NEWS RELEASE

EDWARDS ANNOUNCES SIX-MONTH DATA CONFIRMING TEER AS SAFE AND EFFECTIVE FOR DMR IN FIRST HEAD-TO-HEAD TRIAL

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BOSTON, Sept. 17, 2022 /PRNewswire/ -- Edwards Lifesciences Corporation (NYSE: EW) announced results from CLASP IID, the first randomized controlled trial that directly compares two contemporary transcatheter edge-to-edge repair (TEER) therapies. The study confirms TEER as a safe and effective therapy in patients with degenerative mitral regurgitation (DMR). Results from the CLASP IID pivotal trial were presented as a late-breaking clinical science session at the 34th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation, and published simultaneously in JACC: Cardiovascular Interventions.

Patients enrolled in the CLASP IID pivotal trial had severe symptomatic DMR and were determined to be at prohibitive surgical risk. The CLASP IID trial met its primary safety and effectiveness endpoints, with the PASCAL system demonstrating non-inferiority for safety and effectiveness compared to the MitraClip device. The PASCAL device showed:

- Low composite major adverse event rate of 3.4 percent at 30 days, and
- Significant and sustained MR reduction with 97.7 percent of patients achieving MR ≤2+ at six months.

The PASCAL system further demonstrated significant and sustained MR ≤1+ with 83.7 percent of patients at MR ≤1+ at six months. PASCAL system results also showed favorable ventricular remodeling with improved stroke volume, and patients receiving the PASCAL system experienced significant improvements in functional capacity and quality of life.

"The CLASP IID randomized trial further establishes the PASCAL system as a safe and effective therapy, expanding the armamentarium of transcatheter mitral valve treatment options for patients with DMR," said Scott Lim, MD, director, Advanced Heart Valve Center at University of Virginia Health System and CLASP IID Study Principal Investigator. "Several distinct design characteristics of the PASCAL system, including the flexible nitinol design and elongation capability, contribute to the positive outcomes of this study."

The CLASP IID trial is a prospective randomized controlled trial comparing the safety and effectiveness of the PASCAL system to the MitraClip system. Results were reported on 180 patients with 2:1 randomization (117 PASCAL / 63 MitraClip), with echo core lab adjudication. The trial included 43 sites in the US, Canada and Europe, with most clinical operators new to using the PASCAL system and all having experience with the MitraClip system.

"As we consider the many DMR patients who are suffering with debilitating symptoms and could benefit from a TEER procedure, we are very pleased with the outcomes from the CLASP IID trial," said Bernard J. Zovighian, Edwards' corporate vice president, transcatheter mitral and tricuspid therapies. "Edwards continues to prioritize evidence generation with world-class data in support of our patient-driven therapies, and we are proud to support this and multiple other pivotal trials as we work to transform treatment for these patients in need."

Additional data presentations for the company during TCT 2022 include:

- The PASCAL IID Registry: A Prospective Registry for Transcatheter Edge-to-Edge Repair in Prohibitive Risk Patients With Degenerative Mitral Regurgitation and Complex Mitral Valve Anatomy (Sept. 17) – Late-Breaking Presenter: Jörg Hausleiter.
- Deep Dive Session: Mitral TEER = CLASP IID Trials (Sept. 17) – Moderators: Megan Coylewright, Linda D. Gillam. Discussants: Paul A. Grayburn, Konstantinos P. Koulogiannis, Raj Makkar, Jacob M. Mishell, Ralph Stephan von Bardeleben, Firas Zahr.
- Frequency and Safety of Bioprosthetic Valve Fracture in Patients Undergoing Valve in Valve TAVR for Failed Surgical Valves Using the SAPIEN 3/Ultra Valves: Insights From Real-World Data (Sept. 18) – Presenter: Santiago Garcia.
- Cardiac Damage and Quality of Life After Aortic Valve Replacement: Results from the PARTNER Trials (Sept.

18) – Presenter: Philippe Genereux.

Edwards is committed to transforming the treatment of patients with structural heart disease, supported by robust clinical evidence. As part of Edwards' continued commitment to building a body of real-world evidence, patients receiving the PASCAL Precision therapy 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 and the company's first approved transcatheter therapy for DMR in the US. The PASCAL system first received CE Mark in Europe in 2019, and the PASCAL Precision system received CE Mark in 2022.

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**.

View original content to download multimedia:**https://www.prnewswire.com/news-releases/edwards-announces-six-month-data-confirming-teer-as-safe-and-effective-for-dmr-in-first-head-to-head-trial-301626576.html**

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