Long-Term Survival following Transcatheter Mitral Valve Repair: Pooled Analysis of Prospective Trials with the Carillon Device

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Carillon Mitral Contour System

- Simple right-sided procedure
- Cinches the mitral apparatus via the coronary sinus
- Preserves future therapy options
- Over 1,100 implants to date
Carillon Device Deployment and Cinching

Coronary Sinus Angiogram to Define the Landing Zone

Distal Anchor Deployed

Tension Applied & Proximal Anchor Deployed
Case Example of MR Reduction after Carillon

Baseline: MR 3+*

At 12 Months: MR 1+*

*per core lab assessment
Significant Clinical Evidence

Single Arm, Multi-Center Prospective OUS Trials

TITAN³
TITAN II²

Randomized, Blinded, Sham Controlled Trial

REDUCE FMR¹

Met End Point of Reduction in Regurgitant Volume and Showed Significance in Favorable LV Remodeling

All studies core lab reviewed and CEC/DSMB adjudicated.
Inclusion/Exclusion criteria materially consistent between studies.

Consistent Findings at 12-Months

All studies have shown –

• Reduction in mitral regurgitation
• Reduction in LV volumes (favorable remodeling)
• Improvements in clinical parameters
• Encouraging safety data
COAPT\textsuperscript{1} Data

Assessment of Carillon Long-term Mortality

- A total of 74 patients were assessed
- TITAN Trial included 5-year follow-up for mortality (36 patients)
- Pôle Santé République (Clermont-Ferrand, France) also assessed patients from the TITAN II Trial (15 of 36) and REDUCE FMR (23 of 76 implanted)
Consistent Patient Inclusions

- Symptomatic despite GDMT with > Class II CHF
- Grade 2+ to 4+ MR
- Enlarged LV (LVEDD > 5.5 cm)
- Reduced EF (< 40% in TITAN and TITAN II and < 50% in REDUCE FMR)
Kaplan-Meier Survival Estimate Over 5-years of Follow-up After Carillon Implant

Survival was 56.2% over 5 years
Primary determinants of 5-year survival

At one-year follow-up –

• Decrease in NYHA status
  (HR 2.56 for one class improvement, P < 0.01)

• Increase in 6-minute walk distance
  (HR 1.54 for 100-meter increase, p = 0.03)

• Decrease in mitral regurgitation
  (HR 1.24 for 10% decrease, P = 0.02)

• No baseline determinants
What is a Reasonable Comparator?

- GDMT is current standard
- COAPT now looked at as a potential standard
  - However, COAPT limited FMR patients to 3+ to 4+ MR
  - COAPT has only presented 3-year data for comparison
- Analysis done with subgroup from Carillon studies with 3+ to 4+ MR through 3-years (N = 42)
Kaplan-Meier Survival Estimate Over 5-years of Follow-up After Carillon Implant Among Patients with MR Grade 3+ or 4+

Survival was 56.0% over 5 years
All Cause Mortality Comparing CARILLON to GDMT and COAPT Over 3-years

1. Dr. Michael J. Mack at the Transcatheter Cardiovascular Therapeutics meeting (TCT 2019), San Francisco, CA, September 28, 2019.
Comparison Limitations

• No control arm for comparison
• COAPT patients may not be comparable
  – Anatomic restrictions for use of clip
• Patients who did not receive the device were not followed
• Patient numbers in groups remain small
• Hypothesis generating
Conclusions

• The Carillon device shows extremely encouraging long-term mortality data from prospective controlled trials in comparison to GDMT and COAPT results in symptomatic patients with FMR.

• Long-term clinical benefits will continue to be evaluated in conjunction with The CARILLON Trial:
  – Approved U.S. pivotal trial with 75 sites in US and Europe
  – Randomized, blinded, sham-controlled trial of 352 patients with hierarchical clinical endpoints
  – Currently enrolling patients
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