Mauna Kea Technologies Announces First of Its Kind U.S. FDA 510(k) Clearance for Use of Cellvizio in a New Category of Molecular Imaging-guided Endoscopic, Laparoscopic, Needle-Based Procedures

Completion of a Major Regulatory Milestone for Molecular Imaging and Precision Medicine as Part of Ongoing Collaboration

Paris and Boston, April 12, 2022 – 5:45 pm CEST – Mauna Kea Technologies (Euronext: MKEA, 'Mauna Kea') inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform today announced a new U.S. FDA 510(k) clearance (K220477) for the use of the Cellvizio 100 Series platform with a molecular imaging agent, the first of its kind, for real-time *in vivo* visualization during endoscopic, laparoscopic, and needle-based procedures.

This U.S. FDA clearance is for a new clinical indication for the use of Cellvizio to perform fluorescence imaging of tissues that have taken up the drug Pafolacianine, marketed under the trade name CYTALUX™ and manufactured by On Target Laboratories, consistent with its approved use and administration labeling. Additionally, the clearance includes a new clinical indication for the use of Cellvizio to perform fluorescence imaging and visualization of ICG (indocyanine green), either intravenously or interstitially, consistent with ICG approved use and administration labeling. The 510(k) includes all Cellvizio Confocal Miniprobes™ across all cleared clinical indications.

The pioneering category of medical procedures expanded through this new clearance – Molecular Image-guided Procedures (MIP) – is designed to provide Cellvizio the unique clinical ability to visualize tissues to which the molecular agents bind, allowing the potential for real-time visualization of cancer at the cellular level during minimally invasive interventions. The use of MIP during bronchoscopic lung biopsy may improve the diagnostic accuracy of biopsies while reducing the number of procedures, time, and complications associated with obtaining a diagnosis.

"While the suite of tools to diagnose and treat lung cancer has evolved over the past few decades, there remains a significant unmet need to improve how early and how accurately patients can be staged and treated after lung nodule detection," said Nicolas Bouvier, Interim Chief Executive Officer of Mauna Kea Technologies. "Importantly, this clearance represents a major step forward in the collaboration between On Target Laboratories and Mauna Kea to address significant unmet needs in interventional pulmonology and lung cancer. In addition, it opens the door for a transformational shift in the application of precision medicine to interventional pulmonology and potentially other indications as well."

The clearance represents Mauna Kea's 20th U.S. FDA 510(k) for the Cellvizio® p/nCLE platform and reflects Mauna Kea Technologies' ongoing work with the U.S. FDA to build a unique range of indications for Cellvizio: imaging of the internal microstructure of tissues including, but not limited to, the identification of cells, vessels and their organization or architecture; imaging blood flow in vascular areas, including microvasculature and capillaries; and for the near-infrared version of Cellvizio, fluorescence angiography and visualization of the lymphatic system, including lymphatic vessels and lymph nodes with ICG and fluorescence imaging of tissues that have taken up the CYTALUX drug.

This latest clearance also reflects the U.S. FDA's success in implementing portions of the 21st Century Cures Act and thus facilitating the availability of safe and effective device/drug combination products to healthcare professionals for improved patient care.

About Lung Cancer

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[1]. Its diagnosis remains challenging, despite significant advancements in diagnostic and treatment technologies. The number of lung nodules identified on chest CTs continues to rise with one study estimating that, in the U.S. alone, nearly 1.6 million people who underwent a chest CT had a pulmonary nodule identified[2]. Determining if a suspicious pulmonary nodule is malignant or benign can be challenging and time-consuming, often requiring multiple biopsy attempts and/or invasive procedures that can result in inconclusive results and complications. The rapidly growing field of molecular imaging aims to improve the detection of cancer cells through easier and more precise visualization.

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.

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Mauna Kea Technologies

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[1] International Agency for Research on Cancer, World Health Organization. Cancer fact sheet: all cancers. http://gco.iarc.fr/today/data/factsheets/cancers/39-All-cancers-fact-sheet.pdf. Accessed May 2020.

[2] Gould MK, Tang T, Liu IL, Lee J, Zheng C, Danforth KN, Kosco AE, Di Fiore JL, Suh DE. Recent Trends in the Identification of Incidental Pulmonary Nodules. Am J Respir Crit Care Med. 2015 Nov 15;192(10):1208-14. doi: 10.1164/rccm.201505-0990OC. PMID: 26214244.