

## Mauna Kea Technologies Announces the Publication of Positive Results of a Randomized Controlled Trial in the Field of Interstitial Lung Disease

***Confocal Laser Endomicroscopy with Cellvizio proven superior to X-ray fluoroscopy for the guidance of transbronchial cryobiopsy, offering a ground-breaking new horizon in Interstitial Lung Disease (ILD) diagnosis***

Paris and Boston, October 17, 2023 – 8:00 a.m. CEST – Mauna Kea Technologies (Euronext Growth: ALMKT) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces the publication in the peer-reviewed journal *Respiration* of positive results from a large randomized controlled trial (RCT) proving the superiority in precision and safety of Cellvizio-guided transbronchial cryobiopsy for the diagnosis of Interstitial Lung Disease (ILD).

In a ground-breaking study<sup>1</sup> published online on September 27, 2023, physicians from the Respiratory Center of the Second Affiliated Hospital of Xiamen Medical College, Xiamen, China unveiled a significant advancement in the diagnosis of ILD through the combined application of Confocal Laser Endomicroscopy (CLE) and Transbronchial Cryobiopsy (TBCB).

The trial, conducted between January and November 2022, involved 80 patients with undiagnosed ILD and requiring a biopsy. The patients were divided into two randomized groups, with one utilizing Cellvizio and the other fluoroscopy to guide the transbronchial cryobiopsy device. Remarkably, the CLE group showcased a significantly higher rate of achieving a diagnosis (95% vs. 80%), alongside a 30% reduction in operation time, a 45% reduction in bleeding and most notably a much lower incidence of pneumothorax (0% vs. 25%), compared to the fluoroscopy group.

*“Transbronchial cryobiopsy is becoming a key tool in the diagnosis of ILDs and a fast-growing procedure worldwide. These new results of a large randomized controlled trial show that the use of Cellvizio as a guidance to transbronchial cryobiopsy not only enhances the precision of ILD diagnosis but also ensures a much safer and more efficient procedure for patients, thus opening the door to a new significant market opportunity for Cellvizio in interventional pulmonology”,* stated **Sacha Loiseau, Ph.D., CEO and Founder of Mauna Kea Technologies**. *“We are proud to witness the transformative impact of our Cellvizio platform in advancing the efficacy and diagnosis of Interstitial Lung Disease, a group of diseases that affects millions of people worldwide.”*

### **About Interstitial Lung Diseases (ILDs)**

Interstitial Lung Disease (ILD) represents a diverse group of over 200 lung disorders that primarily affect the interstitium, the tissue and space around the air sacs in the lungs. These diseases can lead to scarring (fibrosis) of the lungs, which can affect a person's ability to breathe and get enough oxygen into the bloodstream. The

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<sup>1</sup> Cuiyun Zuo, Keying Xue, Hui Yang, Rui Huang, Zhiya Yong, Meihua Zhang, Yanli Lin, Xiaoqin Tian, Yingying Gu, Mingyao Ke; Clinical Application of Confocal Laser Endomicroscopy Combined with Cryobiopsy in the Diagnosis of Interstitial Lung Disease. *Respiration* 2023; <https://doi.org/10.1159/000533868>

symptoms often include dry cough and shortness of breath that can be accompanied by fatigue and weight loss. In 2019, there were an estimated 654,841 cases of ILDs in the USA, leading to 21,505 deaths<sup>2</sup>. The crude prevalence per 100,000 was 179.7 in males and 218.9 in females. While the exact cause of many types of ILD remains unknown, some can be linked to prolonged exposure to harmful substances, autoimmune diseases, or certain medications. Early diagnosis and tailored treatment are crucial to managing the disease and improving the quality of life for those affected.

### **About Transbronchial Cryobiopsy (TBCB)**

Transbronchial cryobiopsy is a newer diagnostic procedure used to obtain lung tissue samples for the diagnosis of various lung diseases, especially interstitial lung diseases. Unlike the conventional transbronchial biopsy, which uses forceps, the cryobiopsy utilizes a probe cooled by cryogenic gases to freeze and extract a larger and more intact tissue sample from the lungs. This can provide a more accurate diagnosis, as the obtained samples are generally of better quality and larger size than those from traditional methods.

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### **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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<sup>2</sup> *The prevalence and burden of interstitial lung diseases in the USA*

[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8819246/#:~:text=In%202019%2C%20in%20the%20USA,in%20females%20\(table%201\)](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8819246/#:~:text=In%202019%2C%20in%20the%20USA,in%20females%20(table%201))



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