New clinical trial data assessing the Boston Scientific Lotus™ Valve System continue to support strong performance and safety profile

Results from clinical trials evaluating the Boston Scientific (NYSE: BSX) Lotus™ Valve System continue to show this advanced transcatheter aortic valve implantation (TAVI) therapy delivers excellent clinical outcomes with low rates of paravalvular leakage (PVL) and other complications.

One-year outcomes from REPRISE II with extended cohort and the RESPOND Post Market Registry were presented at PCR London Valves annual meeting, held this year in Berlin.

Highlights from REPRISE II with the extended cohort (n=250) include:

- consistent and sustained hemodynamic performance with a low all-cause mortality of 11.6%;
- accurate positioning, with 0.0% TAV-in-TAV, ectopic placement, valve migration or embolization, and;
- no moderate or severe PVL, as adjudicated by a core lab.

Key, 30-day outcomes in the RESPOND real-world registry (n=500) include:

- a low all-cause mortality of 1.9%;
- 0.0% of cases had severe PVL, 0.4% had moderate PVL and 84% had no PVL, and;
- 0.4% rate of mal-positioning (TAV-in-TAV, ectopic placement, valve migration or embolization) in real-world complex cases.

About REPRISE II

REPRISE II is an ongoing prospective, single-arm, multi-center study designed to evaluate safety and performance of the Lotus Valve System for symptomatic patients with severe calcific aortic stenosis who are considered high risk for surgical valve replacement.

About RESPOND

The RESPOND Registry is a prospective, open label, single arm, multi-center, observational post market study designed to assess real world performance of the Lotus Valve System. The study will collect data on clinical outcomes and device performance in 1,000 patients implanted at 50 centers around the world.

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.eu and connect on Twitter and Facebook.

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