NEWS RELEASE

EDWARDS RECEIVES FDA APPROVAL FOR SAPIEN 3 WITH ALTERRA PRESTENT FOR TRANSCATHETER PULMONIC VALVE REPLACEMENT

12/20/2021

IRVINE, Calif., Dec. 20, 2021 /PRNewswire/ -- Edwards Lifesciences (NYSE: EW) today announced it received approval from the U.S. Food and Drug Administration (FDA) for the use of the Edwards SAPIEN 3 transcatheter valve with the Alterra adaptive prestent (SAPIEN 3 with Alterra) for patients with severe pulmonary regurgitation.

The Edwards SAPIEN 3 Transcatheter Pulmonary Valve (TPV) system combines the proven SAPIEN 3 transcatheter heart valve and the Alterra adaptive prestent to expand transcatheter therapy options for congenital heart valve disease patients. The Alterra prestent compensates for variations in size and morphology of the right ventricular outflow tract to provide a stable landing zone for the SAPIEN 3 valve.

"The FDA approval of the SAPIEN 3 with Alterra is great news for patients around the world, many of whom have endured numerous surgical procedures to treat their congenital heart disease," said Dr. Evan Zahn, M.D., Director of Guerin Family Congenital Heart Program at the Smidt Heart Institute, Cedars-Sinai Medical Center, and principal

investigator for the ALTERRA clinical trial. "The outstanding outcomes achieved by SAPIEN 3 with Alterra will expand the range of patients who require pulmonary valve replacement that we can now treat with minimally invasive therapy. This will result in significant improvements in quality of life and a reduction in the number of surgeries and procedures that a congenital heart patient requires over the course of their lifetime."

While pulmonic heart valve replacements represent a small fraction of the heart valve replacements done each year, it is generally required to replace valves in adolescent and adult patients suffering from Tetralogy of Fallot or other congenital heart valve defects.

"I'm very proud of this advancement, which exemplifies the important work of our team at Edwards to develop life-saving innovations addressing urgent needs of this important patient group," said Larry Wood, corporate vice president, transcatheter aortic valve replacement. "Many of these patients endure repeated open-heart surgeries to address heart conditions present since birth, which takes a huge toll on their ability to lead normal lives. The SAPIEN 3 with Alterra provides a new treatment option that can reduce the number of invasive procedures these patients face in their lifetimes."

The Edwards SAPIEN 3 TPV system with Alterra adaptive prestent is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation as measured by echocardiography, who have a native or surgically repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

Dr. Zahn 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 and 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. Wood and statements regarding expected product benefits, patient outcomes, post-treatment reduction of invasive procedures, 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. These filings, along with important safety information about our products, may be found at **Edwards.com**.

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