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NEWS RELEASE

New Data Confirm Rapid, Unpredictable Progression of Severe Aortic Stenosis and Need for Urgent Referral and Evaluation of Patients

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CHICAGO--(BUSINESS WIRE)-- Edwards Lifesciences (NYSE: EW) today announced new scientific evidence presented and published during the American College of Cardiology's (ACC) Annual Scientific Session & Expo, addressing the critical needs of patients with structural heart disease.

Without treatment, 1 in 10 patients experiencing symptoms of severe aortic stenosis (AS) may die within five weeks. However, the symptoms of severe AS can be difficult to detect and may progress rapidly and unpredictably. New data presented at ACC underscore the importance of urgently referring patients to a heart team for evaluation once diagnosed.

Among the groundbreaking data were findings from the randomized, controlled DETECT AS study, the first to evaluate the impact of automatic electronic provider notifications (echo alerts) for patients with severe AS. In this trial involving 939 patients and 285 physicians, those who ordered an echo for severe AS were randomized to either

receive an echo alert describing treatment guidelines or no notification. The findings revealed echo alerts increased aortic valve replacement (AVR) treatment rates by 11 percent for all patients with severe AS, and 14 percent for symptomatic severe AS patients. Echo alerts also significantly improved AVR treatment rates among older patients and women, thereby reducing age and gender disparities. The results were simultaneously published in *Circulation*.

“These data illuminate the persistent under-referral and under-treatment of severe AS patients and the significant impact a critical echo notification can have on improving treatment of this deadly disease,” said Sammy Elmariah, M.D., Interventional Cardiology Medical Director, Cardiac Catheterization Laboratory, and associate professor at the University of California, San Francisco.

Additional insights from the EARLY TAVR trial were also presented at ACC. The EARLY TAVR trial was the first randomized, controlled FDA pivotal study designed to determine the best strategy for treating asymptomatic severe AS and the benefits of timely intervention with TAVR. The data were published in *The New England Journal of Medicine* and demonstrated that asymptomatic severe AS patients randomized to Edwards TAVR experienced superior outcomes compared with guideline-recommended clinical surveillance (watchful waiting), with no clinical penalty for timely intervention.

The new study presented at ACC evaluated outcomes of patients treated in the EARLY TAVR trial segmented by the severity of their signs and symptoms once they converted to AVR. These data reiterate that watchful waiting is not an effective strategy for the management of severe AS.

In addition, it was hypothesized that cardiac biomarkers may be predictive of the best time for severe AS patients to go from watchful waiting to receiving treatment. Another new study presented at ACC showed that biomarkers were not predictive, further underscoring the rapid and unpredictable progression of the disease and urgency to refer patients to a heart team for evaluation and treatment. Results of the biomarkers study were simultaneously published in *Circulation*.

“The data from these new studies confirm that severe aortic stenosis is a complex disease and reiterate the need for urgent referral and evaluation of treatment for patients with or without symptoms,” said Larry Wood, Edwards’ corporate vice president and group president, transcatheter aortic valve replacement and surgical structural heart. “We remain committed to advancing high-quality science and delivering life-saving structural heart therapies for patients with our leading SAPIEN valve platform, which has been used to treat more than 1 million patients worldwide.”

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. We intend the forward-looking statements contained in this release to be covered by the safe harbor provisions of such Acts. These forward-looking statements can sometimes be identified by the use of forward-looking words, such as “may,” “might,” “believe,” “will,” “expect,” “project,” “estimate,” “should,” “anticipate,” “plan,” “goal,” “continue,” “seek,” “intend,” “optimistic,” “aspire,” “confident” and other forms of these words and include, but are not limited to, statements made by Mr. Wood and Dr. Elmariah and statements regarding expected product benefits, including patient outcomes, 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. These filings, along with important safety information about our products, may be found at Edwards.com.

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