Boston Scientific announces new data from the RESPOND study of the LOTUS™ Valve presented today at EuroPCR2016

Outcomes from this post market study of more than 1,000 patients demonstrate the safety and efficacy of transcatheter aortic valve implantation (TAVI) with the LOTUS™ Valve in routine clinical practice.

Results from the RESPOND Study evaluating the Boston Scientific (NYSE: BSX) LOTUS™ Valve demonstrated excellent outcomes of key safety and efficacy endpoints through 30 days post implant procedure. Building on previously presented interim results with 250, 500 and 750 patients, the new RESPOND data from the full trial population of more than 1,000 patients continue to support the use of the LOTUS™ Valve in routine clinical practice.

The data show excellent device performance, a strong safety profile and extremely low rates of paravalvular leak (PVL) which is associated with long-term survival.

The data from the post-market study were presented by Professor Volkmar Falk, M.D., Director of the Department of Cardiothoracic Vascular Surgery at the German Heart Center in Berlin.

Highlights from the RESPOND Study include:

- All-cause mortality at 30 days post-procedure was 2.2% in the as-treated population
- Disabling stroke at 30 days post-procedure occurred in 2.2% of patients
- Permanent pacemaker (PPM) implantation rate at 30 days was 30%
- Correct positioning of one valve in proper location was 99.7%
- Major vascular complications observed in only 2.1% of patients
- Less PVL than reported with competitive valve: no/trivial PVL in 91.9 percent of patients and mild PVL in 7.7% of patients at hospital discharge; moderate PVL was only 0.3% and there was no severe PVL; PVL with Lotus similar to rates seen with surgical valve replacement

About RESPOND

The RESPOND Registry is a prospective, open label, single arm, multi-centre, observational post market study. Clinical follow-up is at discharge, 30 days, 1 year and annually through five years. It features a primary endpoint of all-cause mortality at 30 days and 1 year, plus secondary endpoints using current Valve Academic Research Consortium guidelines and definitions. Echocardiographic data and key clinical events are independently adjudicated. These measures are designed to increase the quality of the collected data and address inconsistencies with site-reported data commonly observed in post market studies.

About the LOTUS™ Valve

The Lotus Valve System is a differentiated next-generation TAVI device, consisting of a pre-attached, stent-mounted tissue valve prosthesis and catheter delivery system for guidance and percutaneous placement of the valve. It is the first device of its kind that offers controlled mechanical expansion, which allows the valve to be fully deployed, assessed and then released, providing unparalleled control during the procedure. The early valve function provides hemodynamic stability throughout the procedure and if necessary, the valve can be completely repositioned at any time prior to release. The device also features a unique Adaptive Seal™ designed to minimize the incidence of paravalvular regurgitation, which has been identified as a predictor of mortality in multiple clinical trials.

In the U.S., the Lotus Valve System is an investigational device and not available for sale. It is a CE marked device, available for sale in countries where CE marking is the regulation in force.

---

https://news.bostonscientific.eu/2016-05-17-Boston-Scientific-announces-new-data-from-the-RESPOND-study-of-the-LOTUS-TM-Valve-presented-today-at-EuroPCR2016