



FOR IMMEDIATE RELEASE – July 23, 2015

Paragonix Technologies Inc., Announces Publication of “Innovative Cold Storage Of Donor Organs Using The Paragonix Sherpa Pak™ Devices”, the Scientific Journal, *Heart, Lung and Vessels*.

The Sherpa Pak™ Cardiac Transport System combines innovative cooling technology with a safe, consistent method for cold ischemic storage and transport of donor hearts to recipients for implantation.

(July 23, 2015, BusinessWire, Braintree, Massachusetts), Paragonix Technologies, Inc. today announced publication of a "Innovate Cold Storage Of Donor Organs Using The Paragonix Sherpa Pak Devices"¹ by investigators from the Transplantation Biology Research Center, Department of Surgery, Massachusetts General Hospital and Harvard Medical School (Boston) and the Department of Cardiac Surgery, Ludwig-Maximilians-University (Munich).

Sebastian Michel, MD, first author of the study on faculty at the Department of Cardiac Surgery, Ludwig-Maximilians-University, commented, “We are delighted to present data regarding a new, innovative organ preservation technology. This study focused on testing the robustness of the single-use Paragonix Sherpa Pak™ cardiac organ transport device, which is designed to maintain constant organ preservation temperatures between 4°C to 8°C for up to 30 hours. In several evaluations, Sherpa Pak™ was challenged to extremely high and low external temperatures during organ storage. Our data demonstrated that internal organ preservation temperatures were maintained within the design range. We further concluded that the Paragonix Sherpa Pak™ device may decrease cold injury of donor organs undergoing transport and preservation by maintaining the temperature consistently between 4°C to 8°C, thereby potentially decreasing early primary graft failure after organ transplantation.”

Bill Edelman, CEO and Chairman, for Paragonix commented, “The Paragonix Sherpa Pak™ devices for kidney and heart preservation are an important step in improving donor organ transportation. We believe that improving the utilization of donated hearts is critical to patients in end-stage heart failure who are desperate for this precious commodity.”

Previous Announcements

¹ Heart, Lung and Vessels ; (in press): 2446-2447

Paragonix previously announced on February 9, 2015, Innovative Tracking Technology For Real-Time, National Location Tracking of Donor Organs

Paragonix previously announced on December 2, 2014, clearance of two 510(k) Premarket Notifications by the US Food and Drug Administration, allowing the Paragonix Sherpa Pak Transport Systems to be combined and distributed with any FDA-cleared, commercially-available preservation solution.

Paragonix previously announced on Nov 17, 2014, Receipt of ISO 13485:2003 Certification for the Paragonix Sherpa Organ Storage and Transport Systems

Paragonix previously announced on Nov 3, 2014, filing of two 510(k) FDA Pre-Market Notifications to combine the Paragonix Sherpa Pak Cardiac and Kidney Transport Systems with any effective organ preservation solution currently marketed under 510(k) Pre-market Clearance

Paragonix previously announced on Oct 27, 2014, joining of David D'Alessandro, MD, as Medical Director for Paragonix

About Ludwig-Maximilians-University (Munich)

LMU is recognized as one of Europe's premier academic and research institutions. Since being founded in 1472, LMU has attracted inspired scholars and talented students from all over the world, keeping the University at the nexus of ideas that challenge and change our complex world.

About Massachusetts General Hospital

Massachusetts General Hospital, founded in 1811, is the original and largest teaching hospital of Harvard Medical School. The MGH conducts the largest hospital-based research program in the United States, with an annual research budget of more than \$760 million and major research centers in AIDS, cardiovascular research, cancer, computational and integrative biology, cutaneous biology, human genetics, medical imaging, neurodegenerative disorders, regenerative medicine, reproductive biology, systems biology, transplantation biology and photomedicine.

About the Paragonix Sherpa™ and Sherpa Pak™ 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”) guidelines² for the care of heart transplant recipients, the projected ischemic time should not exceed 4 hours^{3,4}, limiting the distance available to transport a donor heart. The Paragonix Sherpa™ 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.

² ISHLT Guidelines for the Care of Heart Transplant Recipients, Task Force 1: Peri-operative Care of the Heart Transplant Recipient (Aug. 4, 2010)

³ J Heart Lung Transplant 2001; 20(2):212.

⁴ J Am Coll Cardiol 2004; 43(9):1553-1561.

Paragonix Sherpa™ is fully disposable, eliminating problems associated with maintenance, device transport and contamination.

About the Cardiac Transplantation Market

Cardiac transplantation is considered the gold standard therapy for patients in end-stage heart failure.⁵ With over 5.8 million Americans currently diagnosed with heart failure (HF), growing at an annual rate of 400,000 per year⁶, 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.⁷ The annual economic burden of treating heart failure exceeds \$34.4 billion⁸, 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 exceed \$30,000¹⁰. In the United States, around 30,000 people die annually from end-stage heart disease. As of June 1, 2012, 3,203 patients in the United States are on the waiting list for a heart transplant¹¹. Based on 2011 data, just over 2,300 patients will receive a live-saving transplant each year, which is reflective of the enormous donor heart shortage. These data, however, only seem to represent the tip of the iceberg. Assuming that up to 50,000 people with end-stage heart failure are candidates for transplantation¹², 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 Sherpa™ Cardiac Transport System, a novel, single-use organ preservation device to improve donor organ quality and extend donor organ preservation times. Paragonix Sherpa™ combines innovative oxygenated perfusion of organs and safe organ storage with the goal of extending ischemic time to 12 hours, significantly altering the transportation range of donor hearts. Paragonix has exclusively licensed University of Texas Health Science Center San Antonio intellectual property from the Office of Technology Transfer and Commercialization. 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.

For Further Information, Contact:

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⁵ 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>

⁶ Circulation 2010;121:e46-e215

⁷ <http://about.datamonitor.com/media/archives/314>

⁸ Circulation 2011;123(8):933-944

⁹ Circulation 2007;115(5)

¹⁰ <http://www.transplantliving.org>

¹¹ <http://optn.transplant.hrsa.gov>

¹² <http://www.uptodate.com/contents/heart-transplantation-beyond-the-basics>

