Pi-Cardia ShortCut™ Device Successfully Treats First Patients in Europe

First Dedicated Device to Enable Coronary Access and Prevent Coronary Obstruction During TAVR

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Pi-Cardia Ltd., a global leader in the development of non-implant, catheter-based solutions for treating heart valves, announced today successful first-in-human procedures in Europe with its ShortCut™ device. ShortCut™ is the world's first dedicated device designed to split the leaflets of a pre-existing valve to enable safe Transcatheter Aortic Valve Replacement (TAVR) in patients at risk for coronary obstruction or compromised coronary access.

Three ShortCut™ compassionate cases were performed at the German Heart Center Berlin, Germany, by Prof. Jörg Kempfert, Dr. Axel Unbehaun, and Dr. Christoph Klein, proctored by Dr. Ulrich Gerckens. "We were able to successfully treat three patients with degenerated valves who were at risk of coronary obstruction after TAVR with the ShortCut™ device," said Prof. Kempfert. "We were able to effectively split the target leaflets in all patients within just a few minutes, allowing for safe implantation of both self-expandable and balloon-expandable TAVR valves."

The TAVR market, currently estimated at $5 billion, is predicted to double over the next few years, with the expansion into low-risk, younger patients. However, this growth may be hindered by the potential life-threatening complication of complete coronary obstruction, due to trapped leaflets blocking the coronaries, in a significant number of patients who may undergo multiple valve implantation due to degeneration of their previous bio-prosthetic valve. ShortCut™ may be used in these situations to split the pre-existing valve leaflets to enable future coronary intervention and prevent coronary obstruction.

"Lifetime management in aortic stenosis is critical, especially as we treat younger patients. Therefore, a simple dedicated tool to prevent coronary obstruction that can easily be utilized across all TAVR centers is greatly needed in the field", said Dr. Gerckens.

ShortCut™ is part of Pi-Cardia's product portfolio, which also includes the Leaflex™ device – a standalone, non-implant-based treatment for patients with aortic stenosis. Leaflex™ performs mechanical scoring of valve calcification in order to restore leaflet mobility and improve hemodynamics. Leaflex™ clinical trials are underway in Europe, US and China.

"We are thrilled about this key milestone of further demonstrating clinical feasibility with ShortCut™, which allows us to move forward with our clinical plan in the US and Europe. The clinical trial in Europe is due to commence in Q1 2022," said Erez Golan, Pi-Cardia CEO. "As the number of patients with aortic stenosis continues to grow, both Shortcut™ and Leaflex™ may offer important new treatment options for both physicians and patients."

About Pi-Cardia
Pi-Cardia is a global leader in the development of a unique portfolio of non-implant-based solutions for treating heart valves. Pi-Cardia's Leaflex™ device is easily delivered and positioned on the valve, to then mechanically score the calcification at multiple locations, restoring leaflet flexibility and improving valve hemodynamics. The Leaflex™ device is designed to be a cost-effective, durable standalone treatment for patients with calcified aortic stenosis. Pi-Cardia's ShortCut™ device offers a safe, simple and effective way to split the leaflets of a pre-existing valve prior to TAVR in order to maintain coronary access in patients at risk for coronary obstruction or compromised coronary access.

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

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