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Second-generation TAVI device—Lotus Valve—shows good performance in REPRISE II

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22 May 2013, Paris, France: The Lotus Valve, a second-generation transcatheter aortic valve implantation (TAVI) device, was successfully implanted in all of the first 60 patients in results from REPRISE II reported at EuroPCR 2013, which showed good device performance and low mortality at 30 days.

"First generation TAVI devices provide significant clinical benefit, but there are opportunities for improvement," explained lead author Ian Meredith, Director of MonashHeart, Southern Health and Professor of Medicine, Monash University, Melbourne, Australia. He suggested that these include controlled deployment, simple, precise and atraumatic aortic/ventricular repositioning, no or trivial paravalvular leakage and lower complication rate.

The Lotus Valve System has been designed to address these issues. The valve is pre-attached to the delivery system, which has a simple handle design, and functions early in deployment for controlled, precise positioning. It is fully retrievable and can be repositioned and has an adaptive seal designed to minimise paravalvular leak.

REPRISE II prospectively evaluated the safety and performance of the Lotus Valve System for TAVI in symptomatic patients with severe calcific aortic stenosis considered high risk for surgical valve replacement. Reporting results for the first 60 patients, Meredith told the

conference, "Successful valve implantation was achieved in all patients." The primary endpoint for device performance – mean aortic valve pressure gradient at 30 days compared to a performance goal of 18mmHg – was met. Mean aortic gradient decreased from 47.5+17.2mmHg before the procedure to 11.3+5.2mmHg at 30 days. At the same time effective orifice area increased from 0.6+0.2mmHg to 1.7+0.4mmHg.

"Results showed successful valve implantation in all 60 patients, meeting the primary device performance endpoint," Meredith said. "Importantly, the rate of moderate or greater aortic regurgitation decreased from 18% at the baseline study to 1.9% (one patient) at thirty-day follow up. More than 80% had either no or trivial aortic regurgitation at 30 days," he reported. He pointed out that the very low rate of moderate or greater aortic regurgitation was ten-folder lower than seen in previous trials with other systems, describing this as 'a monumental improvement.' The mortality rate was low – 1.7% at 30 days.

"Valve repositioning and retrieval was performed successfully in all cases when required. And there was no embolisation, ectopic valve deployment or TAV-in-TAV," he added. Patients suffered negligible aortic regurgitation, while other clinical event rates were consistent with those reported for other valves. "These findings suggest the Lotus Valve may be a valuable addition to the armamentarium for the treatment of severe aortic stenosis," he concluded.

Commenting on the implications of the study findings, Stephan Windecker, Professor and Chief of Cardiology, Swiss Cardiovascular Center and Clinical Trials Unit Bern, Bern University Hospital, Switzerland, said, "An important factor is that this is a truly repositional device. And it is exciting that the rate of moderate to severe aortic regurgitation is so low."