Paragonix Technologies, Inc., Announces Clearance of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the Paragonix Sherpa™ Cardiac Transport System

The Associated Press

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Feb 12, 2013--Paragonix Technologies, Inc. today announced that it has received clearance for its Pre-Marketing Notification Application (510(k)) with the US Food and Drug Administration (FDA) for its Paragonix Sherpa Pak™ Cardiac Transport System 1 (CTS). The Sherpa Pak™ CTS is indicated for the static hypothermic preservation of hearts during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with the heart.

“We are thrilled to have reached this milestone,” stated Bill Edelman, acting CEO. He continued, “Sherpa Pak™ CTS is the first in a series innovative organ transport devices developed by Paragonix that are intended to provide the healthcare community enhanced hypothermic preservation of hearts during transportation and eventual transplantation into a recipient.” Lisa M. Anderson, PhD, Chief Operating Officer and Co-Founder for Paragonix commented, “We are excited to have received FDA clearance of the 510(k) Application for the Sherpa Pak™ CTS. We anticipate significant clinical interest for this innovative technology in the markets where the Sherpa Pak™ CTS will be cleared for commercial distribution. This is the first in a series of regulatory applications while we continue our development of several additional Sherpa CTS products.” Leonard A. R. Golding, MB, BS, FRACS, FRCS(C), FACC, Chief Medical Officer, commented, “The availability of donor hearts has been historically impeded by both organ preservation limitations and the time required from donation to recipient implantation. The Sherpa technology now being developed by Paragonix holds the promise of addressing both critical needs. With an aging population world-wide and an increasing incidence of congestive heart failure leading inexorably to heart transplantation, the clinical community will look to solutions that increase organ availability and organ quality. I look forward to seeing the Sherpa product line on the market.” Previous Announcements Paragonix previously announced on November 6, 2012, filing of a 510(k) Pre-Marketing Notification Application with the US Food and Drug Administration for the Paragonix Sherpa™ Cardiac Transport System.

Paragonix previously announced on July 16, 2012, award of a Phase I Small Business Innovation Research (SBIR) Grant to support the pre-clinical development of the Paragonix Sherpa™ Cardiac Transport in collaboration with the Transplant Center at Massachusetts General Hospital (Boston).

Paragonix previously announced on June 25, 2012, Appointment of Leonard A. R.

Golding, MB, BS, FRACS, FRCS(C), FACC as Chief Medical Officer.

Paragonix previously announced on June 18, 2012, Formation of a Clinical Advisory Board for the Paragonix Sherpa™ Cardiac Transport System.

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”) guidelines 2 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 goal of extending ischemic time to 12 hours, significantly altering the transportation range of donor hearts. Paragonix Sherpa™ is designed to be used in conjunction with any of the currently available organ preservation solutions. Paragonix Sherpa™ is fully disposable, eliminating problems associated with maintenance, and contamination. The Sherpa Pak™ Cardiac Transport System is intended to be used for the static hypothermic preservation of hearts, up to 4 hours, during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with the heart .

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 year 6, 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 billion 8, over 50% of which is due to the cost of hospitalization. 9 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 transplant. 10 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 transplantation 11, maximization of donor organ utilization has enormous potential in cardiac transplantation.

About Paragonix Technologies, Inc. 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 South Texas Technology Management, a University of Texas collaborative technology transfer office. 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.

1 Patents issued and pending.

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.

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 7http://about.datamonitor.com/media/archives/314 8 Circulation 2011;123(8):933-944 9Circulation 2007;115(5) 10http://optn.transplant.hrsa.gov 11http://www.uptodate.com/contents/heart-transplantation-beyond-the-basics

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