New data for the Lotus™ Valve System announced at PCR London Valves

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30-Day outcomes for the 250 patients enrolled in REPRISE II Extended Cohort trial were presented by Prof Ian Meredith at PCR London Valves on September 29th.

The CE Mark Trial, REPRISE II, was designed to evaluate safety and performance of the Lotus™ Valve System for transcatheter aortic valve implantation (TAVI) in symptomatic patients with severe calcific aortic stenosis who are high risk for surgical valve replacement. It was extended to treat an additional 130 patients, with a total of 250 patients enrolled in the trial programme.

Key results from the REPRISE II Extended Cohort at 30 days:

- Mean pressure gradient was low at 11.7 ± 6.8 mmHg
- All-cause mortality rate of 4.4% was also low
- Over 80% of patients showed no sign of paravalvular leakage, and only 0.6% with moderate and none with severe.
- There were no cases of valve migration, embolization, ectopic valve deployment or TAVI-IN-TAVI.

The latest data release followed the Transcatheter Cardiovascular Therapeutics (TCT) meeting earlier this month, where one-year results from the REPRISE II trial were announced for 120 patients, demonstrating sustained safety and performance outcomes with the Lotus Valve System.

Additionally, Boston Scientific initiated the REPRISE III clinical trial on September 22nd, marking the beginning of the process required to support U.S. Food and Drug Administration premarket approval.

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