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**FOR IMMEDIATE RELEASE**

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# EDWARDS INTUITY ELITE VALVE SYSTEM RECEIVES CE MARK

*Next-generation technology built on trusted, proven platform designed for enhanced patient benefits*

**IRVINE, CA, April 4, 2014** – Edwards Lifesciences Corporation (NYSE: EW), the global leader in the science of heart valves and hemodynamic monitoring, today announced it has received CE Mark for the advanced EDWARDS INTUITY Elite valve system. This next-generation, rapid deployment system facilitates smaller incisions in surgical aortic valve replacement (AVR) procedures, and is built upon extensive evidence supporting the durability of the Carpentier-Edwards PERIMOUNT heart valve design.

"Smaller incisions, reduced cross-clamp time and improved haeomodynamics are advances that have the potential to improve outcomes in many patients who undergo surgical aortic valve replacements in the UK each year," said Dr Chris Young, Consultant Surgeon at St. Thomas' Hospital, London. "EDWARDS INTUITY Elite represents the next step in offering patients a less-invasive and more efficient surgical approach, and is designed to greatly enhance the results of surgery."

The next-generation EDWARDS INTUITY Elite valve system combines a unique balloon-expandable frame with Edwards' proven pericardial PERIMOUNT platform, which has demonstrated durability up to 25 years in published studies. The new system has design improvements intended to improve ease of use, including a flexible and lower profile delivery system that is designed to facilitate access and visibility through smaller incisions.

"We've enhanced the EDWARDS INTUITY design to further meet the needs of patients, physicians and hospitals with a valve and procedure that can be readily incorporated into the surgeon's treatment offerings," said Donald E. Bobo, Jr., Edwards' corporate vice president, heart valve therapy. "We believe the EDWARDS INTUITY platform can greatly expand the population of patients who receive the less-invasive approach with important clinical and cost benefits."

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**Advanced Innovation for Surgeons and Patients Backed by Robust Clinical Data**

Data from 100 patients in the CADENCE-MIS trial, a randomized, controlled, multi-center trial comparing minimally-invasive AVR with the EDWARDS INTUITY valve system to full sternotomy AVR with any conventional bioprosthetic aortic valve, were recently presented at the 2014 Annual Meeting of the Society of Thoracic Surgeons (STS). The trial found:

- Minimally-invasive AVR with the EDWARDS INTUITY platform demonstrated a statistically significant reduction (24 percent) in ischemic time (the amount of time blood flow to and from the heart is stopped during surgery) compared to the full sternotomy approach with conventional bioprosthetic valves. These results are especially meaningful as minimally-invasive approaches have traditionally been associated with longer ischemic times; and
- Improved blood flow and hemodynamics with the EDWARDS INTUITY valve compared to conventional bioprosthetic valves at 3-month follow-up.

Additionally, an interim analysis of 158 patients undergoing isolated aortic valve replacement in the prospective, multicenter, single-arm TRITON Trial[1] for the EDWARDS INTUITY platform, found that 55 percent were performed through a minimally invasive approach, as opposed to a full sternotomy.

The EDWARDS INTUITY Elite Valve System is currently being studied as part of the TRANSFORM Trial, the first U.S. clinical trial of a rapid deployment system for surgical aortic valve replacement. It is an investigational device and not yet available for sale or use in the United States. The system will be commercially available at hospitals throughout Europe and is supported with favorable reimbursement in Germany as part of diagnosis-related group (DRG) mapping that includes the new category of rapid-deployment aortic valve systems.

**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.

[1] The TRITON Trial involved six European centers and treated a total of 287 patients with the EDWARDS INTUITY platform between Jan. 2010 and Oct. 2012.

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, Dr. Young and Mr. Bobo's statements and statements regarding the launch and estimated roll-out of the EDWARDS INTUITY Elite Valve System, 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 expanded clinical experience, unexpected changes or delays related to product supply, quality and availability, changes in product indications or reimbursement levels, or regulatory decisions. 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, 2013.



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