First Implant of KingstronBioâ??s ProStyle MÂ® Transcatheter Mitral Valve System Successfully Completed in National Multicenter Confirmatory Study

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SHANGHAI, April 8, 2026 /PRNewswire/ â?? On March 12, 2026, the first implant of the ProStyle MÂ® Transcatheter Mitral Valve System (ProStyle MÂ®) was successfully completed under pure ultrasound guidance as part of its confirmatory clinical study. The device is independently developed by KingstronBio Technology (Changshu) Co., Ltd. (KingstronBio). The procedure was performed by Professor Wang Chunsheng and Professor Wei Lai of the Department of Cardiac Surgery, Zhongshan Hospital Affiliated to Fudan University, marking the official launch of the national multicenter confirmatory clinical study for ProStyle MÂ®.

Prior to this, ProStyle MÂ® had undergone a two-year First-in-Man (FIM) study involving a total of 10 patients with a mean age of 71 years. The study results demonstrated excellent anchoring performance with no regurgitation observed in all cases. As the clinical study progresses, further evidence will be generated to verify the productâ??s safety and efficacy.

KingstronBio takes innovation as its core driving force and has long been deeply engaged in the heart valve field. The company owns a number of patented technologies at home and abroad, including the Micro-Exâ?¢ anti calcification treatment technology and AirBoâ?¢ dry storage technology for heart valves.

With a long-term focus on the R&D and manufacturing of products for structural heart diseases, KingstronBioâ??s product portfolio covers artificial bioprosthetic heart valves, valve annuloplasty rings, cardiac surgical biopatches, and preloaded dry transcatheter aortic valves, among others. KingstronBio aims to provide safer and more reliable treatment options for patients with moderate to severe mitral regurgitation.

Challenges and BreakthroughsMitral Regurgitation (MR) is the most common valvular heart disease in China. Transcatheter Mitral Valve Replacement (TMVR) is a cutting-edge field in interventional therapy for structural heart disease, but it has long faced technical challenges, including complex anatomical

structures, the risk of left ventricular outflow tract obstruction, and difficulties in artificial valve anchoring and sealing.

About ProStyle MÂ®Addressing key clinical challenges: Adopting an eccentric structural design to reduce the difficulty of surgical operation and the risk of left ventricular outflow tract obstruction, while achieving stable anchoring performance and good hemodynamic performance.

Continuation of core patented technologies: The exclusive Micro-Exâ?¢ anti-calcification treatment process is adopted to remove residual cell debris, phospholipids and glutaraldehyde active groups in the pericardium, which can effectively delay leaflet calcification and improve the long-term durability of leaflets. At the same time, the AirBoâ?¢ valve dry storage technology further enhances the durability and biocompatibility of the valve.

About KingstronBioKingstronBio focuses on the R&D and production of products in the field of structural heart disease. With innovation as the core driving force, it deeply cultivates the valve field and aims to provide high-quality innovative medical devices for Chinese cardiac doctors.R&D-Driven InnovationThe companyâ??s research team, led by Beijing Distinguished Experts, holds numerous patents both domestically and internationally in the fields of biomaterial processing and dry-valve technology.

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Micro-Exâ?¢ Anti-Calcification Treatment Technology: The use of patented microemulsion extraction technology to deeply remove cell debris and phospholipids in tissues, along with the modification and elimination of aldehyde groups, significantly reduces valve calcification, as has been validated in animal studies

AirBoâ?¢ Dry Membrane Treatment Technology: Realizes dry preservation of bovine pericardial tissue through special ionic liquid, retaining molecular water to maintain the flexibility of fibrous collagen.

The above-mentioned Micro-Exâ?¢ anti-calcification technology and AirBoâ?¢ dry preservation technology work synergistically, which can significantly improve the anti-calcification performance and long-term durability of bovine pericardial patches.

Full Product Line LayoutRelying on patented technologies and productivity, the company has realized the localization and commercialization of products such as artificial bioprosthetic heart valves, annuloplasty rings, cardiac surgical biopatches and preloaded dry transcatheter aortic valves, and will also strive to provide more reliable treatment options for Chinese patients.

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