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PROGRESS IN THE DEVELOPMENT OF MECHANICAL CIRCULATORY SUPPORT DEVICES FOR CHILDREN TO BE PRESENTED AT INTERNATIONAL HEART AND LUNG TRANSPLANT MEETING

San Diego, Calif. April 14, 2011 – Promising new devices for mechanical circulatory support of children with heart defects or heart failure, and related research, will be revealed this week at the International Society for Heart and Lung Transplantation (ISHLT) 31st Annual Meeting and Scientific Sessions. An update from the Pumps for Kids, Infants and Neonates (PumpKIN) Program will be presented during the Meeting in San Diego. PumpKIN is supported by the National Heart, Lung, and Blood Institute (NHLBI), a branch of the National Institutes of Health (NIH).

Despite rapid advances in the technology of sophisticated mechanical devices for adults, the options for infants and children in need of mechanical circulatory support are very limited. Close to 1,800 children with congenital heart defects die each year in the United States alone, and 25 percent of the 36,000 babies born with these malformations require invasive treatment within the first year of life. Currently, there are no FDA-approved devices designed specifically for patients younger than five-years-old, and the available options are even more limited for newborns and infants up to two-years-old.

"Tremendous advances have been made in assist devices for adults, but there really are no devices for infants and children. The driving force of this program is encouraging development of such devices and sharing of information among developers," said J. Timothy Baldwin, PhD. Dr. Baldwin is Deputy Chief, Advanced Technologies & Surgery Branch and Program Director, Basic and Early Technology Research Program in the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute, and the program officer who supervises the PumpKIN consortium.

Acknowledging this need, the NHLBI awarded four contracts in January 2010 to fund preclinical testing of these pediatric devices, including both miniature ventricular assist devices (VADs) and integrated compact ECMO (extracorporeal membrane oxygenator) devices.

The PumpKIN program builds on the NHLBI Pediatric Circulatory Support Program, which initiated funding for the development of novel circulatory support devices in 2004. The PumpKIN Program will support the realization of the most promising devices in order to gain FDA approval to begin clinical testing, which is anticipated by 2013.

The four PumpKIN contractors are Harvey S. Borovetz, PhD, University of Pittsburgh; Mark Gartner, PhD, Ension, Inc., Pittsburgh; Bartley P. Griffith, MD, University of Maryland School of Medicine; and Robert Jarvik, MD, Jarvik Heart, Inc., New York.

Dr. Griffith will present an update on his research during today's Mid-Day Symposium 4: *Update on Pediatric MCS Therapy*.

During Friday afternoon's poster sessions, there will also be an update from Ension, Inc.: "The Ension Pediatric Cardiopulmonary Assist System (pCAS): Progress and Current Status" (Abstract 651).

According to Dr. Baldwin, the contractors are on schedule and making good progress. He said the miniature pediatric devices are based on the latest technology for VAD and ECMO devices. Preliminary data to be presented at this meeting, and in other forums, suggest that these devices and technology have great promise to perform well in future pediatric patients, based on work ongoing at the PumpKIN study centers.

For more information on the PumpKIN Program, contact the NHLBI Communications Office at nhlbi.nih.gov or visit www.nhlbi.nih.gov.

About ISHLT

The International Society for Heart and Lung Transplantation (ISHLT) is a not-forprofit organization dedicated to the advancement of the science and treatment of end-stage heart and lung diseases. Established in 1981, the Society now includes more than 2,200 members from more than 45 countries. For more information, visit www.ishlt.org.

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