

## Mauna Kea Technologies Announces First Patient Enrolled in the Pivotal CLEVER Clinical Trial in Peripheral Lung Cancer

*Ongoing enrollment of over 200 patients across 7 sites in Europe and the U.S.*

Paris and Boston, November 2, 2023 – 08:00 a.m. CET – Mauna Kea Technologies (Euronext Growth: ALMKT), inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces the first patient enrollment in the multi-center randomized controlled trial (RCT) entitled "Confocal Laser Endomicroscopy VERification" (CLEVER, NCT06079970)<sup>1</sup> in collaboration with the Amsterdam University Medical Centers (UMC) for the diagnosis and management of peripheral lung lesions. In the framework of this trial, over 200 patients will be enrolled across 7 sites in Europe and the U.S. until end of Q2 2025.

Lung cancer is the world's leading cause of cancer deaths claiming over 1.8 million lives every year - more than colorectal, breast, and prostate cancers combined. The rise in lung cancer screening and the increased use of chest-computed tomography (CT) has generated a surge in the detection of suspected malignant lung lesions globally, increasing the need for more effective and efficient diagnostic methods. Over 80% of these incidental lesions develop in the peripheral bronchi and are not easily visualized or accessed during conventional bronchoscopy. Adding nCLE as an adjunctive technique offers a potential solution by providing real-time feedback on the correct positioning of biopsy tweezers or needles (tool-in-lesion) and collecting the right cells samples (lesion-in-tool).

**Jouke T. Annema, M.D., Ph.D., Professor of Pulmonary Endoscopy**, declared: *"Over the past few years, we have established solid foundations for the use of nCLE as an important tool in the armamentarium of the interventional pulmonologist. With this new randomized controlled trial involving some of the best interventional pulmonologists in Europe and in the U.S., we aim at confirming in a definitive way that the addition of needle-based Confocal Laser Endomicroscopy to bronchoscopy enhances the diagnostic yield for peripheral lung lesions, while also improving the clinical workflow."*

**Sacha Loiseau, Ph.D., Chairman and CEO of Mauna Kea Technologies**, commented: *"Diagnosing peripheral pulmonary nodules is a critical step in effectively treating lung cancer patients, but current tools often don't measure up. This collaboration with Amsterdam UMC is another exciting opportunity to evaluate and quantify Cellvizio's superior diagnostic capabilities. As we push forward with this study, our aim is not only to underscore Cellvizio's advantages but also to increase our value proposition for potential strategic partnerships."*

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<sup>1</sup> <https://clinicaltrials.gov/study/NCT06079970>, "Confocal Laser Endomicroscopy VERification (CLEVER)", October 12, 2023

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**About Mauna Kea Technologies**

Mauna Kea Technologies is a global medical device company that manufactures and sells Cellvizio<sup>®</sup>, 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<sup>®</sup> 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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