



Edwards

NEWS RELEASE

## Edwards Announces Six-month Data From Transcatheter Tricuspid Replacement Program

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IRVINE, Calif., Nov. 6, 2021 /PRNewswire/ -- Edwards Lifesciences Corporation (NYSE: EW) announced that results from a clinical trial of the company's EVOQUE transcatheter tricuspid valve replacement system demonstrated that favorable patient outcomes were sustained at six months. Results from the TRISCEND study, treating patients with tricuspid regurgitation, were presented during the late-breaking clinical science session at the 33rd Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

Patients enrolled in the TRISCEND study had symptomatic, moderate or greater functional or degenerative tricuspid regurgitation (TR), despite optimal medical therapy. Following positive 30-day outcomes that were presented earlier this year, the 6-month results (n=56) demonstrated significant TR reduction by core laboratory assessment. Specifically, at 6 months:

- Significant reduction in TR severity, with 100 percent of patients with none/trace or mild TR in 43 patients with paired echocardiographic data available

- Significantly improved functional and quality-of-life outcomes, including 89% of patients in NYHA Class I or II, and a 27-point increase in KCCQ score over baseline
- High survival rate of 96%, and freedom from heart failure hospitalization of 94%

"Severe tricuspid regurgitation is becoming increasingly recognized to have a significant impact on quality of life and may be a predictor of increased mortality. Unfortunately, most patients with TR are at high risk for conventional surgery and there currently are no approved transcatheter options in the US," said Susheel Kodali, MD, Columbia University Irving Medical Center and TRISCEND Study Principal Investigator. "The six-month results that we have seen with patients enrolled in the TRISCEND study who received the EVOQUE tricuspid valve replacement are truly remarkable and very promising for patients who suffer from tricuspid regurgitation."

"We are quite encouraged by these data, not only related to the therapy and procedural success rates demonstrated by the EVOQUE system, but also for the significant TR reduction and sustained improvements in quality-of-life measures experienced by patients," said Bernard J. Zovighian, Edwards' corporate vice president, transcatheter mitral and tricuspid therapies. "Our goal is to lead the transformation of treatment for this diverse and expansive population of tricuspid valve disease patients. We are committed to building a strong body of evidence to support emerging therapies like the EVOQUE system, which will continue with our randomized pivotal trial, TRISCEND II, currently underway."

The TRISCEND study is a prospective, single-arm, multicenter study, designed to evaluate the safety and performance of the transfemoral EVOQUE tricuspid valve replacement system in TR. Results were reported on 132 patients enrolled, with 6-month follow-up results on 56 patients. The study continues to enroll and additional patient follow-up will take place at 1 year and annually up to 5 years. The trial endpoints are device and procedural success, a composite of major adverse events (MAEs) at 30 days and TR reduction.

The EVOQUE valve replacement system is an investigational device and is not available for sale in any country.

### About Edwards Lifesciences

Edwards Lifesciences is the global leader of patient-focused innovations for structural heart disease and critical care monitoring. We are driven by a passion for patients, dedicated to improving and enhancing lives through partnerships with clinicians and stakeholders across the global healthcare landscape. For more information, visit **Edwards.com** and follow us on Facebook, Instagram, LinkedIn, Twitter 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 product benefits, patient outcomes, future plans related to the product lines, 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, including its Annual Report on Form 10-K for the year ended December 31, 2020, and its Quarterly Reports on Form 10-Q for the quarter ended March 31, 2021 and June 30, 2021. These filings, along with important safety information about our products, may be found at **Edwards.com**.

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