Edwards Receives FDA Approval For SAPIEN 3 Transcatheter Heart Valve

Approved For High-Risk Indication and All Valve Sizes

IRVINE, Calif., June 17, 2015 -- Edwards Lifesciences Corporation (NYSE: EW), the global leader in the science of heart valves and hemodynamic monitoring, today announced U.S. Food and Drug Administration (FDA) approval of its most advanced transcatheter aortic heart valve – the Edwards SAPIEN 3 valve with the Commander Delivery System – for the treatment of high-risk patients suffering from severe, symptomatic aortic stenosis.

"The SAPIEN 3 valve sets a new standard for transcatheter heart valve performance and patient outcomes," said Martin B. Leon, MD, director of the Center for Interventional Vascular Therapy at NewYork-Presbyterian/Columbia University Medical Center and professor of medicine at the Columbia University College of Physicians and Surgeons. "We have seen some of the best results to date from the PARTNER II Trial in treating high-risk patients with the SAPIEN 3 valve. The PARTNER II study concluded that this new valve reduced several complications associated with the TAVR procedure such as paravalvular leakage and stroke, and represented a meaningful improvement over data from prior studies with earlier-generation devices," Leon said.

Dr. Leon was the co-principal investigator for the PARTNER II Trial. SAPIEN 3 approval was based on a cohort of the PARTNER II Trial, which enrolled 583 high-risk patients at 29 U.S. sites.

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 new valve, available in 20mm, 23mm, 26mm and 29mm sizes, has an outer skirt – a cuff of fabric surrounding the valve frame – providing a seal to address paravalvular leak.

"U.S. physicians have been eagerly awaiting the launch of the Edwards SAPIEN 3 valve since it became available in Europe last year, and we appreciate the FDA's timely and thoughtful review in making this device available to American patients," said Larry L. Wood, Edwards' corporate vice president, transcatheter heart valves. "Based on extensive research and high quality clinical data, we believe the SAPIEN 3 valve has the potential to transform patient care in the U.S."

Given the earlier-than-anticipated FDA approval of SAPIEN 3, the company is ramping up supply and expects the launch to be largely completed by the end of the year.

The SAPIEN 3 valve has been commercially available in Europe since January 2014. The SAPIEN family of valves has been used in the treatment of more than 100,000 patients globally.

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, enabling them to save and enhance lives. Additional company information can be found at www.edwards.com (http://www.edwards.com/).

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. Leon and Mr. Wood and statements regarding the expected launch of the Edwards SAPIEN 3 valve, design features and 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.

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 more expanded clinical experience, unexpected changes or delays related to product supply, potentials for unexpected regulatory or quality developments, competitive dynamics, global economic conditions 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, 2014.

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Important safety information

Caution: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.