US reviews safety of innovative heart valve (Update 2)

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(AP) — U.S. health officials are asking safety questions about the first artificial heart valve designed to be implanted without major surgery, ahead of a meeting this week to consider broadening its use.

Last November Edwards Lifesciences Corp. won approval for its first-of-a-kind Sapien heart valve, which can be threaded into place through one of the body's major arteries. The valve is currently available for patients who aren't healthy enough to undergo the more invasive open-heart surgery which has been used to replace the valve for decades.

Now the Food and Drug Administration is considering expanding the device to patients who are healthier, but still face serious risks from chest-opening surgery. Many such patients are in their 80s and have complicating medical factors like diabetes.

In an online review posted Monday, FDA reviewers said the heart valve compared favorably to surgery after one year, with patients living about the same amount of time. In Edwards' study submitted to the agency, 24 percent of patients implanted with the heart valve through their artery died after one year, compared with 27 percent of those who had undergone surgery.

Patients who had the valve inserted through an incision between the ribs had a death rate of 22 percent after one year. The numbers were close enough to meet the study's goal of showing that the valve was at least as effective as surgery.

However, reviewers said patients who got the Sapien valve had a higher rate of stroke in the month after the procedure. Additionally, more than half of patients had leaking from the aortic heart valve, a potentially dangerous condition in which blood flows backward into the heart's ventricle chamber.

The FDA will ask a panel of outside advisers to weigh in on these risks at a meeting Wednesday. The panel, composed mainly of expert cardiologists, will take a final vote on whether Sapien's benefits outweigh its risks.

Wells Fargo analyst Larry Biegelsen said the FDA's review "did not raise any major new issues."

"We continue to anticipate a challenging panel on Wednesday but expect a positive vote," he wrote in a note to investors.

About 300,000 U.S. patients suffer from deterioration of the aortic heart valve, which forces the heart to work harder to pump blood, often leading to heart failure, blood clots and sudden death. More than half of patients diagnosed with the condition, called aortic stenosis, die within two years, according to the FDA.

Every year about 50,000 people in the U.S. undergo open-heart surgery to replace the valve, which involves sawing the breastbone in half, stopping the heart, cutting out the old valve and sewing a new one into place. Thousands of other patients are turned away, deemed too old or ill to survive the operation.

Analysts estimate as many as 70,000 to 100,000 patients per year could eventually receive the Sapien valve.

In the most recent quarter Edwards reported Sapien sales of $121.5

million, with the U.S. contributing $41 million. For the full year Edwards expects sales of $530 million to $600 million, down from earlier estimates of $560 million to $630 million. The company attributed the revision to delays in the FDA review process, unfavorable foreign currency exchange rates and difficult market conditions in Europe.

The valve is usually threaded through the femoral artery via a small incision in the leg, and then guided up to the heart via catheter. An alternate procedure inserts the valve through a small incision between the ribs. The valve is then wedged into the aortic opening by an inflatable balloon, replacing the natural heart valve. The device is made from cow tissue and polyester supported by a steel frame.

Shares of California-based Edwards rose 7 cents to $88.30 in afternoon trading.