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# Paragonix Technologies Inc., Announces ISO 13485:2016 Certification

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BRAINTREE, Mass.--(BUSINESS WIRE)--Paragonix Technologies, Inc., a commercial-stage medical device company marketing the Paragonix SherpaPak™ Cardiac Transport System[1,2], announced today that the Company has received ISO 13485:2016 certification for its Quality Management System (QMS) following review by the British Standards Institute (BSI). ISO 13485:2016 is an internationally recognized quality standard specific to the medical device industry. ISO 13485:2016 demonstrates Paragonix's commitment to the highest level of medical device quality controls and to meeting customer and international regulatory expectations. Certification required Paragonix to undergo the BSI Audit before March 2019, to ensure uninterrupted product availability to a growing customer base internationally.

Adam Collette, Ph.D., VP Commercial Operations, for Paragonix commented, "We are very proud to have certified our QMS as compliant with ISO 13485:2016. Our team's focus on creating a "quality-first" culture led to achievement of this milestone well ahead of schedule. "

The Paragonix SherpaPak™ Organ Transport System product portfolio[1,2] combines innovative cooling technology with safe, consistent methods for cold ischemic storage and transport of donor organ to recipients for implantation. 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.

Bill Edelman, Chairman & CEO, for Paragonix commented, "Our dedicated team of safety and quality experts is a key pillar of Paragonix's commitment to world-class, high-quality products. With the implementation of ISO13485:2016, Paragonix is fully aligned with global regulatory requirements. We are looking forward to supporting the transplant community with the Paragonix SherpaPak™ Cardiac Transport System in the US and in Europe."

**Previous Announcements**

Paragonix previously announced July 18, 2018 Partnership with the Lung Transplant Foundation to Support Commercialization of Paragonix™ SherpaLung for improved donor lung transport

Paragonix previously announced April 3, 2018 Presentation of the SherpaPak™ Cardiac Transport Systems and SherpaPerfusion™ Cardiac Transport System at the 38th Annual Meeting of the International Society for Heart and Lung Transplantation (Nice, France, April 11 – 14, 2018).

Paragonix previously announced March 26, 2018 Appointment of Carl Rickenbaugh to the Board of Directors.

Paragonix previously announced February 20, 2018 European Conformity ("CE")[3] Premarket Clearance for the SherpaPak™ Cardiac Transport System and SherpaPerfusion™ Cardiac Transport System Family of Organ Transport Products.

**About ISO13485:2016**

ISO 13485:2016 has been harmonized to the European Medical Devices Directives: MDD, AIMDD and IVDD. EN ISO 13485:2016 now replaces the previous version of the standard, EN ISO 13485:2012. Standard harmonization allows manufacturers to use their compliance to the standard as evidence of conformity to the requirements of relevant legislation.[4]

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

Currently, the availability of cardiac transplantation is governed by the "ischemic time", that being, the elapsed time from heart donation to recipient implantation. According to The International Society Of Heart and Lung Transplantation ("ISHLT") guidelines[5] for the care of heart transplant recipients, the projected ischemic time should not exceed 4 hours[6,7], limiting the distance available to transport a donor heart. Paragonix SherpaPak™ Cardiac Transport System is fully disposable, eliminating problems associated with maintenance, device transport and contamination. 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[8]. With over 6.5 million Americans currently diagnosed with heart failure (HF)[9], 10% of which are diagnosed with end-stage heart failure[10], 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[11]. In 2017, over 2,000 donor hearts were transplanted in Europe[12].

The annual US economic burden of treating heart failure exceeds $34.4 billion[13], over 50% of which is due to the cost of hospitalization[14]. 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[15]. 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[16] and close to 4,000 patients in Europe are on the waiting list for a heart transplant every year[17]. In 2017, 3,244 patients in the United States[18] 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[19], 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™, SherpaPerfusion™ and SherpaLung™ Organ Transport Systems, which are novel, single-use organ preservation devices to improve donor organ quality. 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.

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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) premarket clearances and CE mark approval for both heart and kidney organ storage and transport

[3] The CE mark (*Conformité Européenne*, meaning "European Conformity," formerly EC mark) according to the European Medical Directive (MDD) is a mandatory conformity mark for medical devices placed on the market in the European Economic Area (EEA). With the CE marking on a medical device, the manufacturer ensures that the product conforms to the essential requirements of the applicable EC medical device directives.

[4] https://www.bsigroup.com/en-US/medical-devices/Our-services/ISO-13485-Revision/

[5] ISHLT Guidelines for the Care of Heart Transplant Recipients, Task Force 1: Peri-operative Care of the Heart Transplant Recipient (Aug. 4, 2010)

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

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

[8] 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

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

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

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

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

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

[14] Circulation 2007;115(5)

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

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

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

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

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

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