SynCardia Sets New Records for Total Artificial Heart Implants, Revenue and Profit in 2012

The Associated Press

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 record-setting results for 2012 for implants, revenue and profit.

(Photo: http://photos.prnewswire.com/prnh/20130117/LA44048) "2012 was a momentous year for the SynCardia temporary Total Artificial Heart with a record-breaking 125 implants performed at more than 50 Certified Centers worldwide," said Michael Garippa, SynCardia Chairman/CEO/President. "We expect our growth trajectory to continue in 2013 as we pursue a Humanitarian Device Exemption (HDE) from the FDA for destination therapy and plan to introduce our smaller 50cc Total Artificial Heart designed to fit patients with a body surface area of less than 1.7." SynCardia's accomplishments in 2012 include: -- Completion of required patient enrollment in the FDA clinical study of the Freedom@ portable driver, the world's first wearable power supply for the SynCardia Total Artificial Heart (already approved in Europe) -- Surpassing 100 patients worldwide who have been supported by the Freedom portable driver -- FDA approval of a Humanitarian Use Device (HUD) designation for the Total Artificial Heart to be used for destination therapy -- FDA approval of the Companion 2 Hospital Driver for supporting patients from implant of the Total Artificial Heart until their condition stabilizes -- CE approval in Europe of the Total Artificial Heart with new bileaflet valves In 2013, SynCardia plans to expand the potential patient population for the Total Artificial Heart through achieving the following milestones: -- FDA approval of its Humanitarian Device Exemption (HDE), the final step required for the Total Artificial Heart to be used for destination therapy in the U.S. in up to 4,000 patients annually who are not eligible for transplant -- CE approval of the 50cc Total Artificial Heart in Europe and FDA approval to conduct an Investigational Device Exemption (IDE) clinical study in the U.S. Once approved, together the 70cc and 50cc Total Artificial Hearts will fit almost all adult men and women, and many adolescents, including patients with congenital conditions.

-- FDA approval of the Freedom portable driver for commercial use in the U.S.

There are currently 76 SynCardia Certified Centers worldwide, representing a 280% increase since 2009. There are an additional 32 hospitals currently undergoing SynCardia's four-phase certification program.

To date, six pediatric hospitals have performed one or more implants of the SynCardia Total Artificial Heart: Texas Children's Hospital, Children's Hospital of Philadelphia (CHOP), Phoenix Children's Hospital, Children's Hospital of Wisconsin, Cincinnati Children's Hospital Medical Center and Mattel Children's Hospital UCLA. Two additional children's hospitals are currently undergoing certification: Lucile

Packard Children's Hospital and Arkansas Children's Hospital.

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

The 50cc Total Artificial Heart is not for Human Use. This product is in the research and development phase and will not be available for sale in the United States or Europe until all regulatory requirements have been met.

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 1,100 implants of the Total Artificial Heart, accounting for more than 290 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. It is the only device that provides immediate, safe blood flow of up to 9.5 liters per minute through each ventricle. This high volume of safe blood flow helps speed the recovery of vital organs, helping make the patient a better transplant candidate.

SynCardia Wins Two Gold Stevies@ at 2012 American Business Awards On June 18, 2012, SynCardia was honored with two Gold Stevie@ Awards at the 10th Annual American Business Awards. SynCardia won "Company of the Year - Health Products and Services" and "Most Innovative Company of the Year - up to 100 Employees." See the full list of SynCardia Awards & Recognition, which includes accolades from Forbes, Fast Company and more.

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