NEWS RELEASE

Progress Trial Demonstrates Edwards TAVR Is Superior to Clinical Surveillance for Moderate AS Patients With At-Risk Features

2026-11-02

- TAVR delivered more than 30% reduction in the composite endpoint of death or heart failure event as compared with clinical surveillance; results published in NEJM
- TAVR demonstrated unparalleled safety at 30 days with no mortality and no disabling strokes
- TAVR reduced heart failure hospitalizations by more than 50% and delivered clinically meaningful improvements in patients' quality of life

SAN DIEGO--(BUSINESS WIRE)-- Edwards Lifesciences (NYSE: EW) today announced results from the PROGRESS Trial, marking a turning point in the management of moderate aortic stenosis (AS). The trial demonstrated that transcatheter aortic valve replacement (TAVR) was superior to clinical surveillance in the primary composite endpoint of death or heart failure events at two years in moderate AS patients with at-risk features. The late-breaking results were presented at Transcatheter Cardiovascular Therapeutics (TCT) 2026, Cardiovascular Research Foundation's annual scientific symposium, and simultaneously published in The New England Journal of Medicine.

Moderate AS has historically been viewed as relatively benign and managed through passive clinical surveillance with an echocardiogram every one to two years. The PROGRESS Trial findings showed that moderate AS is not a homogeneous condition and that echocardiographic severity alone may underestimate clinical risk.

In the randomized trial, TAVR demonstrated superiority to clinical surveillance, with a 33% relative reduction in the composite primary endpoint of death or a heart failure event at two years, with event rates of 16.7% and 23.9%, respectively.

- Heart failure events occurred in 10.8% of patients receiving TAVR compared with 19% of patients managed with clinical surveillance.
- Heart failure hospitalizations occurred in 7.4% of patients receiving TAVR compared with 14.9% of patients managed with clinical surveillance.
- All-cause mortality at 2 years was similar between patients treated with TAVR and patients managed with clinical surveillance.

Results consistently favored TAVR across prespecified subgroups. Data also showed patients receiving TAVR experienced a meaningful 15.5-point improvement in Kansas City Cardiomyopathy Questionnaire score assessing quality of life at 30 days.

“The PROGRESS Trial validates TAVR as a treatment strategy for moderate AS patients with at-risk features and challenges the longstanding assumption that these patients can be managed by passive clinical surveillance,” said Philippe Généreux, M.D., director of the Structural Heart Program at Atlantic Health Morristown Medical Center. “Taken together, the practice-changing PROGRESS and EARLY TAVR trials deepen our understanding of aortic stenosis and reinforce the patient benefits of a more proactive approach to disease management. The evidence is now clear that intervening earlier in the disease pathway avoids significant health decline and serious cardiovascular events.”

Patients managed with clinical surveillance also progressed to severe AS more rapidly than previously recognized. The trial demonstrated that 27% of patients underwent delayed aortic valve replacement within one year, and 57% did so within two years. Before receiving delayed treatment, patients experienced a decline in health status and increased procedural complexity. Full results of the primary and secondary endpoints can be found in **NEJM**.

“The PROGRESS Trial represents a paradigm shift in the way the clinical community considers and treats patients with moderate AS,” said Dan Lippis, corporate vice president of TAVR at Edwards. “These findings build on Edwards’ decades-long commitment to generating rigorous clinical evidence that advances the understanding of the serious impact and unpredictable progression of aortic stenosis.”

About the PROGRESS Trial

The PROGRESS Trial is a prospective, global, multicenter, randomized controlled trial evaluating proactive TAVR compared with clinical surveillance in 744 moderate AS patients with at-risk features including symptoms, cardiac damage or dysfunction. Patients were randomized 1:1 to transfemoral TAVR with a valve from the Edwards SAPIEN 3 platform or guideline-recommended clinical surveillance with deferred aortic valve replacement, when indicated. The trial enrolled patients at 74 sites across six countries.

All participants had moderate AS confirmed by an independent echocardiography core laboratory. More than 90% had concordant moderate AS, meaning they met all guideline-defined echocardiographic criteria for moderate AS.

At baseline, more than 95% of patients were symptomatic, and more than 90% had preserved left ventricular function (EF≥ 50). The mean patient age was 78 years.

About Moderate Aortic Stenosis

Aortic stenosis is a progressive disease in which narrowing of the aortic valve restricts blood flow from the heart to the rest of the body. Moderate AS can present differently across patients, and approximately half are estimated to have at-risk features such as symptoms, cardiac damage or dysfunction. These features have been associated with poorer outcomes or more rapid disease progression.

About Edwards Lifesciences

Edwards Lifesciences is the leading global structural heart innovation company, driven by a passion to improve patient lives. Through breakthrough technologies, world-class evidence and partnerships with clinicians and healthcare stakeholders, our employees are inspired by our patient-focused culture to deliver life-changing innovations to those who need them most. Discover more at **www.edwards.com** and follow us on **LinkedIn**, **Facebook**, **Instagram** and **YouTube**.

Investigational use: Use of the SAPIEN 3 TAVR systems to treat moderate aortic stenosis is investigational. Safety and effectiveness for this use have not been established. For complete Important Safety Information see **link**.

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. Lippis, statements regarding expected product benefits, statements regarding confidence to apply proactive disease management strategies to moderate AS

patients, 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. These filings, along with important safety information about our products, may be found at **Edwards.com**.

Edwards, Edwards Lifesciences, the stylized E logo, PROGRESS, SAPIEN, and SAPIEN 3 are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

Media: Heather Bukant, **media@edwards.com**
Investors: Gerianne Sarte, **investor_relations@edwards.com**

Source: Edwards Lifesciences Corporation