Paragonix Technologies, Inc., Announces Clinical Use of the Paragonix SherpaPak™ Cardiac Transport System in World-Renowned Transplant Centers

BRAINTREE, Mass – September 11, 2018 – Paragonix Technologies, Inc., a Boston-based commercial-stage medical device company, announced today, a successful series of clinical use, of the Paragonix SherpaPak™ Cardiac Transport System (CTS) at a leading Boston-based hospital and other world-renowned transplant centers in the United States and in Europe. The Paragonix SherpaPak™ CTS[1,2] is intended for the transport of donor hearts destined for transplantation into a recipient patient. The device combines innovative cooling technology with safe, consistent methods for cold ischemic storage and transport of donor organs. Real-time reporting of preservation temperature allows for continuous monitoring of transport conditions of the donor heart; at completion of the transport, these data are downloaded to Bluetooth-enabled devices for record keeping and sharing among the transplant team.

Recently, the first series of clinical use of Paragonix SherpaPak™ CTS for donor heart transportation and preservation took place at Massachusetts General Hospital (MGH) in Boston.

“The handling, packing and shipping of donor hearts is a critical part of the transplant process,” said David D’Alessandro, MD, surgical director for Heart Transplantation at MGH. “We are always looking for new ways to improve the preservation and monitoring of donor hearts, with a goal of continually improving patient outcomes.”

The Paragonix SherpaPak™ CTS (https://paragonixtechnologies.com/sherpapak-cardiac-transport-system/) has been utilized in both the United States and in Europe; in Europe, the device is currently marketed in the United Kingdom, Spain, Italy, Germany and Austria. Clinical use data of the device show it performs as intended for all currently experienced clinical scenarios, such as short and long distance transports, medically complex cases involving donor heart anatomical anomalies, aircraft and road transport, or utilization by large and small clinical teams. 100% of Centers with clinical use have reported on the ease-of-use and intuitive nature of Paragonix SherpaPak™ CTS.

Bill Edelman, Chairman & CEO, for Paragonix commented, “We are thrilled to collaborate with MGH and others on the clinical use of Paragonix SherpaPak™ Cardiac Transport System. Since commercial launch of the Paragonix SherpaPak™ Cardiac Transport System in April 2018, we are proud to be supporting over 25 world-renowned Transplant Centers and we expect a similar number to be added before year-end. Our effective product implementation plan combined with a variety of clinical support tools tailored individually to each Transplant Center have resulted in sustained clinical utilization of Paragonix SherpaPak™ Cardiac Transport System: all Centers that have initially evaluated Paragonix SherpaPak™ Cardiac Transport System have committed to continued testing for ongoing heart recoveries and transports of donor hearts.“

About the Paragonix SherpaPak™ and SherpaPerfusion™ Cardiac Transport System
In 2014 The International Society Of Heart and Lung Transplantation consensus report was published to provide guidelines on the prevention, diagnosis and treatment of primary graft dysfunction (PGD) following cardiac transplantation[3]. Temperature control during transport was highlighted as an important preventative measure against PGD. Paragonix SherpaPak™ Cardiac Transport System addresses this by providing precise temperature control of the donor heart during transport and

preservation. The Paragonix SherpaPak™ System consists of multiple components; 1) an outer transport shipper which temperature controlled elements, 2) a sterile, nesting organ canister set which provides a double, rigid barrier in which the organ is immersed and suspended in a cold storage fluid cleared for use in storing and transporting donor organs, 3) a data logger that monitors the temperature of the organ during transport, and 4) a Bluetooth-connectivity to monitor, record and download preservation temperature and storage times to handheld devices.

According to The International Society Of Heart and Lung Transplantation ("ISHLT") guidelines[4] for the care of heart transplant recipients, the projected ischemic time should not exceed 4 hours[5,6], limiting the distance available to transport a donor heart. The Paragonix SherpaPerfusion™ Cardiac Transport System combines innovative oxygenated perfusion of organs and safe organ storage with the ultimate goal of extending ischemic time to 12 hours, significantly altering the transportation range of donor hearts.

About the Cardiac Transplantation Market

Cardiac transplantation is considered the gold standard therapy for patients in end-stage heart failure[7]. With over 6.5 million Americans currently diagnosed with heart failure (HF)[8], 10% of which are diagnosed with end-stage heart failure[9], there is a persistent need to provide end-stage heart failure support to this expanding population. Estimates of the prevalence of symptomatic HF in the general European population are similar to those in the United States[10]. In 2017, over 2,000 donor hearts were transplanted in Europe[11].

The annual US economic burden of treating heart failure exceeds $34.4 billion[12], over 50% of which is due to the cost of hospitalization[13]. The financial demands associated with transplantation are considerable. The estimated first year costs for heart transplant are $997,700, and subsequent annual costs can easily exceed $30,000[14]. In the United States, around 30,000 people die annually from end-stage heart disease. As of February 2018, 3,990 patients in the United States are on the waiting list for a heart transplant[15] and close to 4,000 patients in Europe are on the waiting list for a heart transplant every year[16]. In 2017, 3,244 patients in the United States[17] and over 2,000 European patients received a live-saving heart transplant[19]. These data, however, only seem to represent the tip of the iceberg. Assuming that up to 157,000 people with end-stage heart failure are candidates for transplantation[18], maximization of donor organ utilization has enormous potential in cardiac transplantation.

About Paragonix Technologies, Inc.

Based in Massachusetts and founded in 2010, Paragonix Technologies Inc., is a privately held medical device company innovating the Paragonix SherpaPak™ and SherpaPerfusion™ Organ Transport Systems for donor hearts and donor kidneys, and the Paragonix SherpaLung™ System for improved preservation of donor lungs. Paragonix has established a pipeline of donor organ transport devices that address the current donor organ shortage by maximizing donor organ utilization, improving donor organ quality and extending donor organ transport throughout the entire United States and across Europe.

[1] The Paragonix SherpaPak™ Organ Transport product line is protected by patents, both issued and pending

[2] The Paragonix SherpaPak™ Organ Transport product line has received FDA 510(k) pre-market clearances and CE mark approval for both heart and kidney organ storage and transport

[3] https://www.ncbi.nlm.nih.gov/pubmed/?term=Report+from+a+consensus+conference+on+primary+graft+dysfunction+after+cardiac+transplantation

[4] ISHLT Guidelines for the Care of Heart Transplant Recipients, Task Force 1: Peri-operative Care of the

Heart Transplant Recipient (Aug. 4, 2010)

[5] J Heart Lung Transplant 2001; 20(2):212.

[6] J Am Coll Cardiol 2004; 43(9):1553-1561.

[7] Datamonitor senior cardiovascular analyst Dr. Sergey Ishin. "Cardiac transplantation continues to be the gold standard for the treatment of end-stage heart failure. However, the number of potential transplants far exceeds the number of donors." http://about.datamonitor.com/media/archives/314

[8] http://newsroom.heart.org/news/latest-statistics-show-heart-failure-on-the-rise;-cardiovascular-diseases-remain-leading-killer

[9] http://www.heart.org/HEARTORG/Conditions/HeartFailure/LivingWithHeartFailureAndAdvancedHF/Advanced-Heart-Failure_UCM_441925_Article.jsp#.WosY7GNLPjI

[10] http://about.datamonitor.com/media/archives/314

[11] http://www.transplant-observatory.org

[12] Circulation 2011;123(8):933-944

[13] Circulation 2007;115(5)

[14] http://www.transplantliving.org

[15] http://optn.transplant.hrsa.gov

[16] https://ec.europa.eu/health/sites/health/files/blood_tissues_organs/docs/ev_20141126_factsfigures_en.pdf

[17] https://unos.org/data/transplant-trends/#transplants_by_organ_type+year+2017

[18] J Heart Lung Transplant 2011;30:1078-94

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