



Venus Medtech Announces Completion of Patient Enrollment in Pivotal China Trial for Venus-PowerX, the World's First Fully Recoverable Self-Expanding Dry-Valve TAVR System

Descrizione

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The PREVAILS study, now fully enrolled, marks a critical step toward simultaneous regulatory submissions in China and Europe for the next-generation TAVR system

HANGZHOU, China, July 23, 2026 /PRNewswire/ - Venus Medtech (Hangzhou) Inc. (02500.HK) today announced that patient enrollment has been completed in its confirmatory clinical trial for the Venus-PowerX Transcatheter Aortic Valve System. The milestone brings the world's first self-expanding dry-valve TAVR device capable of full release and complete retrieval—even after 100% deployment—one step closer to market approval in China and Europe.

The Venus-PowerX PREVAILS study (Pivotal Study of Severe Aortic Stenosis TReated with the Venus-PowerX TrAns catheter Aortic VaLve System) is a prospective, multicenter, single-arm, objective-performance-criterion trial designed to evaluate the safety, efficacy, and device performance of the Venus-PowerX system in patients with severe aortic stenosis. Data generated from this study will support simultaneous regulatory submissions for CE marking in Europe and regulatory approval by China's NMPA.

Venus-PowerX incorporates multiple innovative technologies that distinguish it from current TAVR platforms:

Venus-PowerX has already secured regulatory approvals in Argentina, Chile, and Venezuela, making it the world's first commercially available fully recoverable self-expanding dry-valve TAVR product. Real-world clinical data from Latin America, particularly from Argentina and Chile, are generating real-world evidence supporting broader clinical adoption and the company's strategy to bring Chinese structural heart solutions to international markets.

“The successful completion of enrollment in the Venus-PowerX confirmatory trial positions this device as a significant addition to our TAVR portfolio,” said Mr. Ma Renzheng, Chief Technology Officer of Venus Medtech. “We are committed to offering patients with severe aortic stenosis a more precise, safer, and more controllable treatment option, and to advancing structural heart intervention from “partially controllable” to “fully controllable” at every step of the procedure.”

About Venus Medtech

Venus Medtech (Hangzhou) Inc. (2500.HK) is a leading innovator in transcatheter heart valve solutions for structural heart disease. The company has developed a comprehensive product pipeline covering all four heart valves – TAVR, TPVR, TMVR, and TTVR – and related accessory products. With global R&D centers in China, the United States, and Israel, the company is committed to providing effective treatment solutions for life-threatening diseases.

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