NEWS RELEASE

Groundbreaking Data Demonstrate Superiority of EARLY TAVR in Asymptomatic Severe Aortic Stenosis Patients

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WASHINGTON--(BUSINESS WIRE)-- Edwards Lifesciences (NYSE: EW) today announced results from the EARLY TAVR Trial, the first randomized, controlled trial designed to study the best strategy for treating asymptomatic severe aortic stenosis (AS) and the benefits of early intervention with transcatheter aortic valve replacement (TAVR). The trial results demonstrated that asymptomatic severe AS patients randomized to Edwards TAVR experienced superior outcomes compared with guideline-recommended clinical surveillance. Trial investigators presented the data today during a late-breaking clinical trials session at Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation (CRF) and published simultaneously in The New England Journal of Medicine .

With a median follow up of 3.8 years, the data demonstrated superiority of early TAVR, with 26.8% of the 455 patients in the TAVR arm experiencing death, stroke or unplanned cardiovascular hospitalization compared to 45.3% of the 446 patients in the clinical surveillance arm. Additionally, the data showed that early intervention with

TAVR:

- Prevented unpredictable and rapid progression of symptoms, which sometimes resulted in emergent intervention and/or hospitalization;
- Prevented clinically meaningful and rapid decline in quality of life; and
- Resulted in numerically lower rate of stroke for patients with early TAVR (4.2% vs. 6.7% at a median follow-up time of 3.8 years).

“What we learned in this trial is that without intervention, patients rigorously confirmed as asymptomatic experienced unpredictable and rapid decline with numerous adverse outcomes. These results shatter 60 years of ingrained belief on the treatment for severe aortic stenosis, with guidelines that currently recommend ‘watchful waiting’ for intervention until symptoms develop,” said Philippe Genereux, MD, director of the structural heart program at Gagnon Cardiovascular Institute, Morristown Medical Center, Morristown, New Jersey. “With no demonstrated clinical penalty for TAVR, these trial results strongly support a change to the practice and current guidelines for the treatment of aortic stenosis patients.”

The EARLY TAVR Trial enrolled 901 patients – with an average age of 76 and average KCCQ-OS score of 92.7 – at 75 sites across the US and Canada. Patients were rigorously confirmed as asymptomatic through a protocol-mandated stress test – a first in TAVR trials – and medical history evaluation. Designed specifically to evaluate if early intervention is a better strategy than clinical surveillance, the EARLY TAVR Trial showed that within the first six months, a striking 26.2% of patients in the clinical surveillance arm converted to aortic valve replacement (AVR) with many presenting progressive or advanced symptoms. In the 12-month follow-up period after randomization, the rate of conversion to AVR was 47.2%.

“This is the first pivotal trial to generate evidence about the best strategy for disease management of severe aortic stenosis,” said Larry Wood, Edwards’ corporate vice president and group president, transcatheter aortic valve replacement and surgical structural heart. “EARLY TAVR challenges the current standard of care by definitively showing that patients who don’t have symptoms of severe aortic stenosis have a deadly disease that requires urgent treatment.”

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 statements regarding expected product benefits, 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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