



PRESS RELEASE

For Immediate Release

### **Singapore approves novel Hydra TAVI system**

Mumbai, October 2024

SMT (Sahajanand Medical Technologies) is proud to announce that its Hydra Transcatheter Aortic Valve Replacement (TAVR) system has received approval from the Singapore Health Sciences Authority (HSA). This marks a significant milestone in the global adoption of Hydra, following its recent success in Europe, Asia, and its triumph with the national tender Consip award in Italy.

The Hydra TAVR system is unique in the market due to its advanced features, such as two sets of markers on the frame that guide implantation depth with precision, reducing the need for contrast. Its large open cells facilitate easy coronary access, ensuring patients benefit from better lifetime management. The bovine pericardium and supra-annular valve positioning help achieve a larger orifice area, delivering industry-leading hemodynamic performance with low gradients. Hydra's innovative flexible design helps navigate aortic arch with relative ease, a common challenge in TAVR procedures.

Anil Suri, Vice President of APAC Commercial at SMT, commented, "Singapore is a highly regulated market, and securing approval from the Health Sciences Authority reaffirms the quality and efficacy of the Hydra valve system. Our continued global expansion reflects our unwavering commitment to making advanced cardiovascular care accessible to patients worldwide."

Hydra has consistently demonstrated remarkable clinical outcomes, with the recent 3-year results from the Hydra CE study reinforcing its strength. These results confirm sustained low, single-digit gradients over three years, paired with larger effective orifice area, further highlighting its performance. Moreover, the Genesis study, published in *Catheterization and Cardiovascular Interventions* in 2021, also validated Hydra's efficacy with low pacemaker rates. The combination of Hydra CE's 3-year results with the findings from Genesis 1 and 2 studies clearly showcases the valve's clinical excellence and the significant benefits it brings to patients.



Ammad Shorbaji, Vice President of Regulatory Affairs at SMT, emphasized: “Singapore’s Health Sciences Authority is recognized globally for its rigorous regulatory standards, which are modeled on international best practices. This approval underscores Hydra’s ability to meet the scrutiny of the world’s top regulators.”

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#### About SMT (Sahajanand Medical Technologies)

SMT is a global leader in cardiovascular medical devices, specializing in drug-eluting stents and structural heart disease solutions. Operating in over 80 countries, SMT is dedicated to advancing patient care through innovative medical technologies and clinical excellence, as demonstrated by the Multivessel TALENT trial. 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.

#### About Hydra

Hydra is re-sheathable, re-positionable and retrievable self-expanding transcatheter aortic valve ensuring patient safety and good results during deployment. It has advanced features like markers on the frame for accurate guidance while deploying the frame. Hydra has a supra-annular design which helps in larger aortic valve area and best-in-class hemodynamic performance post procedure.

Hydra has less metal in the outflow portion which in turn helps in flexibility and ease of delivery of the frame reducing the chance of trauma to the aortic arch and sealing skirt mitigates paravalvular leak. Non-flared inflow part of stent frame reduces interference with the conduction system. Large open cells facilitate easy future coronary access.

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