Pi-Cardia Completes $10M Financing

January 7, 2016 - Pi-Cardia Ltd., the Rehovot, Israel based company, announced today that it has completed a $10 million financing including participation by a new strategic investor. Also participating in the round, are Italian funds Innogest and Fondo Atlante Ventures, Chinese fund VI-Ventures and existing investors in the company, including Clal Biotechnology Industries and Anatomy Medical Technologies Fund.

Pi-Cardia, founded in 2009, developed the Leaflex™ Catheter System – a novel non-implant based technology for treating patients with aortic valve stenosis. The Leaflex™ is a low-profile trans-femoral catheter incorporating unique Nitinol elements, which are optimized for delivering mechanical energy to create substantial fractures in valve calcification. These fractures help restore leaflet mobility and improve valve hemodynamics using a short and simple procedure without the need to implant a new valve.

The design of the Leaflex™ was based on the company's extensive research in the last few years on calcium growth patterns in hundreds 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™ creates multiple targeted fractures at optimal locations of valve calcification thereby restoring leaflet mobility. This unique fracturing 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 a relatively complex and expensive implantation 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 a while".

"Besides the typical case of an eighty-five-year-old patient with a tri-leaflet aortic valve, whom I will simply have more options to offer, there are also some common anatomies such as bicuspid aortic valves, where TAVR delivers suboptimal results", says Dr. Ganesh Manoharan, Consultant Cardiologist at the Royal Victoria Hospital, Belfast. "We believe that if a simpler, lower-cost alternative existed, which could offer patients a reasonable period of time without symptoms, such a technique could have an important role alongside TAVR".

In 2015, Pi-Cardia successfully completed enrolling the first set of patients in its FIM study in Europe, demonstrating safety and feasibility of the procedure. The funds raised would allow the company to complete the development of a second generation device, and to continue the clinical studies for showing its safety and performance, towards CE-Mark.

About Pi-Cardia Ltd.

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