Paragonix Technologies, Inc., Announces 510(k) Clearance Allowing for Use of the Paragonix SherpaPak™ Cardiac Transport System with Pediatric and Small Donor Hearts

First and only FDA cleared and CE marked device that safeguards hearts between donor and recipient patients

Braintree, Massachusetts, December 20, 2018—Paragonix Technologies, Inc. today announced that it received clearance by the Food and Drug Administration (FDA) for a design enhancement allowing for the use of the Paragonix SherpaPak™ Cardiac Transport System (CTS)[1,2] with small and pediatric donor hearts. Starting in Q1 2019, Paragonix SherpaPak™ CTS will now be shipped with heart connectors covering most aortic diameters, permitting the anchoring of various size hearts including small pediatric hearts to its proprietary suspension system for improved donor heart transport. The Paragonix SherpaPak CTS is the only FDA cleared and CE marked system for donor organ heart transport and storage.

The Paragonix SherpaPak™ CTS has been used by heart transplant centers in both the United States and in Europe. The device is currently marketed in the United Kingdom, France, Spain, Italy, Germany, Austria and Slovak Republic in Europe.

"This FDA clearance is an important milestone in making the Paragonix SherpaPak™ CTS accessible for all donor populations, increasing the market reach of this important transplant product," said Bill Edelman, Chairman and CEO of Paragonix Technologies. "Our goal is to establish a new standard of care for donor organ preservation and with our FDA cleared and CE marked devices for both heart and kidney organ stage and transport, we are on our way to make this a reality."

About the Cardiac Transplantation Market

Cardiac transplantation is considered the gold standard therapy for patients in end-stage heart failure[3]. With over 6.5 million Americans currently diagnosed with heart failure (HF)[4], 10% of which are diagnosed with end-stage heart failure[5], 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[6]. In 2017, over 2,000 donor hearts were transplanted in Europe[7].

The annual U.S. economic burden of treating HF exceeds $34.4 billion[8], over 50% of which is due to the cost of hospitalization[9]. 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

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

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

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

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

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

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

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

[9] Circulation 2007;115(5)

exceed $30,000[10]. In the U.S., around 30,000 people die annually from end-stage heart disease. As of February 2018, 3,990 patients in the U.S. were on the waiting list for a heart transplant[11] and close to 4,000 patients in Europe are on the waiting list for a heart transplant every year[12]. In 2017, 3,244 patients in the U.S.[13] 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[14], maximization of donor organ utilization has enormous potential in cardiac transplantation.

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.

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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