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ASIA EDITION

Pi-Cardia completes first-in-human studies with novel non-implant

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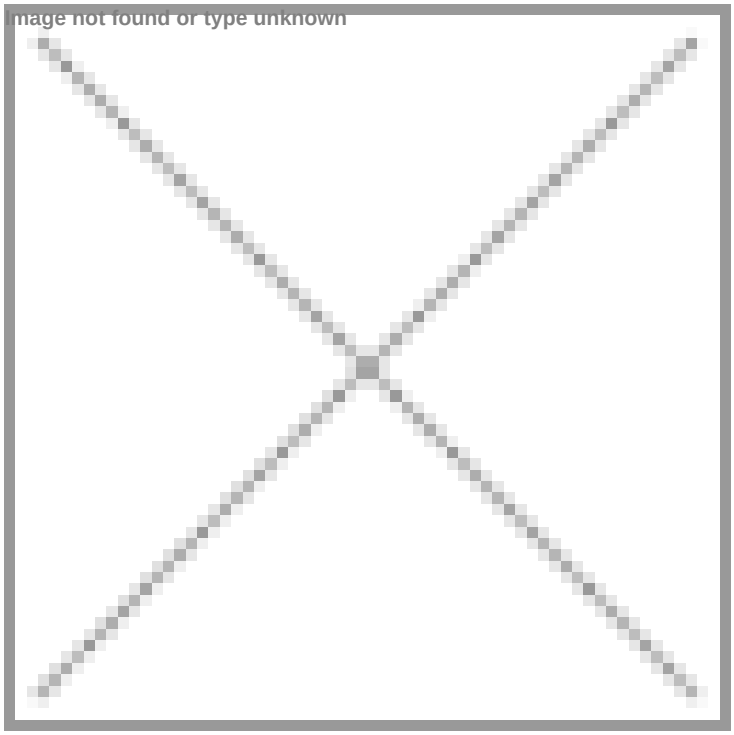

Pi-Cardia has announced that it successfully completed the First-in-Human (FIH) studies with its Leaflex Performer catheter. The Leaflex Performer is a trans-femoral catheter that uses two unique mechanical structures for scoring valve calcification at multiple locations. These scoring lines create separation between the calcium deposits in order to regain the leaflets flexibility, allow their mobility and improve valve hemodynamics. The Leaflex catheter is aimed to be a cost-effective durable standalone treatment or a preparatory step for improving the outcome of valve implantation in heavily calcified and bicuspid aortic valves.

Two sequential First-In-Human studies were done to demonstrate safety, feasibility and device performance: A single center intra-operative study of five (5) patients performed in Krakow, Poland, where Leaflex was used prior to surgical AVR. A following second study included sixteen (16) trans-femoral cases performed by leading TAVR centers acrossEurope and Israel, where Leaflex was used prior to TAVR in order to study the safety, feasibility and acute improvement in valve hemodynamics. Prof. Andreas Baumbach, the study PI, from BARTs Hospital in London, UK, will present the Leaflex study results on May 22nd 2019 at the Late Breaking Trials Session at EuroPCR meeting in Paris - the official annual meeting of the European Association of Percutaneous Cardiovascular Interventions (EAPCI).

The design of the Leaflex Performer was based on the company's extensive research on calcium growth patterns in

thousands of human aortic valves. Pi-Cardia's Leaflex technology and mechanism of action are fundamentally different from those of balloon-based (BAV) devices, in that instead of simply dilating the valve, which might lend itself to the short-term recoil seen in patients treated with BAV, the Leaflex scores the leaflets to create multiple targeted fractures at optimal locations of valve calcification thereby restoring leaflet mobility. This unique scoring method, while preserving the native valve integrity, may facilitate valve replacement therapies, as well as pave the way for providing durable treatment without implanting a new valve.

Pi-Cardia aims to expand the treatment options in the rapidly growing multi-billion dollar market currently dominated by surgical or trans-catheter aortic valve replacement (SAVR/TAVR). "As much as TAVR improves and becomes a routine procedure in lower surgical risk patients, it is still an implant with unknown durability, so there are many cases, where taking this new approach of Aortic Valve Repair to defer TAVR may make a lot of sense. TAVR is also an expensive procedure, which restricts its use to specific centers and specific cases," says Erez Golan, Pi-Cardia's Founder and CEO. "In today's budget sensitive environment, waiting lists for TAVR are common even in the most developed countries, let alone in emerging markets, where TAVR may not be a viable option for most patients.

Pi-Cardia is a global leader in the development of unique non-implant based solutions for treating valve calcification. Pi-Cardia's lead product, the Leaflex Performer catheter, is easily delivered and positioned on the valve, to then mechanically score the calcification at multiple locations, restoring leaflets flexibility and improving valve hemodynamics. The Leaflex catheter is aimed to be a cost-effective standalone treatment or a preparatory step to improve the outcome of valve implantation in heavily calcified and bicuspid aortic valves.