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Clinical Trial of Next Generation Heart Valve Device Expanded
Physicians Comparing Surgical to Transfemoral Treatment

Cincinnati, Ohio – Physicians at [The Carl and Edyth Lindner Center for Research and Education at The Christ Hospital](#) have enrolled and treated the first three patients in the U.S. in the randomized Cohort A of the PARTNER II Trial. This trial, sponsored by [Edwards Lifesciences](#), is studying the company's next-generation Edwards SAPIEN XT transcatheter heart valve in the treatment of aortic stenosis.

This new cohort (Cohort A) represents a non-inferiority study of up to 2,000 patients with severe, symptomatic aortic valve stenosis who have an elevated risk for traditional open-heart surgery (Society of Thoracic Surgeons score >4). Patients will be evenly randomized to receive the transcatheter replacement with the Edwards SAPIEN XT valve or surgical valve replacement. Those undergoing transcatheter valve replacement will be treated using femoral (leg) artery access or transapically, in between the ribs. The primary endpoint to be evaluated is a composite of death and major stroke at two years, with secondary endpoints that include valve performance and quality-of-life indicators.

“We are proud to be able to offer this new leading-edge clinical trial option to high risk surgical patients,” said [Dean Kereiakes, M.D.](#), Medical Director of The Carl and Edyth Lindner Center for Research and Education and The Christ Hospital Heart and Vascular Center. “Based on the success of this device in Europe to date, we are hopeful that this option will provide a longer and better quality of life for our valve patients here in the U.S.”

Aortic stenosis affects nearly 1.5 million Americans. Severe AS results from hardening or thickening of the aortic valve leaflets, which limits leaflet motion and obstructs oxygen-rich blood flow from the heart to the rest of the body. Patients with severe AS may have symptoms of chest pain, fatigue, shortness of breath,

lightheadedness or fainting. Although AS typically progresses slowly without symptoms, once symptoms occur, treatment is required. The prognosis of patients with symptomatic AS is guarded, and previous studies indicate that up to 50 percent of untreated patients may not survive beyond one to three years.

Traditionally, patients with symptomatic AS undergo aortic valve replacement during an open-heart surgery, which can alleviate symptoms, improve survival and improve quality of life. The Christ Hospital has also enrolled patients in the PARTNER II Cohort B trial, which is studying treatment with the SAPIEN XT as compared to the SAPIEN valve in patients considered inoperable, such as elderly, frail individuals with multiple health concerns.

Data from Cohort B is intended to support U.S. commercial approval of the new generation Edwards SAPIEN XT valve. The Edwards SAPIEN XT valve is commercially available in Europe, where it received a CE Mark in March 2010. The Edwards SAPIEN XT transcatheter valve is an investigational device in the U.S. and is not yet available commercially. The original SAPIEN device has been approved for commercial use in the U.S. and will be available at The Christ Hospital in the coming months.

For more information about the PARTNER II Trial at The Christ Hospital, contact the Lindner Research Center at 866-293-0566.

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Embedded link: <http://youtu.be/1vO5uV8Ht8k>

Dean Kereiakes, M.D., describes the delivery of the SAPIEN XT valve to the heart.

About The Lindner Research Center

For the past 25 years, The Carl and Edyth Lindner Center for Research and Education (Lindner Research Center) has provided leading-edge medicines and medical technology research covering a broad spectrum of conditions from obesity, diabetes, coronary disease, hypertension and hyperlipidemia to new vascular interventional devices, adult stem cell therapies, structural heart disease, cardiovascular surgery, heart failure and electrophysiology. Physicians at the Lindner Research Center have conducted more than 1,200 clinical trials including multiple first-in-man and first-in-the-U.S procedures, which have contributed to best practice standards for the care of patients. For information on current trials, please call 513-585-1777.

About The Christ Hospital

The Christ Hospital offers a wide range of medical, surgical and testing services at its main campus just north of Downtown Cincinnati and at numerous outpatient and

physician practice locations throughout Greater Cincinnati. Its mission is to provide the finest patient experience and improve the health of our community. For the past 12 years, The Christ Hospital has been recognized by *U.S. News & World Report* as one of the nation's top hospitals, and has been named Cincinnati's Most Preferred Hospital for 16 consecutive years by National Research Corporation (NRC). The Christ Hospital has been granted Magnet[®] recognition from the American Nurses Credentialing Center for excellence in nursing care. For more information about the award-winning services of The Christ Hospital, visit www.TheChristHospital.com.