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Edwards Lifesciences Announces First Human Implants With 18 French Transcatheter Valve System

IRVINE, CA, May 14, 2009 -- Edwards Lifesciences Corporation (NYSE: EW), the world leader in the science of heart valves, today announced the successful completion of the first human implants of its next-generation transcatheter aortic heart valve used with its new 18 French delivery system. Edwards expects these cases, performed in Canada, to be reviewed next week at EuroPCR 2009.

The 18 French system features the Edwards SAPIEN XT valve paired with its new, smaller NovaFlex transfemoral delivery system. The valve has a cobalt chromium alloy balloon-expandable frame, which allows for a significant reduction in its profile, and bovine pericardial tissue leaflets processed in the same stringently controlled manner as Edwards' market-leading surgical heart valves. The NovaFlex delivery system leverages the ease-of-use features of the Edwards RetroFlex line of delivery systems.

"The clinical success of the Edwards SAPIEN valve has allowed us to treat patients who previously had no good treatment options. The new Edwards SAPIEN XT valve, with its improved design and revolutionary lower profile delivery system, will allow us to treat aortic stenosis patients even more reliably and safely," said John Webb, M.D., who performed the first successful human implants of the new transcatheter system. Webb is director of the cath lab and cardiac intervention at St. Paul's Hospital in Vancouver, British Columbia, and a consultant to Edwards Lifesciences.

While the Edwards SAPIEN XT valve is being evaluated in the PREVAIL EU trial for CE Mark approval, the commercial rollout of Edwards' RetroFlex 3 delivery system to be used with the Edwards SAPIEN valve is underway in Europe. The RetroFlex 3 delivery system is designed to optimize physician control of valve navigation and facilitate crossing of the patient's native calcified aortic valve.

"We are dedicated to leading the rapid advancement of transcatheter heart valve technology," said Larry L. Wood, Edwards' corporate vice president, transcatheter valve replacement. "The commercial launch of the RetroFlex 3 delivery system and the enhancements incorporated into the NovaFlex delivery system with the Edwards SAPIEN XT valve are designed to make transcatheter valve therapy accessible to even more patients."

Representatives from Edwards will be at Booth #F02 at EuroPCR 2009, May 19–22 in Barcelona, Spain. Simulators in the EuroPCR 2009 Training Village will provide the opportunity for a virtual procedural experience with the RetroFlex 3 transfemoral and Ascendra transapical delivery systems.

The Edwards SAPIEN valve is approved for commercial sale in Europe. In the United States, it is being studied as part of a randomized, pivotal clinical trial.

About Edwards Lifesciences

Edwards Lifesciences is the global leader in the science of heart valves and hemodynamic monitoring, with more than five decades of experience in partnering with clinicians to develop life-saving innovations. Headquartered in Irvine, Calif., Edwards treats advanced cardiovascular disease with its market-leading heart valve therapies, and critical care and vascular technologies, which are sold in approximately 100 countries. The company's global brands include Carpentier-

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, the timing and progress of clinical studies relating to the company's transcatheter valve technologies and the market opportunity for transcatheter technologies. 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 actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Factors that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements 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, 2008.

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