NEWS RELEASE

EDWARDS PASCAL PRECISION TRANSCATHETER VALVE REPAIR SYSTEM RECEIVES FDA APPROVAL FOR DEGENERATIVE MITRAL REGURGITATION

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IRVINE, Calif., Sept. 15, 2022 /PRNewswire/ -- Edwards Lifesciences Corporation (NYSE: EW), today announced the company's PASCAL Precision transcatheter valve repair system for transcatheter edge-to-edge repair (TEER) has received FDA approval for the treatment of patients with degenerative mitral regurgitation (DMR).

"Patients suffering with debilitating symptoms as a result of degenerative mitral regurgitation represent a large and significantly underserved group in the US," said Bernard J. Zovighian, Edwards' corporate vice president, transcatheter mitral and tricuspid therapies. "Edwards' 60-year history of innovation and leadership within structural heart disease positions our team well to bring the PASCAL Precision system to US clinicians, supporting excellent real-world outcomes for patients."

The PASCAL Precision system, with its independent grasping, atraumatic clasp and closure, and ability to elongate, enables safe and effective treatment for patients with DMR. Engineered with an intuitive catheter and handle, the

system is designed for maneuverability and stability, enabling precise navigation and implant delivery.

"The mitral valve is highly complex and challenging to treat," said Firas Zahr, M.D., Associate Professor of Medicine, Division of Cardiovascular Medicine, School of Medicine, Oregon Health & Science University, whose patients participated in the CLASP IID clinical trial. "Through my participation in the CLASP IID pivotal trial, I have performed many cases with the PASCAL system. With FDA approval of the PASCAL system, US clinicians now have an additional option for treating patients with severe mitral regurgitation."

Data from the CLASP IID pivotal trial, the first randomized controlled trial to directly compare two contemporary TEER therapies, will be presented as a late-breaking clinical science session on Sept. 17 at the 34th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation.

The PASCAL Precision system has CE Mark certification for the treatment of both mitral and tricuspid regurgitation. As part of Edwards' continued commitment to building a body of real-world evidence, patients receiving treatment with the PASCAL Precision system in the US will be enrolled in the TVT registry for five years.

The PASCAL Precision system is one of multiple transcatheter repair or replacement therapies in development by Edwards that are designed to address mitral and tricuspid valve disease, and the company's first such therapy approved for DMR in the US. Edwards is committed to transforming the treatment of mitral and tricuspid patients, supported by a robust body of clinical evidence. The commercial opportunity related to this approval is factored into 2022 financial expectations.

About TEER

Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve is used in the treatment of mitral regurgitation. TEER approximates the anterior and posterior mitral valve leaflets by grasping them with a clipping device in an approach similar to a treatment developed in cardiac surgery called the Alfieri stitch.

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, 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, 2021, and its Quarterly Reports on Form 10-Q for the quarters ended March 31 and June 30, 2022. These filings, along with important safety information about our products, may be found at **Edwards.com**.

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