

Media Contact: Heidi Pallares Heidi.Pallares@Hoag.org (949) 764-6939

Hoag Clinical Trial Contributes to 'Eye-Popping' National Heart Surgery Data

Presentation at American College of Cardiology shows TAVR outcomes equivalent to surgery, Hoag among clinical trial sites

NEWPORT BEACH, Calif., March 18, 2019 --- The Jeffrey M. Carlton Heart & Vascular

Institute at Hoag, the largest volume cardiovascular program in Orange County, was the first hospital to bring transcatheter aortic valve replacement (TAVR) to the community. Today, the American College of Cardiology (ACC) released data from two trials showing that select patients who were at low-risk for surgical complications still benefited from a minimally invasive, transcatheter aortic valve replacement.

Hoag contributed to what the ACC referred to as "eye-popping" data at its annual meeting in New Orleans. As part of the PARTNER 3 trial, the Hoag TAVR team participated in research that included 1,000 low-surgical-risk patients. Participants were randomized to minimally invasive TAVR with the Edwards Lifesciences Sapien 3 valve or to open surgical aortic valve replacement, the standard procedure for aortic stenosis.

"Currently, TAVR is only offered to high-risk or intermediate-risk patients for open-heart surgery. These results are expected to expand TAVR as an option for select patients who are at low risk for surgical aortic valve replacement, allowing them to reap the benefits of valve replacement without undergoing open heart surgery," said <u>Anthony Caffarelli, M.D.</u>, Hoag co-principle investigator for the PARTNER 3 Trial, director of Hoag Cardiovascular Surgery and Newkirk Family Endowed Chair in Aortic Care.

More than 1.5 million people in the U.S. suffer from <u>aortic stenosis</u>, a condition that can progress to restrict every day activities, including walking short distances. Without an operation, most aortic stenosis suffers die within two years.



HOAG MEMORIAL HOSPITAL PRESBYTERIAN One Hoag Drive, PO Box 6100 Newport Beach, CA 92658-6100

PARTNER 3 included 1,000 patients with severe aortic stenosis at 71 centers in the U.S. and several other countries with over 95 percent of patients enrolled at U.S. sites. Participants were carefully screened to be low risk for either TAVR or surgery and were randomly assigned to receive the SAPIEN 3 TAVR valve, the newest generation technology, or surgical valve replacement. Compared with the earlier PARTNER trials with intermediate- and high-risk surgical patients, this low-risk group was younger (73 years on average), had fewer co-morbid conditions and had fewer symptoms. There were also more men than women enrolled (67.5 percent vs. 32.5 percent, respectively). A total of 16 patients died during follow up. Of these, 11 were in the surgery group and five were in the TAVR group, so the one-year mortality rate was 1 percent for TAVR and 2.5 percent for surgery. Twenty patients suffered a stroke, 14 of which occurred in the surgery group (3.1 percent) and six in TAVR (1.2 percent). Patients in the surgical group were also more likely to go back to the hospital compared with those in the TAVR group (11 percent and 7.3 percent, respectively).

Hoag became a site for the PARTNER 3 trial in 2016 and is a leader in performing these procedures. In 2012, Hoag began offering TAVR, an innovative percutaneous procedure that offered hope to individuals at high risk for surgery. Since then, the implications for TAVR have grown to include moderate risk patients, and now low risk patients, as evaluated in the PARTNER 3 Trial.

"Hoag not only is helping guide research for these procedures, but we are able to provide it directly to our community. Hoag and a dedicated physician and clinical team have made a significant investment into Hoag's TAVR Program to provide this care people go out of county to seek," said <u>Richard Haskell, M.D.</u>, one of the founding physicians for Hoag's TAVR Program and interventional cardiologist. "Our commitment to incorporating the most innovative technology available is one reason Hoag cardiac patients achieve some of the highest clinical outcomes in the nation."

Transcatheter aortic valve replacement is a minimally invasive procedure where a collapsible artificial valve is guided into the heart using a catheter through a blood vessel in the leg or alternate site by an interventional cardiologist and cardiac surgeon. The artificial heart valve is then inserted across the patient's own aortic valve where it immediately goes to work.



HOAG MEMORIAL HOSPITAL PRESBYTERIAN One Hoag Drive, PO Box 6100 Newport Beach, CA 92658-6100

"These results are a game changer for the treatment of aortic stenosis. We are excited that the Hoag team was able to contribute to this study and advance the science and innovation in cardiac care," said Dr. Caffarelli. "We are proud that the Hoag team will continue to provide the most expert, state-of-the-art care available to our community."

For individuals with aortic stenosis, who have additional heart conditions, standard surgical aortic valve replacement is still recommended. Hoag's cardiac surgery program has received a 3-star rating – which is the top 5% in the country – the highest rating awarded by The Society of Thoracic Surgeons – one of the most sophisticated and highly regarded organizations that measures quality and compares cardiothoracic surgery programs across the U.S. and Canada.

ABOUT HOAG MEMORIAL HOSPITAL PRESBYTERIAN

Hoag is an approximately \$1 billion nonprofit, regional health care delivery network in Orange County, California, that treats more than 30,000 inpatients and 450,000 outpatients annually. Hoag consists of two acute-care hospitals – Hoag Hospital Newport Beach, which opened in 1952, and Hoag Hospital Irvine, which opened in 2010 – in addition to eight health centers and 11 urgent care centers. Hoag is a designated Magnet[®] hospital by the American Nurses Credentialing Center (ANCC). Hoag offers a comprehensive blend of health care services that includes five institutes providing specialized services in the following areas: cancer, heart and vascular, neurosciences, women's health, and orthopedics through Hoag's affiliate, Hoag Orthopedic Institute, which consists of an orthopedic hospital and two ambulatory surgical centers. Hoag has been named one of the Best Regional Hospitals in the 2018 - 2019 *U.S. News & World Report*, and *Becker's Healthcare* named Hoag as one of the 2018 "100 Great Hospitals in America" – a designation Hoag has received five times. For an unprecedented 23 years, residents of Orange County have chosen Hoag as one of the county's best hospitals in a local newspaper survey. Visit www.hoag.org for more information.