Edwards Sapien 3 Transcatheter Heart Valve Receives Expanded Indication In Europe

LONDON, Sept. 19, 2016 -- Edwards Lifesciences Corporation (NYSE: EW), the global leader in patient-focused innovations for structural heart disease and critical care monitoring, today announced that it has received CE Mark to expand use of the Edwards SAPIEN 3 transcatheter heart valve for the treatment of patients suffering from severe, symptomatic aortic stenosis who are at intermediate risk for open-heart surgery.

"This expanded intermediate-risk indication allows for the treatment of even more patients whose only previous option was an open-heart surgical procedure," said Prof. Helge Möllmann, Director, Clinic for Internal Medicine (Cardiology) at St. Johannes Hospital, Dortmund, Germany. "I am encouraged by the adoption of the position paper of the German Cardiac Society that recommends the use of transcatheter aortic valve implantation (TAVI) in intermediate-risk patients based on growing clinical evidence."

For patients with severe aortic stenosis who are at intermediate risk for an open-heart surgical procedure, TAVI using the Edwards SAPIEN 3 valve has been shown[1] to demonstrate outcomes that are superior to surgery at one year on a composite primary endpoint of mortality, stroke and moderate or severe aortic regurgitation.

The SAPIEN 3 valve builds on Edwards' decades of experience in the development of tissue heart valves, and the proven benefits of the Edwards SAPIEN valves. The valve was first approved in Europe in January 2014 for the treatment of patients with severe, symptomatic aortic stenosis who are at high-risk for open heart surgery. The U.S. Food and Drug Administration approved the SAPIEN 3 valve for the treatment of intermediate-risk patients in August 2016.

(1)	Thourani V et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. The Lancet 2016;1-8.

About Edwards Lifesciences

Edwards Lifesciences, based in Irvine, Calif., is the global leader in patient-focused medical innovations for structural heart disease, as well as critical care and surgical monitoring. Driven by a passion to help patients, the company collaborates with the world's leading clinicians and researchers to address unmet healthcare needs, working to improve patient outcomes and enhance lives. For more information, visit www.Edwards.com (http://www.edwards.com/) and follow us on Twitter @EdwardsLifesci.

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 Prof. Möllmann and statements regarding expected product benefits, procedural outcomes and changes to guidelines. 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.

Forward-looking statements involve risks and uncertainties that could cause the roll-out and benefits of the technology to differ materially from those expressed or implied by the forward-looking statements based on a number of factors including but not limited to unexpected outcomes after longer term clinical experience, unexpected changes or delays related to product supply, potentials for unexpected regulatory, clinical or quality developments, competitive dynamics, litigation and customer acceptance. These factors are 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, 2015.

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Important safety information

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