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Edwards SAPIEN 3 Transcatheter Heart Valve Receives Expanded Indication From FDA

IRVINE, Calif., Aug. 18, 2016 -- Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, today announced U.S. Food and Drug Administration (FDA) approval to expand use of the Edwards SAPIEN 3 transcatheter heart valve for the treatment of patients suffering from severe, symptomatic aortic stenosis who have been determined by a Heart Team to be at intermediate risk for open-heart surgery. The SAPIEN 3 valve is the first transcatheter aortic valve replacement (TAVR) therapy to obtain this indication in the United States.

"The SAPIEN 3 valve has set a new standard for performance and patient outcomes with aortic valve replacement," said Vinod Thourani, M.D., co-director of Emory Heart and Vascular Center's Structural Heart and Valve Center and professor of cardiothoracic surgery at Emory University School of Medicine. "The clinical outcomes of 1.1 percent mortality and 1.0 percent disabling stroke at 30 days in this intermediate-risk population treated with the SAPIEN 3 valve are changing the paradigm of how we treat patients with aortic stenosis."

Thourani is the co-principal investigator of the SAPIEN 3 valve study.

"The intermediate-risk approval of the SAPIEN 3 valve is a major milestone, since it provides a less-invasive therapy that has demonstrated better outcomes for aortic valve patients, and is supported by the largest and rigorous comparative body of evidence for the treatment of aortic stenosis," said Larry L. Wood, Edwards' corporate vice president, transcatheter heart valves.

The SAPIEN 3 valve intermediate-risk approval was based on data from a cohort of the PARTNER II Trial, which studied 2,005 intermediate-risk patients at 51 sites in the United States and Canada. The study demonstrated that patients treated with the SAPIEN 3 valve experienced clinically significant improvements for the composite primary endpoint of mortality, stroke and moderate or severe aortic regurgitation at one year as compared to those treated with surgery. The data were presented in April at the American College of Cardiology's 65th Annual Scientific Session and simultaneously published in *The Lancet*.

The expanded intermediate-risk indication granted by the FDA enables Heart Teams to treat patients with the SAPIEN 3 valve who they determine to have a predicted risk of surgical mortality of greater than or equal to 3 percent at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator.

About Edwards Lifesciences

This news release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements include, but are not limited to, statements by Dr. Thourani and Mr. Wood and statements regarding expected product benefits and procedural outcomes. 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.

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6/21/2017

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