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NEWS RELEASE

TRISCEND II Trial Demonstrates Superior Clinical and Quality-of-life Benefits With Edwards EVOQUE System for Severe Tricuspid Regurgitation

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WASHINGTON--(BUSINESS WIRE)-- Edwards Lifesciences Corporation (NYSE: EW) today announced that the EVOQUE system demonstrated superiority compared to medical therapy alone for the one-year primary endpoint of the TRISCEND II trial. TRISCEND II is a randomized controlled pivotal trial designed to study the groundbreaking EVOQUE transcatheter tricuspid valve replacement (TTVR) system with optimal medical therapy (OMT) compared to OMT alone with 2:1 randomization. The data, presented during the late-breaking clinical trial sessions at the Transcatheter Cardiovascular Therapeutics (TCT) meeting, included the full cohort of 400 patients. TRISCEND II trial one-year primary endpoint outcomes will be simultaneously published in *The New England Journal of Medicine* , and TRISCEND II trial one-year quality-of-life (QoL) outcomes will be simultaneously published in the *Journal of the American College of Cardiology* .

Patients enrolled in the TRISCEND II trial had at least severe tricuspid regurgitation (TR). The EVOQUE valve was successfully implanted in 95.4 percent of patients, and of those who received the valve, nearly all (95.3 percent)

achieved almost complete TR elimination with \leq mild TR at one year, compared to 2.3 percent of patients receiving OMT alone. These TR reductions were associated with significant improvements in symptoms, function and QoL at one year, with favorable numerical outcomes in mortality and heart failure hospitalization.

“It is exciting to have the EVOQUE system available as a treatment option for patients who are very sick and otherwise have limited, if any, options,” said Susheel Kodali, MD, Avanesians Professor of Medicine at Columbia University Vagelos College of Physicians and Surgeons and director of interventional echocardiography at the Structural Heart & Valve Center at New York-Presbyterian/Columbia University Irving Medical Center and TRISCEND II Study Principal Investigator. “The one-year outcomes from the TRISCEND II trial demonstrate the benefits of this therapy in these patients and the favorable trends in all-cause mortality and heart failure hospitalization are encouraging to see. We are pleased to see TTVR reach this stage after nearly a decade of development.”

“The TRISCEND II trial results also demonstrated sustained quality-of-life benefits for patients receiving the EVOQUE system,” said Suzanne Arnold, MD, MHA, Professor of Medicine at the University of Missouri-Kansas City (UMKC) School of Medicine, and Clinical Scholar at Saint Luke's Mid America Heart Institute. “Patients receiving TTVR with the EVOQUE system were twice as likely to be alive with a good quality-of-life at one year, compared with the control group.”

The EVOQUE system is approved for use in both Europe and the US, making it the world's first and only approved TTVR system. The EVOQUE system includes four valve sizes (44mm, 48mm, 52mm and 56mm), with the 56mm valve recently approved in the US.

“Edwards' commitment to innovation is inspired by the millions of patients around the world suffering with debilitating symptoms and poor quality-of-life as a result of structural heart diseases and in desperate need of effective treatment options,” said Daveen Chopra, Edwards' corporate vice president, transcatheter mitral and tricuspid therapies. “We are building a portfolio of transcatheter repair and replacement technologies for both the mitral and tricuspid valves, and we are dedicated to supporting those therapies with world-class evidence like what is being generated through the TRISCEND II trial.”

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. Chopra and statements regarding expected product benefits, patient outcomes, Edwards’ objectives, commitment and dedication in building a portfolio of technologies and evidence supporting those technologies, 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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Many Columbia University Vagelos College of Physicians and Surgeons physicians and scientists maintain relationships and collaborate with external organizations to foster scientific innovation and provide expert guidance.

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