BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Heartware receives FDA approval for HeartWare Ventricular Assist System

21 November 2012 | News | By BioSpectrum Bureau

Singapore: HeartWare International, a leading innovator of less invasive, miniaturized circulatory support technologies that are revolutionizing the treatment of advanced heart failure, announced that it has received approval from the US FDA for the HeartWare Ventricular Assist System as a bridge to heart transplantation in patients with end-stage heart failure. The firm had recetly sucessfully completed its studies regarding the system.

The HeartWare Ventricular Assist System features the HVAD pump, a small full-support circulatory assist device (up to 10L/min flow) designed to be implanted next to the heart, avoiding the abdominal surgery generally required to implant competing devices. The HVAD pump, with sintered inflow cannula, weighs approximately five ounces and displaces a volume of approximately 50 milliliters. The HeartWare System is intended for use as a bridge to cardiac transplantation in patients who are at risk of death from refractory end-stage left ventricular heart failure.

The HeartWare System is currently the leading ventricular assist device implanted in patients outside the US, having received CE Marking in the European Union in 2009, and Australian Therapeutic Goods Administration (TGA) approval in 2011. Today, more than 2,500 advanced heart failure patients globally have received the HVAD pump.

"FDA approval marks the culmination of an extensive clinical effort and represents an exciting advance in the treatment of late-stage heart failure patients," said Mr Doug Godshall, president and CEO, HeartWare. "We wish to extend our most sincere thanks to the patients, and to their families, for participating in the study of this innovative device, and we also are grateful to each of the nurses, coordinators, surgeons and cardiologists who provided care to those patients."

"I've had the opportunity to work on the HVAD project since its conception over a decade ago. The goal was to develop a miniaturized device with an integrated inflow cannula that could be placed within the pericardial sac, avoiding the necessity of creating a pump pocket with its attendant infection risks, as well as simplifying the surgical insertion," stated Dr OH Frazier, chief, Center for Cardiac Support; and co-director, Cullen Cardiovascular Research Laboratories, at Texas Heart Institute and a global pioneer in mechanical circulatory support.