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NEWS RELEASE

FDA Approval of Edwards Lifesciences' PASCAL Precision System Opens New Treatment Pathway for Patients With Tricuspid Valve Disease

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Recent FDA Approval of PASCAL Ace with Capture Clarity Simplifies Mitral TEER Procedures for Clinicians

IRVINE, Calif.--(BUSINESS WIRE)-- Edwards Lifesciences Corporation (NYSE: EW) today announced that the U.S. Food and Drug Administration (FDA) has approved its PASCAL Precision system for tricuspid valve repair. The system is indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation (TR) despite optimal medical therapy who are deemed at intermediate or greater risk for surgery and deemed appropriate for transcatheter edge-to-edge tricuspid valve repair (T-TEER) by a multidisciplinary heart team. With this approval, Edwards is now the only company to provide a portfolio of repair and replacement transcatheter therapies for the mitral and tricuspid valves in the United States.

Edwards Lifesciences' PASCAL transcatheter tricuspid valve repair system

"The PASCAL system has been a valuable option for treating patients suffering with

debilitating symptoms from degenerative mitral regurgitation in the US for several years, and we're pleased that this differentiated therapy is now available to tricuspid patients in the US," said Daveen Chopra, Edwards' corporate vice president, transcatheter mitral and tricuspid therapies. "With the addition of the PASCAL tricuspid valve repair system to our portfolio of tricuspid transcatheter therapies, Edwards is able to support the treatment of a broader group of tricuspid patients, empowering clinicians to select the most appropriate therapy to treat more patients and support optimal clinical results."

"The differentiated features of the PASCAL system provide many benefits in navigating complex and challenging anatomies, and it is exciting to now have this therapy available for our tricuspid patients in the US," said Santiago Garcia, MD, director of The Structural Heart Program, The Christ Hospital Health Network.

The company also shared that the FDA has approved the PASCAL Ace with Capture Clarity system for use in degenerative mitral TEER procedures (M-TEER). The PASCAL Ace with Capture Clarity system has become the first FDA-approved TEER device to include fluoroscopic indicators that provide confirmation when valve leaflets have been grasped, addressing a challenging step in TEER cases and simplifying procedural complexity.

"Building on the PASCAL system's intuitive design, the Capture Clarity indicators provide a novel and easy way of confirming leaflet capture, which is critical and can be challenging. This simplifies placement of the device and increases confidence in our ability to achieve a successful M-TEER outcome," continued Dr. Garcia.

One-year data from the CLASP IITR pivotal trial studying the PASCAL tricuspid system will be presented during late-breaking sessions at Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

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. These forward-looking statements include, but are not limited to, statements made by Mr. Chopra, statements regarding expected product benefits, including the benefits of the novel features of the device, statements regarding increasing confidence for successful results, 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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