

FACTS AT-A-GLANCE

THE EDWARDS SAPIEN TRANSCATHER HEART VALVE (THV)

The Edwards SAPIEN Transcatheter Heart Valve (THV) Technology

- The Edwards SAPIEN transcatheter heart valve is the first of its kind tissue valve, incorporating proprietary technology 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 new heart valve is implanted without open-heart surgery, using minimally-invasive techniques. The Edwards SAPIEN transcatheter heart valve is mounted and crimped onto the balloon delivery catheter and then threaded through the patient's circulatory system from the leg (transfemoral approach) or inserted between the ribs (transapical approach) directly into the heart's pumping chamber.
- Upon reaching the site of the patient's diseased or "stenotic" heart valve, the balloon is expanded and the Edwards SAPIEN transcatheter heart valve is deployed across the patient's diseased valve.
- The therapy was originally developed in conjunction with Prof. Alain Cribier, M.D., chief of cardiology at the University Hospital in Rouen, France, who performed the first transcatheter aortic valve replacement in April 2002.

The PARTNER (Placement of AoRTic traNscathetER valves) Trial

- Edwards Lifesciences received conditional approval from the U.S. Food and Drug Administration in March 2007 to initiate a first-ever pivotal trial of its Edwards SAPIEN transcatheter heart valve technology.
- The PARTNER trial will evaluate the Edwards SAPIEN transcatheter heart valve in patients who are considered high-risk or non-operable for conventional open-heart valve surgery. Annually, some 200,000 people in the U.S. need a new heart valve, but nearly half of them do not receive a new valve for a variety of reasons.
- The PARTNER trial is a prospective randomized clinical trial of up to 1,040 patients divided into two separate treatment arms – a surgical arm and a medical management arm. Each arm of the trial contains a sufficient number of patients to support independent statistical analysis.

The two arms are outlined as follows:

The Surgical Arm

- Will enroll approximately 690 high-risk patients who are candidates for conventional open-heart surgery.
- Patients will first be evaluated for femoral access to determine if they can receive a transcatheter valve via their femoral artery or if it needs to be implanted via a small incision between the ribs.
- Once segmented between the two delivery options, the patients will be evenly randomized – essentially like the flip of a coin – to receive either the Edwards SAPIEN transcatheter heart valve or an Edwards surgical valve.
- Success in the surgical arm is determined if the clinical results demonstrate that the Edwards SAPIEN transcatheter heart valve is not statistically inferior to conventional open-heart surgery.

The Medical Management Arm

- Will focus on approximately 350 patients who are considered too high-risk for conventional open-heart surgery.
- Patients will be evenly randomized to receive either the Edwards SAPIEN transcatheter heart valve or appropriate medical therapy.
- The clinical results of this arm will need to demonstrate that the Edwards SAPIEN transcatheter heart valve is statistically superior to medical management.

- The primary endpoint in both arms of the trial is mortality at one year with secondary endpoints that focus on valve performance and quality-of-life indicators.

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