Paragonix Initiates Global Post Market Registry Evaluating Clinical Outcomes in Patients who Receive Donor Hearts Transported with Paragonix SherpaPak™ Cardiac Transport System

Only FDA-Cleared and CE-Marked System for Donor Heart Transport

Cambridge, Massachusetts, April 18, 2019— Paragonix Technologies, Inc. today announced the opening of the Global Utilization And Registry Database for Improved heart preservation (“GUARDIAN”) post-market registry, which will assess clinical outcomes when employing the Paragonix SherpaPak™ Cardiac Transport System (CTS) for heart transplantations.

“Clinical feedback regarding the Paragonix SherpaPak™ CTS has been extremely encouraging and we firmly believe we are on the path to improve the standard of care in how donor hearts are transported,” commented Dr. Lisa Anderson, President and Chief Operating Officer of Paragonix. “An investment in a global registry reflects our commitment to patients as well as to the clinical community who have embraced the Paragonix SherpaPak™ CTS as a means of advancing donor heart preservation and transport. Based on ongoing clinical observations, we believe that a comparison to existing organ transport methods of a conventional cooler with ice will further reveal the exciting benefits of Paragonix SherpaPak™ CTS.”

About the GUARDIAN Registry
The registry study will include multiple transplant centers across the U.S. and Europe. The primary objectives of the post-market registry study are to evaluate short term post-transplant outcomes (within the first 48 hours), intermediate term outcomes (within the first 30 days) and long-term outcomes (1 year survival). There will be no changes to existing standard protocols involved in donor heart transplantation. The registry study will also further analyze the impact of a variety of donor, recipient and transport-related parameters on patient outcomes, including donor clinical backgrounds, total ischemic times and recipient factors. For people interested in learning more about the GUARDIAN registry, please contact info@guardianheartregistry.com

“We will continue to evaluate the Paragonix SherpaPak™ CTS for donor heart preservation,” said Dr. David D’Alessandro, Surgical Director for Heart Transplantation at Massachusetts General Hospital. “Contributing to GUARDIAN is an important step in that process.”

“Temperature control is a critical aspect of the organ transportation process and with the Paragonix SherpaPak™ CTS we are able to remotely monitor the temperature of the
“Organ through the journey to the recipient patient, thereby safeguarding the organ from cold injury,” said Dr. Andreas Zuckermann, Principal Investigator of GUARDIAN and Co-Director of Heart Transplantation at AKH Vienna, Austria. “We have been an early adopter of the Paragonix SherpaPak™ CTS and it is an honor to kick off this important registry.”

**About the Paragonix SherpaPak™ Cardiac Transport System**

The Paragonix SherpaPak™ Cardiac Transport System (CTS) safeguards hearts during the journey from donor to recipient patient. Our device incorporates clinically proven and medically trusted cold preservation techniques in a novel suspension system to provide unprecedented physical and thermal protection. Paragonix SherpaPak™ CTS is the only commercially available FDA cleared and CE marked medical device for heart transportation. More than 35 transplant centers throughout the world are trained to use the Paragonix SherpaPak™ CTS for donor heart transport. The System is currently marketed in the United States, United Kingdom, France, Spain, Italy, Germany, Austria, Sweden, Switzerland, Slovak Republic and The Netherlands.

**About Paragonix Technologies, Inc.**

Paragonix Technologies markets organ transportation devices that safeguard organs during the journey between donor and recipient patients. Our devices incorporate clinically proven and medically trusted cold preservation techniques in a novel suspension system to provide unprecedented physical and thermal protection. Paragonix SherpaPak™ CTS is the only commercially available FDA cleared and CE marked transport device for heart transportation. Paragonix is also developing transport devices for the lung and kidneys designed to improve donor organ quality and extending donor organ transport time.

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