



Edwards Lifesciences

About Us

Edwards Receives Approval to Begin U.S. Clinical Trial of Next-Generation Transcatheter Valve

IRVINE, CA, September 23, 2010 -- Edwards Lifesciences Corporation (NYSE: EW), the global leader in the science of heart valves and hemodynamic monitoring, today announced that the U.S. Food and Drug Administration (FDA) conditionally approved the first of two planned cohorts of the randomized, controlled The PARTNER II Trial. Building upon the learnings of the world randomized transcatheter heart valve trial -- Edwards' The PARTNER Trial -- the first cohort of The PARTNER II Trial will study the next-generation Edwards SAPIEN XT transcatheter heart valve. This trial includes the low-profile NovaFlex transfemoral delivery system, which broadens the number of eligible patients.

This cohort of The PARTNER II Trial will study up to 450 patients with severe, symptomatic aortic stenosis using two-to-one randomization, where for every two patients who receive the Edwards SAPIEN XT valve delivered transfemorally, one will receive standard therapy. The primary endpoint of the trial is a composite of death, major stroke and repeat hospitalization, with secondary endpoints that include valve performance and quality-of-life indicators.

Edwards anticipates a second patient cohort for the trial to compare traditional open-heart surgery with the Edwards SAPIEN valve delivered either transfemorally or transapically.

The Edwards SAPIEN XT valve is commercially available in Europe, where it received a CE Mark in March 2010. The Edwards SAPIEN XT transcatheter valve is an investigational device in the U.S. and not yet available commercially in this country.

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 cardiac monitoring that enable them to save and enhance lives. Additional company information can be found at 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 can sometimes be identified by the use of words such as "may," "will," "should," "anticipate," "believe," "plan," "project," "estimate," "expect," "intend," or other similar expressions and 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, 2009.

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