

## Mauna Kea Technologies Announces 5 Communications Highlighting the Clinical Value of Cellvizio® in Interventional Pulmonology Presented During the European Respiratory Society (ERS) International Congress 2021

*Further validation of how Cellvizio is a complementary technology to manual and robotic-assisted bronchoscopy, potentially impacting patient management and improving outcomes in multiple pulmonology indications*

Paris and Boston, October 4, 2021 – 05:45 PM CEST – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces that 5 communications supporting Cellvizio® were presented during the recent European Respiratory Society (ERS) International Congress 2021. These presentations focused on the safety, efficacy, and feasibility of Cellvizio when used with manual and robotic-assisted bronchoscopy, fine-tuning sampling location and reduction of the bronchoscopic near-miss rate, and the application of Cellvizio in detecting fibrotic changes *in vivo* in patients diagnosed with COVID-19.

“Following the publication of the peer-reviewed article, ‘Bronchoscopic needle based confocal laser endomicroscopy (nCLE) as a real-time detection tool for peripheral lung cancer’ in *Thorax*<sup>1</sup>, we are pleased to have had the opportunity to share some of our clinical cases in greater detail and an exciting new study on robotic-assisted bronchoscopy during the ERS International Congress,” said J. T. Annema, M.D. Ph.D., Professor of Pulmonary Endoscopy, Amsterdam University Medical Center. Professor Annema also added: “The studies’ conclusions demonstrate that physicians can differentiate, with high reproducibility, between malignant tissue and airway/lung parenchyma, demonstrating the potential of nCLE imaging as a real-time biopsy guidance tool during manual and robotic-assisted bronchoscopy to reduce the near-miss rate of peripheral lung cancer.”

The first results of the clinical study, co-funded by the Lung Cancer Initiative (LCI) at Johnson & Johnson<sup>2</sup>, combines needle-based confocal laser endomicroscopy and robotic-assisted bronchoscopy using both Cellvizio and the Monarch® Platform from Auris Health, Inc.<sup>3</sup> to aid in diagnosing peripheral lung nodules. Christopher Manley, M.D., Director of Interventional Pulmonology and Associate Professor of Medicine at Fox Chase Cancer Center in Philadelphia and the principal investigator of this study, commented on the preliminary results: “In our study, the vision and stability of the robotic-assisted bronchoscope from the Monarch Platform allowed us to navigate farther into the lung to precisely target smaller lesions. Additionally, *in vivo* cellular imaging with nCLE provided very important real-time feedback to help identify abnormal tissue with nCLE imaging detecting a malignant pattern in 93% of patients with cancer.”

As detailed in the [study<sup>4</sup> presentation](#) during the ERS International Congress, one patient with a malignant nCLE image but a negative result during robotic-assisted bronchoscopic lesion sampling was diagnosed with malignancy after surgery, and in 6/17 (35%) of patients, nCLE guidance resulted in readjustment of the robotic bronchoscope with optimization of the sampling location.

“The potential impact real-time *in vivo* cellular imaging with Cellvizio can have in the intervention of lung cancer early in the disease progression is well supported through these presentations and we look forward to broadening the adoption of Cellvizio in the Interventional Pulmonology community,” said Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies.

<sup>1</sup> DOI: [10.1136/thoraxjnl-2021-216885](https://doi.org/10.1136/thoraxjnl-2021-216885)

<sup>2</sup> The legal entity of the Lung Cancer Initiative at Johnson & Johnson is Johnson & Johnson Enterprise Innovation, Inc.

<sup>3</sup> Auris Health, Inc. is part of Johnson & Johnson Medical Devices Companies

<sup>4</sup> [Manley C, Kramer T, et al. Needle based confocal laser endomicroscopy for the diagnosis of peripheral lung nodules by robotic navigational bronchoscopy. ERS 2021](#)

**Highlighted featured presentations:****[Needle based confocal laser endomicroscopy for the diagnosis of peripheral lung nodules by robotic navigational bronchoscopy](#)**

Oral presentation by Dr. Christopher Manley  
(Clinicaltrials.gov: [NCT04441749](https://clinicaltrials.gov/ct2/show/study/NCT04441749))

**[Robotic bronchoscopy combined with needle based confocal laser endomicroscopy \(nCLE\) for peripheral lung cancer](#)**

Skills lab presented by Dr. Christopher Manley

**[Needle based confocal laser endomicroscopy: a novel real-time diagnostic approach for suspected peripheral lung lesions](#)**

Challenging clinical cases and discussion presented by Dr. Tess Kramer

**[Lungs on fire: Respiratory critical care, COVID-19](#)**

Case review and discussion presented by Dr. Kirsten Kalverda

**[Correlation between probe-based confocal laser endomicroscopy \(pCLE\) and chest CT patterns in pulmonary tuberculosis](#)**

E-poster by Dr. Igor Mamenko

For more information, view our ERS 2021 page: <https://www.landing.maunakeatech.com/en/ers-2021>

**About Mauna Kea Technologies**

Mauna Kea Technologies is a global medical device company that manufactures and sells Cellvizio®, the real-time in vivo cellular imaging platform. This technology uniquely delivers in vivo cellular visualization which enables physicians to monitor the progression of disease over time, assess point-in-time reactions as they happen in real time, classify indeterminate areas of concern, and guide surgical interventions. The Cellvizio platform is used globally across a wide range of medical specialties and is making a transformative change in the way physicians diagnose and treat patients. For more information, visit [www.maunakeatech.com](http://www.maunakeatech.com).

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