Four-Year Clinical Outcomes Following TAVR with the Repositionable and Fully retrievable Lotus Valve System: an Update from the REPRISE I Study

Ian T. Meredith AM, MBBS, PhD1; Stephen G. Worthley, MD2; Robert J. Whitbourn, MBBS, BMedSc, BSc3; Joseph Montarello, MBBS2; Andrew E. Newcomb, MBBS3; Dominic J. Allocco, MD4; Keith D. Dawkins, MD4

1MonashHeart, Clayton, Victoria, Australia; 2Royal Adelaide Hospital, Adelaide, South Australia, Australia; 3St. Vincent’s Hospital, University of Melbourne, Fitzroy, Victoria, Australia; 4Boston Scientific Corporation, Marlborough, MA, USA

STUDY DESIGN

STUDY DESIGN: prospective, single-arm feasibility study

STUDY OBJECTIVE: assess the acute safety and performance of the transcatheter Lotus™ Aortic Valve (23 mm valve) in patients with severe aortic stenosis and at high risk for surgical intervention

PRIMARY ENDPOINT: Device success (VARC-1 definition) without in-hospital MACCE

STUDY POPULATION:

- Age ≥70 years
- Aortic valve stenosis and NYHA Class ≥II
- Aortic annulus size 19-22mm
- High risk for surgical AVR
- NYHA Class III or IV
- Diabetes, medically treated
- Hypertension, medically treated
- History of coronary artery disease
- History of cerebrovascular accident
- Atrial fibrillation
- AVA <1.0cm² (or AVA index <0.6cm²/m²)
- Major bleeding
- All cause mortality
- Peri-procedural MI (≤72 hours)
- Urgent or emergent conversion to surgery or repeat procedure for valve-related dysfunction
- NYHA Class III or IV
- Diabetes, medically treated
- Hypertension, medically treated
- History of coronary artery disease
- History of cerebrovascular accident
- Atrial fibrillation

Patient Population

Baseline Characteristics

- Age (years) 83.0±3.6
- Gender (female) 11/11
- NYHA Class III or IV 5/11
- Diabetes, medically treated 2/11
- Hypertension, medically treated 10/11
- History of coronary artery disease 5/11
- History of cerebrovascular accident 2/11
- Atrial fibrillation 5/11

Conduction disturbance requiring new pacemaker

VALVE HEMODYNAMICS

Aortic Valve Regurgitation

SAFETY

4-Year Event Rate n/11

- MACCE components 4
- All cause mortality 3
- Peri-procedural MI (≤72 hours) 0
- Major stroke 1
- Urgent or emergent conversion to surgery or repeat procedure for valve-related dysfunction 0
- Myocardial infarction 0
- Minor stroke 1
- Major vascular complication 1
- Bleeding 2
- Major bleeding 3
- Acute kidney injury – Stage 2 or 3 0

4-Year results from the REPRISE I study demonstrate excellent valve function with minimal paravalvular regurgitation and low event rates.

These data support the safety and performance of the Lotus Valve for the treatment of patients with severe aortic stenosis.