

FDA Panel Recommends Approval of Edwards Sapien Valve for High-Risk Indication

On June 13, 2012, Edwards Lifesciences (Irvine, CA) announced that the US Food and Drug Administration's (FDA) Circulatory System Devices Panel of the Medical Devices Advisory Committee voted in favor of recommending approval of the Edwards Sapien transcatheter heart valve via transfemoral and transapical delivery for the treatment of high-risk patients with severe, symptomatic aortic stenosis. The panel voted 11 to 0, with one abstention, that the benefits of the heart valve outweighed the risks for these patients, the company stated.

The FDA panel conducted a public meeting in Gaithersburg, Maryland, to discuss, make recommendations, and vote on information related to Edwards' pre-market approval (PMA) application for the device in this indication. The FDA provided background documents on its website for 2012 Circulatory Meeting Materials.

According to documents posted by the FDA in advance of the meeting, the panel wanted the company representatives to address concerns about the safety of the device. Data summarized by the FDA show that the Sapien device, compared to surgical aortic valve replacement, resulted in an increase in strokes perioperatively and an increase in the overall rate of major vascular complications. Also, there was a 53% rate of mild or greater aortic insufficiency with the Sapien device that appears to correlate with poorer long-term health outcomes.

The panel was also interested in questions about trial conduct, comparative safety rates of a transfemoral and a transapical approach, proposed indications for use of the two approaches, gender differences in outcomes, the valve's performance and durability, informed consent of patients, the overall safety and effectiveness of the valve, considerations for a postapproval study, and device labeling.

The FDA advised that the voting questions for the Circulatory System Devices Panel were:

1. Is there reasonable assurance that the Sapien heart valve system is safe for use in patients with critical

aortic stenosis who have been determined to be at a high (> 15%) risk for open surgical aortic valve replacement by a highly experienced cardiac surgery/interventional cardiology team? *The 12-member panel voted 10 to 2 that the device is safe.*

2. Is there reasonable assurance that the Sapien heart valve system is effective for use in patients with critical aortic stenosis who have been determined to be at a high (> 15%) risk for open surgical aortic valve replacement by a highly experienced cardiac surgery/interventional cardiology team? *The panel voted 12 to 0 that the device is effective.*
3. Do the benefits of the Sapien heart valve system for use in patients with critical aortic stenosis who have been determined to be at a high (> 15%) risk for open surgical aortic valve replacement by a highly experienced cardiac surgery/interventional cardiology team outweigh the risks of the Edwards Sapien heart valve system for use in patients who have been determined to be at a high (> 15%) risk for open surgical aortic valve replacement by a highly experienced cardiac surgery/interventional cardiology team? *The panel voted 11 to 0, with one abstention, that the benefits of using the device outweighed the risks.*

Edwards' PMA application was based on data from the high-risk cohort (Cohort A) of the PARTNER trial, which compared outcomes after treatment of 699 patients with either surgical valve replacement or the Edwards Sapien valve via transfemoral or transapical delivery. The PMA application was submitted in April of 2011. The 1-year Cohort A results were presented in April 2011 at the American College of Cardiology's annual scientific sessions and published in *The New England Journal of Medicine* in June 2011. The Edwards Sapien transcatheter heart valve received FDA approval for the treatment of certain inoperable patients in November 2011 and is currently an investigational device for the treatment of high-risk patients in the United States, advised the company. ■