NEWS RELEASE

EDWARDS MITRIS RESILIA VALVE RECEIVES FDA APPROVAL FOR MITRAL REPLACEMENT SURGERIES

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IRVINE, Calif., March 31, 2022 /PRNewswire/ -- Edwards Lifesciences (NYSE: EW) today announced it received approval from the U.S. Food and Drug Administration (FDA) for the MITRIS RESILIA valve, a tissue valve replacement specifically designed for the heart's mitral position.

The MITRIS RESILIA valve has a saddle-shaped sewing cuff that mimics the asymmetric shape of the native mitral valve. It also features a low-profile frame that helps avoid obstruction of the left ventricular outflow tract by stent posts and is visible under fluoroscopy, to facilitate potential future transcatheter interventions for patients. This therapy is the company's latest innovation offering advanced RESILIA tissue with an anti-calcification technology that also allows devices to be stored under dry packaging conditions, facilitating ease of use.

RESILIA tissue is bovine pericardial tissue and serves as the platform for Edwards' new class of valves. RESILIA tissue has been studied in two robust pre-market clinical trials, as follows: (i) the COMMENCE trial comprised of 694 patients enrolled in an aortic arm who were followed for five years, some of whom will be followed for 10 years,

and 83 patients enrolled in a mitral arm who were followed for five years, some of whom will be followed for 10 years, and (ii) the EU Feasibility trial comprised of 133 patients enrolled who were followed for five years. These studies together represent outcomes on 904 patients and more than 3,800 patient years of follow-up.

"For patients who need mitral valve replacement, the advanced MITRIS RESILIA valve is based on a trusted pericardial valve platform, designed to mimic the native valve and incorporating tissue with integrity-preservation technology that will potentially allow the valve to last longer," said Kevin Accola, M.D., Cardiovascular Surgeon, AdventHealth Orlando.

"Mitral valve disease is prevalent, and the patients impacted experience the disease in variable ways," said Daveen Chopra, Edwards' corporate vice president, surgical structural heart. "It was important to design the MITRIS RESILIA valve to perform like the native mitral valve, handling the highest pressures in the heart and offering sustained hemodynamic performance, so that surgeons and patients can have confidence in this new therapy option."

Edwards is dedicated to partnering with clinicians to develop patient-centric innovations for complex surgical structural heart procedures that improve long-term care and outcomes for patients. The introduction of the MITRIS RESILIA valve completes the portfolio of surgical heart valve innovations incorporating the advanced RESILIA tissue, including an aortic valve, an aortic valved conduit and now a mitral valve. Edwards continues to invest in innovations in the surgical structural heart field.

The MITRIS RESILIA valve is built on the trusted Carpentier-Edwards PERIMOUNT platform, which in 2021, celebrated 40 years of innovative valve replacements for patients. In addition to FDA approval, the MITRIS RESILIA valve has also received regulatory approval in Japan, Canada, and other countries globally.

Dr. Accola is a consultant to Edwards Lifesciences.

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 Dr. Accola and Mr. Chopra 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 U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2021. These filings, along with important safety information about our products, may be found at **Edwards.com**.

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