El Camino Hospital Enrolls Second Patient in Global Clinical Trial Evaluating the Medtronic CoreValve® System in Intermediate Risk Patients with Aortic Valve Disease

Business Wire

El Camino Hospital, in partnership with the Taft Center for Clinical Research and the Fogarty Clinical Research Institute, both a part of the Fogarty Institute for Innovation, announced today that it has enrolled its second patient in a global clinical trial comparing the Medtronic CoreValve® System with surgical aortic valve replacement in patients with severe aortic stenosis who are at intermediate risk for open-heart surgery. The Medtronic CoreValve Su rgical R eplacement and T ranscatheter A ortic V alve I mplantation (SURTAVI) Trial is the largest global, randomized, controlled trial to evaluate minimally-invasive transcatheter aortic valve implantation in less-sick patients who today are typically treated with open-heart surgical aortic valve replacement (SAVR).

El Camino Hospital is one of only 75 clinical sites globally that will enroll approximately 2,500 patients through experienced heart teams including interventional cardiologists and cardiac surgeons. El Camino Hospital's team is led by co-investigators James Joye, D.O., interventional cardiologist at El Camino Hospital, and Vincent Gaudiani, M.D., a senior cardiothoracic surgeon and medical staff member at El Camino Hospital. The trial will evaluate whether the CoreValve System is non-inferior to surgical valve replacement based on the composite primary endpoint of all-cause mortality and disabling stroke at 24 months.

"El Camino Hospital is a leader in advanced procedures for treating various heart conditions," said Dr. Joye. "We are proud to be one of the first centers to enroll a patient in the SURTAVI trial to explore the possibility of a less-invasive treatment option for patients with severe aortic stenosis." Aortic stenosis occurs when the heart's aortic valve is narrowed, restricting blood flow from the heart to the body. The condition primarily affects older people and typically develops in individuals between the ages of 50 and 70, and research shows that, if left untreated, as many as 50 percent of aortic stenosis patients with severe symptoms may die within one year.

Currently, the standard treatment for severe aortic stenosis, which affects approximately 300,000 people worldwide, is open-heart valve replacement surgery. However, due to possible health complications, one-third of these patients are considered ineligible for the procedure.

The Medtronic CoreValve System received CE (Conformité Européenne) Mark in 2007. Since 2007, it has been implanted in more than 30,000 people in more than 60 countries outside the U.S. The CoreValve System is currently limited to

investigational use in the United States.

For more information on the Medtronic CoreValve System or the SURTAVI trial, visit http://fogartyclinicalresearch.com/.