS-II study reinforces the safety and efficacy of the Hydra THV, marking a significant advancement in transcatheter aortic valve technology. With its novel active release mechanism and exceptional clinical outcomes, the Hydra THV stands poised to offer renewed hope and improved quality of life for patients battling severe aortic stenosis.

About SMT

SMT is a global medical device company committed to make advanced medical technologies accessible to everyone around the world. With presence in 79 countries, SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of coronary healthcare. SMT also pioneered the introduction of biodegradable polymers in the cardiovascular segment. SMT will continue the journey to heal hearts around the world by creating healthcare future promising for everyone.

About Hydra

Hydra is a self-expandable nitinol stent frame and 3 (three) bovine pericardium leaflets in a supra-annular position to provide large effective orifice area and low transvalvular pressure gradient. A high sealing skirt to the inflow part of the stent frame to mitigate paravalvular leak. The contoured non-flared inflow part of the stent frame aims to reduce the interference with the conduction system and thereby new conduction abnormalities.

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