



SAINT LUKE'S HEALTH SYSTEM

Directed by Cardiovascular Consultants, P.A.

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NEWS

FOR IMMEDIATE RELEASE

Sept. 10, 2008

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Saint Luke's Mid America Heart Institute selected for transcatheter aortic valve replacement procedure clinical trial

High-risk, non-operable traditional open heart surgery patients now being evaluated

KANSAS CITY, Mo. – Patients who are considered high-risk or non-operable for conventional open heart valve surgery now have a potential new option available only through Saint Luke's Mid America Heart Institute.

The Heart Institute is the only hospital in the region selected to participate as a U.S. Food and Drug Administration (FDA) investigative site in the PARTNER (Placement of AoRTic traNscathetER valves) pivotal clinical trial. The trial is evaluating the Edwards SAPIEN transcatheter aortic heart valve in patients who otherwise did not have many treatment options.

The transcatheter heart valve integrates balloon-expandable stent technology with a bovine pericardial bioprosthetic tissue valve. The valve is mounted and crimped onto the balloon delivery catheter to the approximate diameter of a pencil and threaded through the patient's circulatory system from the leg (transfemoral) or inserted between the ribs (transapical) and deployed across the patient's stenotic (diseased) aortic valve, providing physicians with two options for treating patients based on their individual anatomies.

Both procedures are performed on a "beating heart," without the need for cardiopulmonary bypass and its associated risks. The Edwards SAPIEN transcatheter heart valve is a proprietary technology designed to treat patients with severe aortic heart valve stenosis (a narrowing of the valve that restricts blood flow).

Advancements in transcatheter technologies hold promise for the large number of high-risk patients suffering from severe aortic stenosis. 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.

Edwards received conditional approval for the pivotal clinical trial from the FDA in March 2007.

Saint Luke's Mid America Heart Institute is among one of the select sites qualified to participate in the PARTNER trial. Doctors at Saint Luke's were chosen because of their expertise in valve replacement surgery and vast experience in interventional procedures. "This exciting new treatment option holds great promise for patients with severe stenosis who previously were too risky or too sick for traditional open heart valve replacement surgery," said A. Michael Borkon, M.D., director of cardiovascular surgery at Saint Luke's, and co-principal investigator of the PARTNER trial along with David Cohen, M.D. "The ability to now treat these patients adds another element to our comprehensive valve treatment program at Saint Luke's."

The procedure marries the expertise of two distinct cardiac disciplines for which Saint Luke's is well known nationally – cardio thoracic surgery and interventional cardiology. In addition, Saint Luke's is performing the procedure in its new hybrid suite. This state-of-the-art cath lab/operating room houses all the equipment, imaging, and monitoring devices necessary to perform open-heart surgeries, like coronary bypass, as well as percutaneous coronary interventions and procedures like balloon angioplasty and stenting. These procedures typically are performed in separate areas with different equipment and sterile fields. The novel "one stop" approach benefits patients by saving time and boosting patient safety.

"At Saint Luke's Mid America Heart Institute, the two specialties have combined to provide an advanced standard of care," said Dr. Cohen, director of Saint Luke's Cardiovascular Research program and co-investigator for the PARTNER trial. "This collaborative approach – rarely seen at most heart centers – provides the best of both worlds and ultimately better care and outcomes for patients."

Randomized study with surgical and medical management arms

The PARTNER trial is a prospective randomized study with two separate treatment arms. The surgical arm of the trial will focus on approximately 690 high-risk patients who are candidates for conventional open-heart surgery. These patients will be evenly randomized – like the flip of a coin – to receive either the Edwards SAPIEN transcatheter heart valve or an Edwards surgical valve. The type of delivery (via the femoral artery or through the chest wall) will be determined based on the patient's individual anatomy. The clinical results of this arm will need to demonstrate that the Edwards SAPIEN transcatheter heart valve is not statistically inferior to conventional surgery for these high-risk individuals.

The non-surgical, medical management arm of the trial will focus on approximately 350 patients who are considered to be non-operable, generally due to multiple co-morbid conditions. Those 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.

Individuals interested in learning more about the clinical trial may call (816) 932-0218 or visit saintlukeshalthsystem.org.

Saint Luke's Mid America Heart Institute is a member of Saint Luke's Health System, which consists of 11 area hospitals and many primary care practices, and provides a range of inpatient, outpatient, and home care services. Founded as a faith-based, not-for-profit organization, our mission includes a commitment to the highest levels of excellence in health care and the advancement of medical research and education. The health system is an aligned organization in which the physicians and hospitals assume responsibility for enhancing the physical, mental, and spiritual health of people in the metropolitan Kansas City area and the surrounding region.

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