Pi-Cardia Receives FDA Breakthrough Device Designation for ShortCut™

First dedicated leaflet modification device to enable TAVR in patients at risk of coronary obstruction

REHOVOT, ISRAEL / BUSINESSWIRE / January 22, 2023 /

Pi-Cardia Ltd., a global leader in the development of non-implant, catheter-based, leaflet modification solutions for treating heart valves, announced today it received Breakthrough Device Designation from the US Food and Drug Administration for ShortCut™ - the world's first dedicated leaflet modification device facilitating valve-in-valve Transcatheter Aortic Valve Replacement (TAVR) procedures in patients at risk of coronary obstruction. This announcement comes after completion of enrollment in the ShortCut™ Pivotal Study in the US and Europe in September 2023.

“Having been part of Pi-Cardia’s rigorous clinical program, I am thrilled to see the recognition in the importance of ShortCut™” said Philippe Genereux, MD from Morristown Medical Center in New Jersey. “Lifetime management calls for leaflet modification solutions like ShortCut™ to ensure that we are carefully addressing the risk of coronary obstruction before implanting a valve. From what we have seen regarding the ability to easily teach and perform the procedure, ShortCut™ could be easily adopted by every TAVR center as a critical step pre-implantation, so that patients at risk of coronary obstruction may be safely treated, without disruption of TAVR work-flow.”

“We are so excited to receive this important recognition by FDA”, said Erez Golan, Pi-Cardia's Chief Executive Officer. “Breakthrough Device Designation is only awarded to technologies that have the potential to provide more effective treatment or diagnosis for life-threatening or irreversible debilitating diseases or conditions, and it may help accelerate our review process with FDA this year and bring ShortCut™ to market for the benefit of patients.”

ShortCut™ is part of Pi-Cardia's leaflet modification product portfolio, which includes the ShortCut™ Mitral for splitting leaflets in patients at risk for left ventricular outflow tract obstruction following TMVR, and Leaflex™ - a standalone, non-implant-based mechanical scoring device to restore leaflet mobility and improve hemodynamics for patients with aortic stenosis. Leaflex™ global clinical trials are underway.

About Pi-Cardia

Pi-Cardia is a global leader in the development of a unique portfolio non-implant, catheter-based, leaflet modification solutions for treating heart valves. Pi-Cardia's ShortCut™ device is designed to provide a safe, simple and effective way to split valve leaflets: ShortCut™ Aortic is designed to split leaflets of a pre-existing valve prior to TAVR in patients at risk for coronary obstruction and may assist in preserving coronary access; ShortCut™ Mitral is designed to split the anterior mitral leaflet prior to TMVR in patients at risk for LVOT obstruction. Pi-Cardia's Leaflex™ device mechanically scores valve calcification at multiple locations, with the intention of restoring leaflet flexibility and improving valve hemodynamics. Leaflex™ is designed to be a cost-effective, durable standalone treatment for patients with calcified aortic stenosis. Additional leaflet modification technologies are being developed to further expand treatment options in challenging anatomies such as bicuspid valves. The ShortCut™ device and Leaflex™ device are investigational devices, limited by United States law for investigational use.

For more information, please visit: www.pi-cardia.net

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