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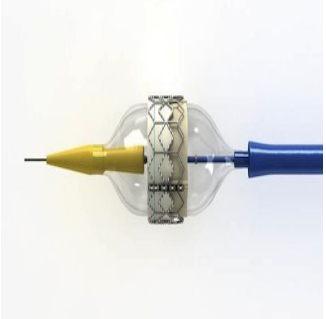
US Trial of Edwards' Sapien3 Valve to Begin



Enrollment Completed in Trial of High-Risk Patients

Edwards Lifesciences Corporation, the global leader in the science of heart valves and hemodynamic monitoring, announced that it received Investigational Device Exemption (IDE) approval from the US Food and Drug Administration (FDA) to initiate a single-arm, non-randomised clinical trial of the Sapien 3 transcatheter aortic heart valve in the treatment of intermediate risk patients with severe symptomatic aortic stenosis. The company also completed enrollment in its US clinical trial studying the Sapien 3 valve in the treatment of high-risk or inoperable patients.

The Sapien 3 valve is the only transcatheter heart valve available to US patients that can be delivered through a low-profile 14-French expandable sheath (eSheath). It also has an outer skirt, a cuff of fabric surrounding the bottom of the frame, to provide a seal to address paravalvular leak. The Sapien 3 valve can be implanted with the transfemoral approach through an incision in the leg, as well as alternative access approaches. It is an investigational device that is not available commercially in any country; CE Mark approval in Europe is anticipated in the near future.

The new US trial of the Sapien 3 valve will enroll up to 1,000 patients with a Society of Thoracic Surgeons score of four to eight percent, which indicates the average predicted risk of operative mortality at 30 days. All enrolled patients can receive a Sapien 3 valve.

"The Sapien 3 valve is a significant advancement, and we're excited to make progress toward bringing this sought-after transcatheter therapy to US patients. It represents a big step toward fulfilling the promise of a simpler procedure with fewer complications and faster patient recovery," said Larry L. Wood, corporate vice president, transcatheter heart valves. "Last year, we completed enrollment in the first US randomised controlled trial involving intermediate risk patients with severe aortic stenosis. This unique dataset of 2,000 patients receiving surgery or transcatheter valve replacement will provide a thorough baseline comparison for this new study of the Sapien 3 valve in intermediate risk patients."

Source: Edwards Lifesciences

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