Fact Sheet:

**Freedom® Portable Driver**

**Background:**
Prior to the development of the Freedom® portable driver, the only FDA-approved driver for powering the SynCardia temporary Total Artificial Heart was the “Big Blue” hospital driver, which weighs 418 pounds and is the size of a washing machine. Due to the shortage of donor hearts, Total Artificial Heart patients supported by Big Blue were confined to the hospital for months, sometimes years, while they waited for a matching donor heart.

Weighing 13.5 pounds, the Freedom® portable driver is the world’s first wearable power supply for the SynCardia Total Artificial Heart. The Freedom® portable driver allows stable Total Artificial Heart patients who meet discharge criteria to wait for a matching donor heart at home and in their communities instead of in the hospital.

**Regulatory Approvals:**
- CE approved for commercial use in Europe
- FDA approved in the U.S.

**Benefits of Discharge:**
- Frees stable Total Artificial Heart patients from the hospital
- Improves patient quality of life/helps speed patient recovery
- Eliminates most in-hospital costs for this portion of patient care
- Frees up in-hospital resources to serve additional critically ill patients

**Features:**
- The Freedom® portable driver weighs 13.5 pounds, including two onboard batteries and a power adaptor.
- The batteries can be charged using a standard electrical outlet or the cigarette lighter adaptor in a car.
- The Freedom® portable driver can be carried by the patient in the Backpack or Shoulder Bag.
- The Freedom® portable driver uses a “dark cockpit” design, meaning the driver only flashes a light and sounds an alarm when something requires the user’s attention.

**Milestones:**
- **May 3, 2010:** The first Total Artificial Heart patient in the world was discharged from the hospital using the Freedom® portable driver as part of the FDA clinical study in the U.S.
- **April 24, 2012:** SynCardia completed the minimum enrollment required by the FDA clinical study of the Freedom® portable driver when the 30th Total Artificial Heart patient was discharged home.
- **October 2012:** The number of patients supported by the Freedom® portable driver worldwide surpassed 100.
- **June 26, 2014:** The Freedom® portable driver received FDA approval for use with the SynCardia temporary Total Artificial Heart as a bridge to transplantation in cardiac transplant candidates who are clinically stable.