



Mauna Kea Technologies Announces Positive Results from Mayo Clinic Sponsored Prospective Multi-center Trial in Lung Transplant Patients

Cellvizio's optical biopsy could become a safe and effective alternative to invasive biopsies in transplanted patients

Paris and Boston, June 20, 2018 – 5.45 PM CEDT – Mauna Kea Technologies (Euronext: MKEA, OTCQX: MKEAY) inventor of Cellvizio®, the multidisciplinary probe-based confocal laser endomicroscopy (pCLE) platform, today announced the publication of a prospective multicenter study (ClinicalTrials.gov Identifier: NCT01033201) that demonstrates the potential of Cellvizio to aid in the diagnosis of acute cellular rejection in lung transplant patients. The article, entitled “Diagnosis of Acute Cellular Rejection Using Probe-Based Confocal Laser Endomicroscopy in Lung Transplant Recipients: a Prospective, Multi-Center Trial,” was published in *Transplantation* (2018, DOI: [10.1097/TP.0000000000002306](https://doi.org/10.1097/TP.0000000000002306)) and can be downloaded here: https://journals.lww.com/transplantjournal/Abstract/onlinefirst/Diagnosis_of_Acute_Cellular_Rejection_Using.96508.aspx.

“The lung has the highest rate of acute rejection of any transplanted organ,” said Cesar Keller, M.D., Lung Transplant Program, Mayo Clinic, Jacksonville, Florida and first author of the study. “However, the current standard of care, transbronchial biopsy, requires multiple samples to be obtained per biopsy and carries a high risk of serious adverse events including pneumothorax and/or pulmonary bleeding. Considering the relatively frequent need to monitor these patients for acute rejection, better and less invasive methods to assess acute rejection would significantly improve patient care and outcomes.”

Acute cellular rejection (ACR) in lung transplant recipients is diagnosed by identifying perivascular cellularity (PVC) from alveolar tissue typically obtained via invasive transbronchial biopsies. This study compared *in vivo* real-time histological imaging using Cellvizio for the identification of alveolar, vascular, and cellular microstructures of lung transplants to transbronchial biopsies. The prospective, multi-center study enrolled 24 patients who had undergone a lung transplant within the prior 12 months and who were scheduled for diagnostic biopsies. The study showed that pCLE identification of PVC is a feasible and reproducible criterion for assessment of acute cellular rejection *in vivo*. The PVC criterion exhibited a perfect sensitivity for the ACR diagnosis for a pCLE-trained pneumologist. After training, the inter-observer agreement among four pneumologists to recognize this feature was significant (Fleiss Kappa of 0.77). The authors concluded that “optical biopsy obtained with pCLE identifies micro-vascular structures with and without perivascular cellularity, which correlates with standard histological diagnosis of acute cellular rejection.”

“Cellvizio is the only probe-based Confocal Laser Endomicroscopy system available to physicians for clinical use in pulmonology,” said Sacha Loiseau, Ph.D., CEO and co-founder of Mauna Kea Technologies. “This study adds further validation to Cellvizio’s unique capabilities to not only identify microscopic cellular and vascular structures within the tissues inside the human body in real time, but to also generate actionable results with significant impact on patient outcomes.”

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real time *in vivo* microscopic visualization. The Company’s flagship product, Cellvizio, has received clearance to sell a wide range of applications in more than 40 countries, including the United States, Europe, Japan, China, South Korea, Canada, Brazil and Mexico. For more information on Mauna Kea Technologies, visit www.maunakeatech.com



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