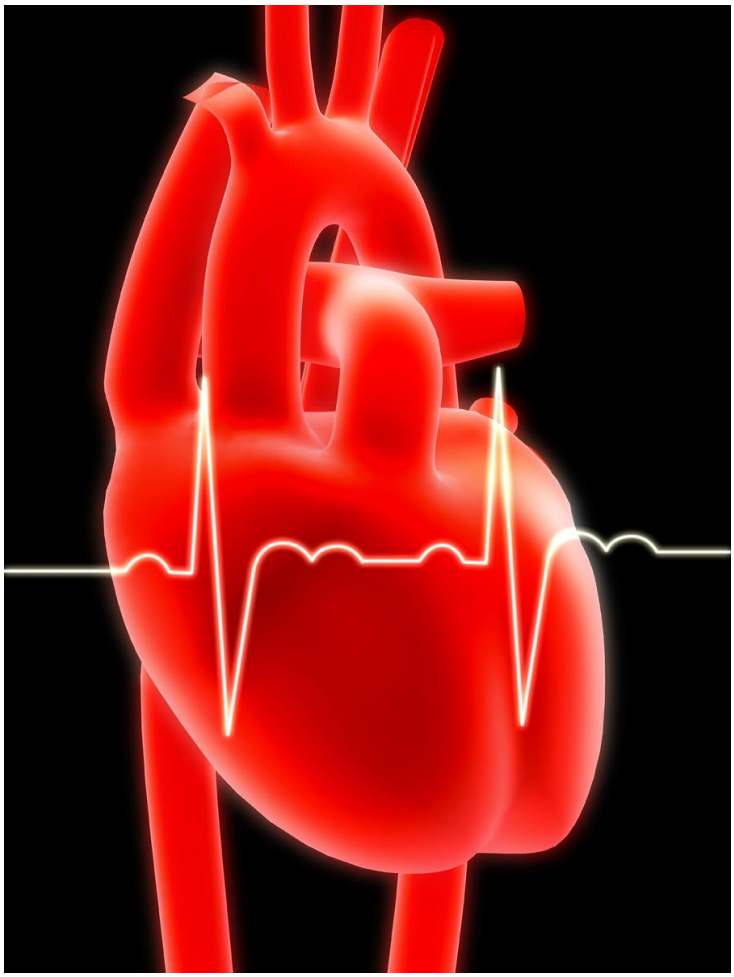
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HeartWare ventricular assist system trial results positive

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HeartWare ventricular assist system trial results positive



Singapore:Ã?Â HeartWare International, a leading innovator of less invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, reported positive results from the company's US clinical trial evaluating the use of the HeartWare Ventricular Assist System as a bridge to heart transplantation in patients with advanced heart failure.

The detailed findings from this study are published in the American Heart Association's journal Circulation, and demonstrate the potential utility of the HVAD Pump to improve treatment outcomes for end-stage heart failure patients.

"With the publication of the ADVANCE trial in Circulation, cardiologists and cardiac surgeons treating advanced heart failure will now have the opportunity to thoroughly review the excellent results our investigators obtained using the HVAD Pump to

bridge their patients to transplant," said Dr Keith Aaronson, co-principal investigator and professor in the Division of Cardiovascular Medicine and Medical Director of the Heart Transplant Program and Center for Circulatory Support at the University of Michigan, on behalf of the ADVANCE investigators, including Dr Mark Slaughter, professor and chief in the Division of Thoracic and Cardiovascular Surgery and director of the Mechanical Assist Device and Heart Transplant Program at the University of Louisville.

The publication describes results from the ADVANCE study of 140 patients from 30 US hospitals who received the HeartWare investigational device. The authors noted high rates of 180-day success and survival and improvements in quality of life and functional capacity for patients with end-stage heart failure that were similar to those seen with cardiac transplantation. Success was achieved for the primary endpoint by establishing non-inferiority between the investigational device and comparator arm of the study, which was derived from contemporaneous patients from the Interagency Registry for Mechanically Assisted Circulatory Support.

The HeartWare Ventricular Assist System is under FDA review for a bridge-to-transplant indication. On April 25, 2012, the FDA's Circulatory System Devices Advisory Committee voted nine to two that the benefits outweigh the risks for the use of the HeartWare Ventricular Assist System as a bridge to heart transplantation in patients with end-stage heart failure. The Advisory Committee's recommendation, while not binding, will be considered by the FDA in its review of the pre-market approval application submitted for the HeartWare Ventricular Assist System in December 2010.