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NEWS RELEASE

Ten-Year Pivotal Data Demonstrate Long-Term Durability of Edwards Lifesciences' Resilia Tissue

2026-05-02

CHICAGO--(BUSINESS WIRE)-- Edwards Lifesciences (NYSE: EW) today announced 10-year results from the COMMENCE aortic trial, reinforcing the long-term durability and sustained performance of its proprietary RESILIA tissue. The data were presented at the 106th American Association for Thoracic Surgery Annual Meeting.

As evidence increasingly supports treating patients earlier in the valve disease pathway, the need for durable valve solutions continues to grow. The COMMENCE trial provides prospective, 10-year data demonstrating the durability of Edwards' RESILIA tissue and its role in lifetime management for patients with aortic stenosis. To date, more than 500,000 patients worldwide have been treated with Edwards' surgical and transcatheter innovations featuring RESILIA tissue.

At 10 years, COMMENCE trial data showed that patients treated with Edwards' surgical valves featuring RESILIA tissue experienced:

- 97.9% freedom from structural valve deterioration (SVD)

- 97.8% freedom from reoperation due to SVD
- 98.6% freedom from non-structural valve dysfunction (other than PVL)
- Sustained hemodynamic performance, including stable gradients and effective orifice area over time

For patients, long-term durability matters because it can reduce the likelihood of repeat procedures over a lifetime, helping preserve quality of life as life expectancy increases.

“These 10-year data from the COMMENCE trial suggest this tissue technology has the potential to change the way we think about durability in biological valves, including in younger patients,” said Lars G. Svensson, MD, PhD, chief of the Sydell and Arnold Miller Family Heart, Vascular & Thoracic Institute and professor of surgery at Cleveland Clinic. “What is striking is the low rate of structural valve deterioration and need for reoperation, even though the trial enrolled younger patients who historically face higher risks of valve deterioration, underscoring the importance of long-term evidence when physicians are making treatment decisions with their patients.”

For nearly 70 years, Edwards has led structural heart innovation, advancing evidence generation that has helped set the standard for evaluating valve performance, durability and treatment options in severe aortic stenosis. The COMMENCE trial builds on the totality of Edwards’ clinical evidence, reinforcing the durability of outcomes supporting its surgical and transcatheter therapies, including large, randomized, FDA-approved studies such as the PARTNER series of trials.

The PARTNER trial series advanced the field with long-term patient outcomes on treatment with SAPIEN TAVR and SAVR, with 10 years of follow-up data. The new COMMENCE trial data build on that foundation with the latest evidence on the long-term durability of RESILIA tissue.

RESILIA tissue was designed to enhance the durability of tissue valves by helping resist calcification, a leading cause of valve failure over time. The technology combines advanced calcium blocking processes with dry storage to support long-term valve performance.

“As patients live longer and expect to remain active, structural heart therapies must be designed with lifetime care in mind,” said Bernard Zovighian, Edwards’ CEO. “The COMMENCE 10-year study is the latest addition to our breadth of long-term data reflecting our commitment to advancing durable valve technologies through continuous evidence development, so Heart Teams and patients can make informed decisions over time.”

The COMMENCE aortic trial is an FDA-approved, pivotal, prospective, multicenter clinical study designed to evaluate the safety and effectiveness of a bioprosthetic valve with RESILIA tissue used in SAVR, with follow-up through 10 years. Safety endpoints were defined according to established guidelines and independently adjudicated.

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](#).

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. Zovighian and statements regarding expected long-term durability and sustained performance, reduction of the likelihood of repeat procedures, therapies helping to preserve quality of life, outcomes of the surgical and transcatheter therapies, expectations for remaining active, 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.

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Source: Edwards Lifesciences Corporation