News releases

Edwards Lifesciences Receives CE Mark for Edwards SAPIEN Transcatheter Heart Valve

IRVINE, Calif., Sept. 5, 2007 -- Edwards Lifesciences Corporation (NYSE: EW), the world leader in the science of heart valves, today announced that it has received CE Mark approval for European commercial sales of its Edwards SAPIEN transcatheter aortic heart valve technology with the RetroFlex transfemoral delivery system.

The Edwards SAPIEN transcatheter heart valve is implanted via a minimally-invasive procedure, without requiring open-heart surgery. It is the first transcatheter bovine pericardial valve incorporating technological advancements and design elements that allow for greater ease of implantation by physicians. The valve is designed to treat patients with severe aortic heart valve stenosis (a narrowing of the valve that restricts blood flow), who are considered to be high-risk or non-operable for conventional open-heart valve replacement surgery.

"This is a landmark achievement for this transformational technology, which holds promise for the large number of high-risk patients suffering from severe aortic stenosis," said Michael A. Mussallem, Edwards Lifesciences' chairman and CEO. "As the global leader in heart valve therapy, we are committed to working closely with our European clinical partners on this transcatheter technology, in order to provide optimal clinical outcomes for the many high-risk patients in need of aortic valve replacements, who might otherwise have limited or no treatment options."

"In this pioneering procedure, the skill sets of the surgeon and the interventional cardiologist complement each other to provide for better patient care," said Martin B. Leon, MD, Professor of Medicine and Associate Director of the Center for Interventional Vascular Therapy at Columbia University Medical Center and the principal investigator for the Edwards PARTNER pivotal trial in the United States. "Several years of clinical experience have demonstrated that optimal outcomes can be achieved with a collaborative, multi-disciplinary team."

The Edwards SAPIEN transcatheter heart valve integrates balloon-expandable stent technology that leverages Edwards' proprietary bovine pericardial tissue and 30 years of design and manufacturing expertise. With the RetroFlex transfemoral delivery system, the Edwards SAPIEN valve is compressed onto the balloon to the approximate diameter of a pencil and threaded through the patient's circulatory system from the leg and expanded securely into place directly over the diseased aortic valve.

Edwards has achieved almost 500 implants of the transcatheter heart valve through a series of extensive clinical trials and feasibility studies in Europe, the U.S. and Canada. The company is proceeding on schedule with European launch preparations, including establishing training centers, selecting proctors for commercial site training, and progressing country-specific reimbursement plans, and will begin selling the device, as planned, in the fourth quarter of 2007.

The company has also submitted for CE Mark approval the Edwards SAPIEN transcatheter heart valve with the Ascendra transapical delivery system -- in which the valve is inserted between the ribs -- providing interventional cardiologists and surgeons with a second valve delivery option. The Ascendra transapical delivery system is expected to receive CE Mark by the end of the year.

About Edwards Lifesciences

Edwards Lifesciences, a leader in advanced cardiovascular disease treatments, is the number-one heart valve company in the world and the global leader in acute hemodynamic monitoring. Headquartered in Irvine, Calif., Edwards focuses on specific cardiovascular disease states including heart valve disease, peripheral vascular disease and critical care technologies. The company's global brands, which are sold in approximately 100 countries, include Carpentier-Edwards, Cosgrove-Edwards, FloTrac, Fogarty, LifeStent, PERIMOUNT Magna and Swan-Ganz. Additional company information can be found at http://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 timely regulatory approval of the Edwards SAPIEN transcatheter aortic heart valve; the timing and progress of clinical studies relating to the company's transcatheter valve technologies and the market opportunity for these products; the expected European launch of the Edwards SAPIEN valve and the anticipation of beginning sales in fourth quarter of 2007; and the market 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.

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, 2006.

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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.