Approval of HDE Will Allow Up to 4,000 U.S. Patients Not Eligible for Transplant to Receive the Total Artificial Heart on a Permanent Basis

TUCSON, Ariz., April 12, 2012

SynCardia Systems, Inc. (www.syncardia.com), manufacturer of the world's first and only FDA, Health Canada and CE (Europe) approved Total Artificial Heart, announced today that the FDA has approved a Humanitarian Use Device (HUD) designation for the SynCardia temporary Total Artificial Heart to be used for destination therapy in addition to its current PMA approval as a bridge to transplant.

"This is a huge milestone that with approval of our HDE, will allow the Total Artificial Heart to save the lives of up to 4,000 U.S. patients each year who are not eligible for transplant," said Michael Garippa, SynCardia Chairman/CEO/President.

The FDA approval letter of the HUD request designates the Total Artificial Heart for use in U.S. patients "at risk of imminent death from non-reversible biventricular heart failure who are not eligible for cardiac transplant and have a body surface area (BSA) of greater-than or equal to 1.7m2." SynCardia is now preparing a Humanitarian Device Exemption (HDE) to submit to the FDA....the last step in the process.

"Historically, the Total Artificial Heart had been limited to temporary use because U.S. patients couldn't leave the hospital with the 400-pound driver," said Garippa. "However, the new 13.5-pound Freedom® portable driver* has leveled the playing field in mechanical circulatory support. By making patient discharge possible, the Freedom driver has made the Total Artificial Heart a viable option to support patients for the rest of their lives while allowing hospitals to make the best choice for each individual patient based on their medical needs."

Originally used as a permanent replacement heart, the SynCardia Total Artificial Heart received FDA approval in 2004 as a bridge to transplant for transplant-eligible patients dying from end-stage biventricular heart failure. Currently, the longest a patient has been supported with the Total Artificial Heart is 1,374 days (almost four years) prior to receiving his heart transplant.

During 30 years of use, the valves in the SynCardia Total Artificial Heart have never failed. The diaphragm has a failure rate of less than 1% over more than 1,000 implants (2,000+ diaphragms).
*The Freedom portable driver is the world's first wearable power supply for SynCardia's Total Artificial Heart. It is CE approved for use in Europe and undergoing an FDA-approved Investigational Device Exemption (IDE) clinical study in the U.S.

CAUTION - The Freedom® portable driver is an investigational device, limited by United States law to investigational use.

About the SynCardia temporary Total Artificial Heart

SynCardia Systems, Inc. (Tucson, AZ) is the privately-held manufacturer of the world's first and only FDA, Health Canada and CE approved Total Artificial Heart. Originally used as a permanent replacement heart, SynCardia's Total Artificial Heart is currently approved as a bridge to transplant for people dying from end-stage biventricular heart failure. There have been more than 1,000 implants of the Total Artificial Heart, accounting for more than 250 patient years of life.

Similar to a heart transplant, SynCardia's Total Artificial Heart replaces both failing heart ventricles and the four heart valves, eliminating the symptoms and source of end-stage biventricular failure. Unlike a donor heart, the Total Artificial Heart is immediately available at SynCardia Certified Centers and does not require expensive anti-rejection medication, which can cause subsequent complications. It is the only device that provides immediate, safe blood flow of up to 9.5 liters per minute through both ventricles. This high volume of safe blood flow helps speed the recovery of vital organs, helping make the patient a better transplant candidate.

SynCardia Ranked #20 Among World's 50 Most Innovative Companies

In March 2011, Fast Company magazine ranked SynCardia #20 in its annual list of the "World's 50 Most Innovative Companies" for "giving mobility to artificial heart recipients." Weighing 13.5 pounds, SynCardia's Freedom® portable driver is the world's first wearable driver designed to power the Total Artificial Heart both inside and outside the hospital. The Freedom driver is CE approved for use in Europe and undergoing an FDA-approved Investigational Device Exemption (IDE) clinical study in the U.S.