TransMedics, Inc. Receives FDA Pre-Market Approval (PMA) For Its OCS Lung System For Near-Physiologic Preservation And Assessment Of Lungs For Transplantation

April 12, 2018

ANDOVER, Mass., April 12, 2018 /PRNewswire/ — TransMedics, Inc., a medical technology company that is transforming the important therapy of solid organ transplantation for patients with end-stage lung, heart and liver failure, announced today that the U.S. Food and Drug Administration (FDA) approved its Pre-Market Approval Application (PMA) for the Organ Care System (OCS™) Lung platform for the standard double lung transplant indication on March 22, 2018. The INSPIRE Trial that supported the PMA was the first and largest controlled clinical organ preservation trial ever in lung transplantation and was conducted at 21 leading international academic institutions. The primary objective of the INSPIRE Trial was to compare the safety and effectiveness of the OCS Lung System to the current cold storage standard of care for the preservation of standard criteria donor lungs. The trial results demonstrated reasonable assurance of safety and effectiveness of the OCS Lung System in standard criteria double lung transplantation.

“This is a major milestone for TransMedics and the field of thoracic transplantation. We are honored and humbled that with this PMA approval, the OCS Lung System is now the only approved medical technology for ex-vivo perfusion and assessment for standard criteria lung transplants in the U.S.,” said Dr. Waleed Hassanein, CEO of TransMedics, Inc. “I want to take this opportunity to thank the FDA staff who participated in the review of our PMA, as well as Dr. Jeffrey Shuren, Director, Center for Devices and Radiological Health (CDRH) and Dr. William Maisel, Director, Office of Device Evaluation and Chief Medical Officer, CDRH for their leadership and efforts to bringing this U.S. developed innovation to U.S. lung transplant patients.” Dr. Hassanein continued, “In addition, we are grateful for the dedication and commitment of our INSPIRE Trial investigators and most importantly, we would like to thank the lung transplant patients who participated in the INSPIRE trial.” Dr. Hassanein added that the company is committed to working tirelessly to complete its ongoing FDA clinical trials for other products and indications, explaining that the OCS Lung System PMA is “the first of many PMA approvals that TransMedics has in the pipeline to address the needs of patients on the waiting list for lung, heart and liver transplants.”

“The OCS platform is a paradigm-shifting technology developed to address the current clinical limitations in the transplant field. This PMA approval is the first crucial step forward towards dramatically improving clinical outcomes and expanding the number of life-saving organ transplant procedures in the U.S. and worldwide,” said Dr. Abbas Ardehali, Director of Heart and Lung transplantation at UCLA Medical Center and the U.S. Principal Investigator of the INSPIRE Trial. “I want to congratulate my co-investigators of the INSPIRE Trial and TransMedics for successfully completing this first of its kind trial in lung transplantation,” said Dr. Ardehali.

TransMedics has developed the Organ Care System (OCS™), a revolutionary first-in-class technology and multi-organ platform with the potential to both improve outcomes for transplant patients and increase the number of transplantable organs worldwide. The OCS™ is the only fully portable technology that maintains donor organs in a near-physiologic state outside of the human body and addresses the current limitations of the cold storage.

The OCS™ Heart, OCS™ Lung, and OCS™ Liver systems are CE Marked and are in use at leading transplant centers in Europe, Australia an Canada. To-date there has been >950 successful human transplants using the OCS System world-wide.

Contact:
TransMedics, Inc.
Stephen Gordon, CFO
sgordon@transmedics.com
Tel: +19785525071
www.transmedics.com