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Edwards Wins Panel Support to Sell First Less-Invasive Heart Valve in U.S.

By Anna Edney - Jul 20, 2011 10:01 PM MT

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Edwards Lifesciences Corp. (EW) won an advisory panel's support for the first less-invasive [heart valve](#) to be marketed in the U.S. for patients who are too sick for chest-opening surgery.

The benefits of the device for patients with a narrowing of their aortic valve outweighed the risk of stroke and hemorrhage associated with the product, advisers to the [Food and Drug Administration](#) said in a 9-0 vote yesterday with one abstention in Gaithersburg, [Maryland](#). The panel earlier voted 7-3 that the Irvine, California-based company's

valve, called Sapien, is safe and 9-1 that it is effective.

If it gains approval, the Edwards device would be the first so-called transcatheter valve sold in a U.S. market estimated to reach \$1.3 billion by 2014, according to a report from Bloomberg Industries. The valve has been available in [Europe](#) since 2007.

"We feel this reduction in mortality in inoperable patients outweighed the significant risks with the device, most notably stroke and vascular injury," Julia Swain, with the FDA's circulatory support and prosthetics branch in the division of cardiovascular devices, told the panel.

Edwards fell \$2.12, or 2.4 percent, to \$87.53 at 4:15 p.m. yesterday in New York Stock Market trading before the panel's votes. The company's shares gained 8.3 percent this year.

About 300,000 people in the U.S. suffer from severe aortic stenosis, which is a narrowing of the valve, according to Edwards. Two-thirds undergo standard chest-cracking surgery to replace the valve, while the risk of surgery may be too high for the rest. Minneapolis-based [Medtronic Inc. \(MDT\)](#) began a clinical trial in December in the U.S. of a rival device.

'Strong Recommendation'

"We are pleased with the panel's strong recommendation for approval," Michael A. Mussallem, Edwards's chairman and chief executive officer, said in a statement. "This represents another important step on the path to what we hope will lead to FDA approval."

The Sapien can be implanted by a catheter threaded through the leg or ribs rather than conventional chest-opening surgery. Transcatheter sales generated \$206 million last year for Edwards, according to data compiled by Bloomberg. The FDA and Edwards agreed patients with severe aortic valve narrowing who are allowed to use the device should also be symptomatic.

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Sixty-nine percent of patients who received the Sapien valve lived after one year compared with 50 percent in a clinical trial group receiving standard therapy, according to an FDA staff report released July 18. The agency called the results “an impressive reduction of mortality” while raising concerns that not much data exists beyond two years.

Panel’s Concerns

The panel raised concerns that death rates were higher in a small group of patients enrolled in a continuing access program after the study was complete. Thirteen patients, or 32 percent, who received the valve, died after one year in the continuing access program compared with 10 patients, or 20 percent, who received other therapy.

Inclusion of the additional data may decrease the benefit of the device, they said.

The FDA staff recommended a post-approval study to provide long-term follow up. Edwards plans to analyze the durability of the valve and patient quality of life for five years in additional post-approval research, according to a company presentation to the panel.

In the clinical trial, 20 patients, or about 11 percent, who received the Sapien valve experienced stroke after one year compared with eight patients, or 4.5 percent, who were treated with other therapy, such as balloon aortic valvuloplasty, according to the report. Edwards underreported stroke in its analysis of the study by counting only “major strokes” when stroke severity wasn’t measured during the trial, the FDA said.

One hundred patients, or 60 percent, who received the valve experienced complications such as blood clots after one year, compared with 25 patients, or 14 percent, who were treated with other therapy, according to the report.

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