



Mauna Kea Technologies Announces Positive Results on Needle-Based Endomicroscopy as a Real-Time Detection Tool for Lung Cancer

New peer-reviewed evidence in the prestigious Thorax journal shows lung cancer can be accurately diagnosed with Cellvizio® AQ-Flex™ 19 Confocal Miniprobe™ used through fine needles

Paris and Boston, June 28, 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 the publication in a high impact journal, Thorax, on nCLE as a real-time detection tool for lung cancer. The peer-reviewed article entitled “Bronchoscopic needle based confocal laser endomicroscopy (nCLE) as a real-time detection tool for peripheral lung cancer” (DOI: [10.1136/thoraxjnl-2021-216885](https://doi.org/10.1136/thoraxjnl-2021-216885)) provides further evidence that bronchoscopic nCLE imaging of peripheral lesions suspected of lung cancer is feasible, safe, and enables real-time malignancy detection at the needle tip with very high accuracy.

The U.S. Preventive Services Task Force (USPSTF) new recommendation, published last March, nearly doubles the number of people eligible for lung cancer screening and is estimated to increase the number of screening-detected lung cancer cases at early stage by 27%¹. Despite the development of novel technologies, transbronchic biopsy diagnostic yield and accuracy remain low (between 30 and 65%)² with an inability to confirm with high level certainty that the biopsy needle is sampling within the targeted lesion. There is a growing evidence that nCLE imaging has the potential to significantly increase diagnostic yield and accuracy of transbronchic needle biopsies³, consistent with the company’s goal of delivering advanced imaging techniques and improved patient outcomes.

“This new study provides further confirmation that bronchoscopic nCLE imaging in peripheral lung cancer is feasible, safe, and allows real-time malignancy detection at the tip of the needle with an accuracy equal to 95%,” said J. T. Annema, M.D. Ph.D., Professor of Pulmonary Endoscopy, Amsterdam University Medical Center. Professor Annema also added that “physicians can differentiate, with high reproducibility (with excellent and substantial inter and intra-observers equal to 0.82 and 0.78, respectively) between malignant tissue and airway/lung parenchyma, demonstrating the potential of nCLE imaging as a real-time guidance tool to reduce the bronchoscopic near miss rate of peripheral lung cancer.”

“This study brings very strong additional clinical data to our formal evaluation of the interventional pulmonology market,” said Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. “Thanks to its *in vivo* cellular imaging capability, Cellvizio can be used as a real-time detection tool for lung cancer with very high accuracy. In 2021, an estimated 235,760 Americans will be diagnosed with lung cancer⁴ and will be receiving an average of 1.6 lung nodule biopsies of which 40% to 60% will be bronchoscopic⁵. This represents an expected 150,000 to 225,000 bronchoscopic biopsy procedures in 2021 alone. Importantly, this annual procedure run-rate is expected to grow as a result of more early-stage screening-detected lung cancer cases, which represents a very compelling market opportunity to further expand the use of Cellvizio in the years to come.”

¹ Ito Fukunaga M, Wiener RS, Slatore CG. The 2021 US Preventive Services Task Force Recommendation on Lung Cancer Screening: The More Things Stay the Same.... *JAMA Oncol.* 2021;7(5):684–686. doi:10.1001/jamaoncol.2020.8376. https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/file/supporting_documents/lung-cancer-newsbulletin.pdf

² Ost DE, Ernst A, Lei X, Kovitz KL, Benzaquen S, Diaz-Mendoza J, Greenhill S, Toth J, Feller-Kopman D, Puchalski J, Baram D, Karunakara R, Jimenez CA, Filner JJ, Morice RC, Eapen GA, Michaud GC, Estrada-Y-Martin RM, Rafeq S, Grosu HB, Ray C, Gilbert CR, Yarmus LB, Simoff M; AQUIRE Bronchoscopy Registry. Diagnostic Yield and Complications of Bronchoscopy for Peripheral Lung Lesions. Results of the AQUIRE Registry. *Am J Respir Crit Care Med.* 2016 Jan 1;193(1):68-77. doi: 10.1164/rccm.201507-1332OC. PMID: 26367186; PMCID: PMC4731617.

³ Wijmans L, Yared J, de Bruin DM, Meijer SL, Baas P, Bonta PI, Annema JT. Needle-based confocal laser endomicroscopy for real-time diagnosing and staging of lung cancer. *Eur Respir J.* 2019 Jun 20;53(6):1801520. doi: 10.1183/13993003.01520-2018. PMID: 31023849.

⁴ Source: SEER - Cancer Stat Facts: Lung and Bronchus Cancer : <https://seer.cancer.gov/statfacts/html/lungb.html>

⁵ Chiu YW, Kao YH, Simoff MJ, Ost DE, Wagner O, Lavin J, Culbertson RA, Smith DG. Costs of Biopsy and Complications in Patients with Lung Cancer. *Clinicoecon Outcomes Res.* 2021 Mar 17;13:191-200. doi: 10.2147/CEOR.S295494. PMID: 33762834; PMCID: PMC7982449.



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 revolutionizing the way physicians diagnose and treat patients — making a transformative change in medicine. For more information, visit www.maunakeatech.com.

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