

Pittsburgh, PA, September 4, 2009: EVAHEART MEDICAL USA, Inc announced today that their investigational device exemptions (IDE) application for the EVAHEART Left Ventricular Assist System (LVAS) was conditionally approved for patients who are at risk of imminent death, for use as a bridge to transplantation in candidates listed for cardiac transplant. The letter, received from the, Office of Device Evaluation in the Center for Devices and Radiological Health at the Food and Drug Administration, limits the investigation to twenty (20) clinical sites. Further details of the study are not being released by the company.

Dr. Robert Kormos, Professor of Surgery, Director of the Artificial Heart Program at the University of Pittsburgh Medical Center and the Study Director for the US clinical trial said "The data from the Japanese trial demonstrating a 4 year actuarial patient survival on the pump of over 75% are very encouraging and indicates a true role for the Evaheart in long-term support."

The EVAHEART LVAS has been designed to assist the cardiac function of a diseased native heart by delivering partial or complete blood flow from the left ventricle to the ascending aorta via an implantable centrifugal pump. An inflow cannula connects the apex of the left ventricle and the blood pump inlet, and an outflow graft connects the blood pump outlet to the ascending aorta. The external controller contains pump controlling elements, a monitoring system and the CS System, which is used to continuously circulate sterile filtered water to and from the pump for its unique bearing and seal configuration. A percutaneous driveline made of a multi-lumen cable connects the blood pump to the controller.

The concept for the EVAHEART LVAS originated with Dr. Kenji Yamazaki, a Professor of Surgery at Tokyo Women's Medical University. The device has been developed and manufactured by Sun Medical Technology Research Corporation, located in Suwa City in the Nagano Prefecture of Japan. The LVAS completed a clinical trial in Japan in 2008 and is currently being reviewed by the Pharmaceutical and Medical Device Agency (PMDA) for commercial distribution.

EVAHEART MEDICAL USA, Inc was established in Pittsburgh, Pennsylvania by Sun Medical to commercialize and support the EVAHEART LVAS. In April of 2009, the Company became a joint venture between Misuzu and Sun Medical Holdings (MSHD) and Asahi Kasei Corporation. Dr. Mitsunobu Mohri, President of EVAHEART MEDICAL USA, Inc. and General Manager of the Advanced Medical Device Center at Asahi Kasei Corporation (Tokyo, Japan) said "We are extremely pleased to reach this major milestone in the development of Evaheart in the United States. I believe that our technology based on our precision industries will provide great benefits to patients with heart failure."

Evaheart™ is a trademark of Sun Medical Technology Research Corp.

For further information, please write to contactUs@evaheart-usa.com: