



NEWS RELEASE

Study Data Presented at TVT on the Economics of Minimalist TAVR, PARTNER 3 Bicuspid TAVR

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IRVINE, Calif., July 22, 2021 /PRNewswire/ -- Edwards Lifesciences (NYSE: EW) today announced that clinical and economic results from the 3M (multidisciplinary, multimodality, but minimalist) Transcatheter Aortic Valve Replacement (TAVR) Economic Study and the PARTNER 3 Bicuspid Registry for SAPIEN 3 TAVR Study were presented at TVT 2021: The Structural Heart Summit.

The 3M-TAVR study demonstrated positive findings supporting similar clinical outcomes and substantial cost savings associated with minimalist TAVR when compared with conventional TAVR in patients at intermediate risk for surgery. Clinical results from the PARTNER 3 Bicuspid Registry for SAPIEN 3 TAVR in low-risk patients with bicuspid aortic valves demonstrated similar outcomes and benefits, such as symptom relief and quality of life, when compared to matched tricuspid anatomy patients.

Economics of 3M-TAVR

The clinical data presentation provided the following findings:

- Index hospitalization costs for patients in the 3M cohort were \$10,843 lower per patient, driven by reductions in procedure duration, anesthesia costs and length of stay. Cumulative cost differences out to 30 days post procedure were \$11,305 lower in the 3M cohort compared to traditional TAVR.
- Use of the 3M pathway was associated with significant reductions in hospital length of stay (reduction of 0.5 ICU days and 1.7 non-ICU days), new pacemaker implantation (3.4% vs. 8.3%), and rehabilitation days during follow-up (0.4 days vs. 1.4 days). Additionally, there were no differences in death, stroke or rehospitalization through 30 days of follow-up utilizing this new approach.
- Based on previous comparisons with surgical aortic valve replacement (SAVR), researchers determined that these findings suggest that minimalist TAVR for intermediate-risk patients may reduce 30-day costs by greater

than \$20,000 per patient compared with SAVR.

"The 3M pathway, which builds on innovations in both TAVR design and technique, was designed to improve procedural efficiency and facilitate next-day discharge of TAVR patients," said David Cohen, MD, MSc, Director of Clinical and Outcomes Research at the Cardiovascular Research Foundation in New York. "In our study, we found that this approach was not only safe and effective, but also led to substantial cost savings compared with more traditional care patterns. These findings add to a substantial body of evidence demonstrating that TAVR is a unique technology that extends life, improves quality of life and is more efficient for the healthcare system."

The study compared healthcare costs for patients in the 3M trial to healthcare costs for patients enrolled in the SAPIEN 3 Intermediate Risk (S3i) registry who underwent conventional transfemoral TAVR, and whose outcomes were linked to Medicare claims.

PARTNER 3 Bicuspid Registry for SAPIEN 3 TAVR in Low-Risk Patients

The clinical data presentation included the following findings:

- The composite primary endpoint of death, stroke or cardiovascular rehospitalization related to valve or procedure and heart failure at one year were similar for both the bicuspid and tricuspid cohorts: 10.9% vs. 10.2%, respectively (p-value = 0.9).
- The individual components of the primary endpoint were also similar at one year (bicuspid vs. tricuspid: 0.7% vs. 1.4% mortality; 2.1% vs. 2.0% stroke; 9.6% vs. 9.5% rehospitalization related to valve or procedure and heart failure). Additionally, the new pacemaker implantation rate was similar between the two groups (6.8% vs. 7.4%).
- Both cohorts experienced similar symptomatic relief and quality of life gains at 30 days and one year when measured by both the New York Heart Association (NYHA) Classification and the Kansas City Cardiomyopathy Questionnaire (KCCQ).

The study compared the 1-year safety and efficacy of the SAPIEN 3 TAVR system in selected low surgical risk patients with severe symptomatic aortic stenosis and bicuspid anatomy to a clinically similar cohort of patients with tricuspid anatomy treated with SAPIEN 3 TAVR in the PARTNER 3 trial.

"The excellent results of these two studies add to the continually growing body of data that support the SAPIEN 3 valve as an impactful therapy that not only offers spectacular results in areas that matter to patients – like a rapid recovery – but also saves the healthcare system significant resources when compared to traditional treatments," said Larry Wood, Edwards' corporate vice president, transcatheter aortic valve replacement. "These data continue to build on the PARTNER 3 trial that demonstrated SAPIEN 3 TAVR to be superior to surgery for low-risk surgical patients."

About Edwards Lifesciences

Edwards Lifesciences is the global leader of patient-focused innovations for structural heart disease and critical care monitoring. We are driven by a passion for patients, dedicated to improving and enhancing lives through partnerships with clinicians and stakeholders across the global healthcare landscape. For more information, visit **Edwards.com** and follow us on Facebook, Instagram, LinkedIn, Twitter and YouTube.

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements include, but are not limited to, statements made by Mr. Wood and statements regarding expected product benefits, patient outcomes, future plans related to the product lines, objectives and expectations and other statements that are not historical facts. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain and difficult to predict. Our forward-looking statements speak only as of the date on which they are made, and we do not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause results to differ materially from those expressed or implied by the forward-looking statements based on a number of factors as detailed in the company's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2020, and its Quarterly Report on Form 10-Q for the quarter ended March 31, 2021. These filings, along with important safety information about our products, may be found at **Edwards.com**.

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