Early clinical outcomes in the first 50 patients enrolled in the RESPOND EDGE registry

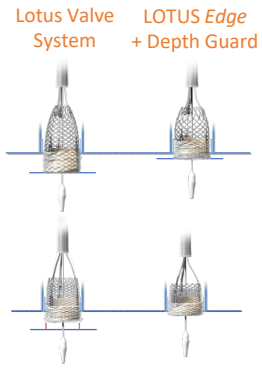
RESPOND *Edge*™ LOTUS *Edge*™ Aortic Valve System

Rajesh Kharbanda, PhD, FRCP[1]; Nicolas van Mieghem, MD, PhD[2]; David Hildick-Smith, MD[3]; Daniel Blackman, MD[4]; Dominic J. Allocco, MD[5]; Ian T. Meredith, MBBS, PhD[5]; Nicolas Dumonteil, MD[6]

[1]John Radcliffe Hospital, Oxford, United Kingdom; [2]Erasmus Medical Center, Rotterdam, Netherlands; [3]Leeds General Infirmary, Leeds, United Kingdom; [4]Royal Sussex County Hospital, Brighton, United Kingdom; [5]Boston Scientific Corporation, Marlborough, MA, USA; [6]Clinique Pasteur, Toulouse, France

The LOTUS *Edge* Valve

- Controlled mechanical expansion
- Repositionable and fully retrievable
- Adaptive seal to minimize PVL
- Flexible, low profile catheter
- Optimized deployment and positioning, with Depth Guard to limit depth of implant and reduce interaction with LVOT
- One-view locking with radiopaque markers



The RESPOND EDGE Study

Prospective, open-label, single-arm, post-market surveillance registry will enroll 200 patients at up to 20 European centers

- Pre-specified interim analyses: discharge data from first 50 patients enrolled
- Clinical follow-up through 2 years

Primary Safety Endpoint

- 30-day all-cause mortality

Primary Effectiveness Endpoint

- Mean AV pressure gradient at discharge
- Assessed by an independent core laboratory

Other Key Endpoints

- Device performance
- Echocardiographic outcomes: EOA, mean AV gradient, grade of PVL
- VARC-2 clinical efficacy and safety endpoints

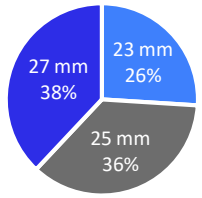
Study Population

Baseline characteristic	N=50
Age at time of consent (years)	81.1 ± 6.4
Gender, female	48.0% (24/50)
BMI (kg/m^2)	28.1 ± 5.8
STS Score (%)	3.6 ± 3.1
EuroSCORE (%)	3.0 ± 2.2
Diabetes (medically treated)	24.0% (12/50)
Hyperlipidemia (req. medication)	38.0% (19/50)
Hypertension	52.0% (26/50)
CAD	50.0% (25/50)
Prior MI	12.0% (6/50)
CHF	42.0% (21/50)
AF	40.0% (20/50)
Prior pacemaker	20.0% (10/50)
Prior cerebrovascular accident	8.0% (4/50)
Severe aortic valve calcification (site-reported)	*64.0% (32/50)*

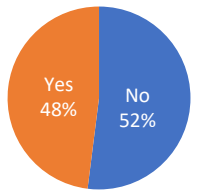
Baseline echocardiography	
Mean AV gradient (mmHg)	37.8 ± 10.6
Peak AV gradient (mmHg)	63.7 ± 17.7
Peak velocity (m/s)	4.0 ± 0.6
LVEF (%)	51.8 ± 13.3
Mean effective orifice area (cm^2)	0.7 ± 0.2

Core laboratory adjudicated

Valve Size Implanted



Cerebral Embolic Protection Used



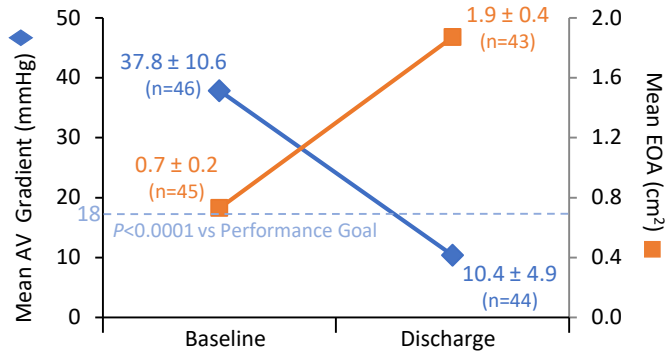
Valve Performance & Safety

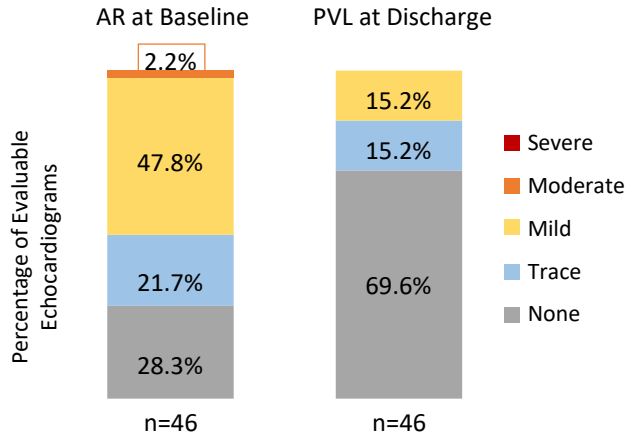
- 100% successful vascular access, delivery and deployment of study valve, and retrieval of the delivery system (50/50)
- 50/50 subjects with single LOTUS Edge valve implanted in the proper anatomical location

Clinical outcome	N=50
All-cause mortality	0.0% (0/50)
All stroke*	4.0% (2/50)
LT or disabling bleeding	0.0% (0/50)
Acute kidney injury, Stage 2 or 3	2.0% (1/50)
Coronary obstruction (periprocedural)	0.0% (0/50)
Major vascular complication	2.0% (1/50)
Repeat procedure for valve-related dysfunction	0.0% (0/50)
Periprocedural MI (≤72 h)	0.0% (0/50)
Hospitalization for valve-related symptoms	0.0% (0/50)
Permanent pacemaker implantation	
All patients	18.0% (9/50)
PM-naïve patients	22.5% (9/40)
New onset of Afib or atrial flutter	4.0% (2/50)
Valve embolization	0.0% (0/50)
TAV-in-TAV	0.0% (0/50)
Valve thrombosis or endocarditis	0.0% (0/50)

*1 stroke within 72h (CEP not used); 1 stroke >72h (CEP was used)

Echocardiographic Analyses





- Initial observations from this 50-patient interim analysis demonstrate good early clinical outcomes with no safety or efficacy concerns
  - No procedural deaths, repeat procedures for valve-related dysfunction, or re-hospitalizations for valve-related symptoms
  - Permanent pacemaker implantation at discharge: 18% (9/50)
- Patients demonstrated excellent valve hemodynamics and low PVL rates
  - Discharge mean AV gradient = 10.4±4.9 mmHg (p<0.0001 vs perf. goal)
  - No/trace PVL in 84.8%; no patients exhibited ≥moderate PVL