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NEWS RELEASE

Edwards Lifesciences Receives FDA Approval for AUTUS Valve, the First Surgical Pulmonary Valve for Pediatric Patients

2026-10-01

IRVINE, Calif.--(BUSINESS WIRE)-- Edwards Lifesciences (NYSE: EW) today announced that the U.S. Food and Drug Administration (FDA) has approved the AUTUS Size-Adjustable Valve, a surgical pulmonary valve designed specifically for pediatric patients with congenital heart disease who require pulmonary valve replacement.

For many pediatric patients, pulmonary valve replacement is not a one-time event. The AUTUS valve is the first FDA-approved surgical pulmonary valve designed for pediatric anatomy, with the ability to be expanded as a child grows. Valve expansion is performed through a minimally invasive transcatheter procedure, potentially reducing the need for repeat open-heart surgeries.

"Children with congenital pulmonary valve disease have long needed prosthetic valves that can account for growth over time," said Dr. Emile Bacha, surgeon-in-chief at NewYork-Presbyterian/Columbia University Irving Medical Center and a professor of surgery at Columbia University Vagelos College of Physicians and Surgeons who was one

of the investigators in the trial. “The AUTUS valve gives congenital heart teams a new way to think about long-term care planning for pediatric patients who may otherwise face multiple surgeries.”

FDA approval of the AUTUS valve was based on the totality of clinical evidence from the pivotal study. The study met its primary safety and effectiveness endpoints, with 100% of patients free from device-related complications through 30 days and demonstrating favorable valve performance with no AUTUS valve reinterventions through six months. Among patients who completed one-year follow-up, 100% showed consistent outcomes, demonstrating an RVOT mean gradient of 40 mmHg or less, less than moderate pulmonary regurgitation and no valve reinterventions. Patients will continue to be followed for 10 years. The AUTUS valve previously received FDA Breakthrough Device designation for its potential to address an important unmet need.

The AUTUS valve reflects Edwards’ decades-long focus, commitment and leadership in structural heart innovation designed to address patients’ needs throughout their lives. The AUTUS valve provides an important opportunity to support pediatric patients with congenital heart disease. This approval expands Edwards’ congenital treatment options, which also include SAPIEN 3, the Alterra Adaptive Presept and pediatric atrioseptostomy catheters.

“For decades, Edwards has worked to address the needs of structural heart patients with complex conditions,” said Bernard Zovighian, Edwards’ CEO. “The AUTUS valve represents a meaningful advancement for children who have historically had limited treatment options. Our commitment extends beyond innovation to generating clinical evidence and collaborating with physicians, medical societies and patient groups to help address the evolving needs of patients with congenital heart disease.”

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 Dr. Bacha and Mr. Zovighian and statements regarding expected product benefits, including supporting pediatric congenital heart patients from childhood through adulthood, reducing the need for repeat open-heart surgeries, 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](https://www.edwards.com).

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Note: Dr. Emile Bacha has received reimbursement from Edwards Lifesciences for travel and lodging related to educational activities.

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Source: Edwards Lifesciences Corporation