Edwards Lifesciences Receives FDA Approval for First Catheter-Based Aortic Heart Valve in the U.S.

IRVINE, CA, November 02, 2011 -- Edwards Lifesciences Corporation (NYSE: EW), the global leader in the science of heart valves and hemodynamic monitoring, today announced that it has received approval from the United States Food and Drug Administration (FDA) for the transfemoral delivery of the Edwards SAPIEN transcatheter aortic heart valve for the treatment of inoperable patients with severe symptomatic aortic stenosis. This is the first U.S. commercial approval for a transcatheter device enabling aortic valve replacement without the need for open-heart surgery.

Transcatheter aortic valve replacement (TAVR) with the Edwards SAPIEN valve enables multi-disciplinary heart teams to replace a patient's diseased aortic valve without traditional open-heart surgery and while the heart continues to beat -- avoiding the need for cardiopulmonary bypass.

"This day marks an important milestone for inoperable American patients who have long been awaiting a therapeutic option for the often debilitating symptoms associated with severe aortic stenosis," said Michael A. Mussallem, Edwards' chairman and CEO. "We are extremely proud of the dedication of the heart teams and the patients involved in the clinical trial for this therapy, who have paved the way for this therapy to help even more people around the world."

In performing the TAVR procedure, the valve is crimped onto the catheter-based transfemoral delivery system, which is inserted into the body through a small cut in the leg. Once delivered to the site of the patient's diseased valve, the Edwards SAPIEN valve is expanded with a balloon and immediately functions in place of the patient's native valve.

The Edwards SAPIEN valve is indicated for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.

The safety and effectiveness of the Edwards SAPIEN transcatheter valve were evaluated in a randomized, controlled pivotal study called The PARTNER Trial. The name of the trial signifies the important partnership between cardiac surgeons and interventional cardiologists, who were brought together to collaborate in patient evaluation, treatment and follow-up. Additional analyses of data from The PARTNER Trial demonstrated that patients receiving the SAPIEN valve experienced substantially better quality of life as compared to the control group patients, and also that TAVR was cost effective.

As part of this approval, FDA has requested the implementation of two substantial post-approval studies. One study will follow patients already enrolled in The PARTNER Trial, and the second study will track new U.S. patients. The company anticipates the second study will be incorporated into a new national patient registry.

About Edwards Lifesciences

Edwards Lifesciences is the global leader in the science of heart valves and hemodynamic monitoring. Driven by a passion to help patients, the company partners with clinicians to develop innovative technologies in the areas of structural heart disease and critical care monitoring that enable them to save and enhance lives. Additional company information can be found at www.edwards.com (http://ctt.marketwire.com/?release=816991&id=950137&type=1&url=http%3a%2f%2fwww.edwards.com%2f).

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 made by Mr. Mussallem and statements regarding the post-approval studies for, and the benefits of, the Edwards SAPIEN valve. 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 outcomes 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 regulatory or reimbursement decisions and longer-term clinical experience. 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, 2010.

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