

**Paragonix and the Lung Transplant Foundation Announce Expansion of Partnership to Accelerate Commercialization of Innovative Lung Preservation Technologies**

*Paragonix Completing Development of Paragonix SherpaLung™ Preservation System and Expects Regulatory Clearances by Q4 2019*

Cambridge, Massachusetts, April 26, 2019 — [Paragonix Technologies, Inc.](#) and the [Lung Transplant Foundation \(LTF\)](#) today announced an expansion of their partnership for the development of a series of innovative technologies for improved donor lung preservation.

At a joint meeting held during the International Society for Heart and Lung Transplantation (ISHLT) 2019 Annual Meeting in Orlando, FL, The Lung Transplant Foundation reviewed how the [2017 OPTN/UNOS policy](#)<sup>1</sup> covering the distribution of lungs donated for transplant has impacted waitlist removal, logistical burden on organ procurement, distances traveled to retrieve lungs and overall lung retrieval costs. Notably, the updated policy expanded the geographical boundaries for lungs to travel, with first priority offered to patients within a 250-mile radius of the donor's hospital and then expanding within 575 miles, and then finally across the nation if a matching patient cannot be found. The expanded travel distances results in organs needing to be stored longer, making it imperative that as little damage as possible is done to the organ during transit.

Paragonix is currently completing commercial development of the [Paragonix SherpaLung™ Preservation System](#) and expects the filing of FDA pre-market notification and European CE clearance by Q4 2019. The Paragonix SherpaLung™ Preservation System is designed to ensure optimal lung preservation during its journey from donor to recipient patient by incorporating medically proven and clinically validated preservation techniques combined with lung inflation pressure control, ensuring stable inflation pressure on the ground or during air transport.

Jeff Goldstein, CEO and Founding Member of the Lung Transplant Foundation, commented, "There is no more urgent time than now to provide those patients on the lung transplant waitlist with any possible advantage they can get. With longer travel distances observed since implementation of the new lung distribution policy, there is a desperate need for better lung preservation: improved and controlled donor lung preservation technologies that will take into account more extensive travel by aircraft.<sup>2</sup> And we applaud Paragonix for developing these types of technologies that will also work in a cost-conscious healthcare environment."

"We are entering a new paradigm of broader geographic sharing in solid organ transplantation, and current technologies for lung preservation do not adequately address the extensive travel and longer transport times experienced by most lung transplant centers in the United States," says Matthew Hartwig, MD, MHS, a lung transplant surgeon at Duke Medical Center and co-Director of the Duke Ex-Vivo Organ Perfusion Laboratory.

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<sup>1</sup> Callahan and Uccellini. OPTN/UNOS Mini-Brief Broader Sharing of Adult Donor Lungs, Nov 2017.

<sup>2</sup> [https://medicine.wustl.edu/news/new-rules-for-lung-transplants-lead-to-unintended-consequences/?utm\\_source=linkedin&utm\\_medium=organic\\_social&utm\\_campaign=research&utm\\_content=new\\_rules\\_for\\_lung\\_transplants\\_lead\\_unintended\\_consequences&hootPostID=fba2caf8e15deca220b1c67b21280c2f](https://medicine.wustl.edu/news/new-rules-for-lung-transplants-lead-to-unintended-consequences/?utm_source=linkedin&utm_medium=organic_social&utm_campaign=research&utm_content=new_rules_for_lung_transplants_lead_unintended_consequences&hootPostID=fba2caf8e15deca220b1c67b21280c2f)

“We are thrilled to strengthen our partnership with the Lung Transplant Foundation and are highly encouraged that such a preeminent group as the LTF is working with us to accelerate our commercialization program for multiple products that will address improved lung preservation,” said Bill Edelman, Chairman and CEO of Paragonix Technologies. “Based on our positive clinical results reported for the Paragonix SherpaPak™ Cardiac Transport System, we believe the extension of our product line to lung transplantation will be an important contribution in this field and ensure the best possible practices for the preservation of the precious gift of life.”

### **About the Lung Transplantation Market**

Lung transplantation is considered the gold standard therapy for patients in end-stage pulmonary failure<sup>3</sup> due to Idiopathic Pulmonary Fibrosis (IPF) and Chronic Obstructive Pulmonary Disease (COPD). IPF is a non-neoplastic pulmonary disease that is characterized by the formation of scar tissue within the lungs in the absence of any known provocation. IPF is a rare disease which affects approximately 5 million persons worldwide.<sup>4</sup> COPD is a heterogeneous disease with various clinical presentations. The basic abnormality in all patients with COPD is airflow limitation and it is a major public health problem. According to WHO estimates, 65 million people have moderate to severe chronic COPD. More than 3 million people died of COPD in 2005, which corresponds to 5% of all deaths globally.<sup>5</sup> According to data from the Organ Procurement and Transplantation Network, there have been more than 34,000 lung transplants completed in the United States since 1988. In 2016, 2,400 lung transplants took place. The majority of those surgeries were in patients age 18 to 64 years old.<sup>6</sup> The direct and indirect costs for single and double lung transplantation is estimated at \$790,000 and over \$1M, respectively.<sup>7</sup> The costs for donor lung procurement are estimated at \$90,000 - \$130,000, respectively.<sup>8</sup>

### **About the International Society for Heart and Lung Transplantation**

The International Society for Heart and Lung Transplantation (ISHLT), established in 1981, is a professional organization committed to research and education in heart and lung disease and transplantation. It holds annual scientific meetings and publishes The Journal of Heart and Lung Transplantation. It also holds the largest registry of heart and lung transplant data in the world.

### **About The Lung Transplant Foundation**

In June 2009, the national Lung Transplant Foundation (LTF) was founded as a non-profit organization by a group of lung transplant recipients from Durham and Chapel Hill, NC. These recipients from Duke University and UNC Hospitals realized promotion and funding of research to improve the post lung transplant experience and long term outcomes was severely lacking, so they created the LTF to tackle one of the most difficult and life-threatening issues facing transplant recipients, chronic rejection or bronchiolitis obliterans syndrome (BOS). The LTF now includes a Board of Directors comprised of lung transplant recipients, caregivers and connected individuals who graciously donate their time to further the mission of the LTF. What began as a small foundation has grown to become an outspoken advocate for the advancement of research to cure BOS and one of the most widely recognized organizations promoting lung transplant as a viable alternative to end-stage lung disease.

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<sup>3</sup> J Thorac Dis. 2010 Jun; 2(2): 111–116.

<sup>4</sup> Orphanet J Rare Dis. 2008; 3: 8.

<sup>5</sup> <http://www.who.int/respiratory/copd/burden/en/>

<sup>6</sup> <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>

<sup>7</sup> <http://www.transplants.org/faq/how-much-does-transplant-cost>

<sup>8</sup> Milliman Research Report, “2014 US Organ and Tissue Transplant Cost Estimates and Discussion”

**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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