



Mauna Kea Technologies Announces Positive Results on Needle-Based Endomicroscopy for Real-Time Diagnosis and Staging of Lung Cancer

Clinical study results published in the European Respiratory Journal demonstrate that lung cancer characteristics can be accurately recognized with Cellvizio® AQ-Flex™ 19 Confocal Miniprobe™ used through fine needles

Paris and Boston, May 6, 2019 – 5.45 PM CEST – Mauna Kea Technologies (Euronext: MKEA,) inventor of Cellvizio®, the multidisciplinary probe-based and needle-based confocal laser endomicroscopy (pCLE/nCLE) platform, today announced the publication of a prospective study (ClinicalTrials.gov Identifier: [NCT02689050](https://clinicaltrials.gov/ct2/show/study/NCT02689050)) that demonstrates the potential of nCLE to aid in the diagnosis and staging of lung cancer. The article, entitled “Needle-based confocal laser endomicroscopy for real-time diagnosing and staging of lung cancer,” was published in the *European Respiratory Journal* (2019, DOI: 10.1183/13993003.01520-2018) and can be downloaded here: <https://erj.ersjournals.com/content/early/2019/03/15/13993003.01520-2018>.

Lung cancer is the world’s leading cause of cancer deaths. According to the Centers for Disease Control, more than 400 Americans die every day from this disease. The majority of suspicious lesions found during screening are located in difficult to access areas making accurate diagnoses challenging. Novel navigation techniques could improve minimally invasive access to these difficult to access peripheral nodules. However, sub-millimetric guidance to the core of a peripheral nodule remains difficult to achieve without direct through-the-needle visualization. The recently 510(K) cleared Cellvizio AQ-Flex™ 19 confocal Miniprobe™ provides direct through-the-needle visualization.

“The use of needle-based endomicroscopic imaging provides accurate results on the nature of pulmonary lesions and metastatic lymph nodes,” said J. T. Annema, M.D. Ph.D., professor of Pulmonary Endoscopy, Amsterdam University Medical Centers. “In this well designed clinical pilot study, we have shown that nCLE enables an 89% accuracy for detecting malignancy in lung tumors and metastatic lymph nodes with substantial intra- and inter-observer agreements. These promising results support the fact that nCLE might qualify as an important adjunct to navigation bronchoscopy for real-time targeting and identification of lung tumors.”

“This is an important publication that further supports new market opportunity within interventional pulmonology,” said Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. “It provides evidence that the use of our needle-based endomicroscopy platform is opening a new era in interventional pulmonology, paving the way toward more precise guidance to identify the optimal area for sampling and as a real-time feedback technique for diagnostic, staging and treatment procedures in lung tumors. Cellvizio® is the first-to-market endomicroscopic device integrable in robot-assisted bronchoscopic navigational platforms.”

Mr. Gershon continued: *“One of our three strategic priorities for 2019 is evaluating the interventional pulmonology market as Mauna Kea’s next commercial focus-area. We look forward to providing updates as we progress through this formal evaluation process. Importantly, we remain focused on executing the other two strategic priorities for 2019: driving consumable growth in our installed base in the U.S. GI market, our primary market for commercialization focus, and driving revenue growth in GI markets outside the U.S., but doing so in a targeted fashion in an effort to maximize the resources we invest in international markets.”*

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real time in vivo microscopic visualization. The Company’s flagship product, Cellvizio®, has received clearance/approval in a wide range of applications in



more than 40 countries, including the United States, Europe, Japan, China, Canada, Brazil and Mexico. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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