Mauna Kea Technologies Announces Start of Enrollment in Peripheral Lung Cancer Multi-Center Clinical Trial

Study will advance the validation of Cellvizio® as a real-time biopsy guidance tool during robotic-assisted bronchoscopy that may reduce the near-miss rate of peripheral lung cancer

Paris and Boston, February 22, 2022 – 5:45 PM CET – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces that, as part of its collaboration with the Lung Cancer Initiative ("LCI") at Johnson & Johnson[1], initial enrollment of patients has begun in a prospective, multi-center, open-label, single-arm clinical feasibility study sponsored by LCI. The study will combine nCLE and robotic-assisted bronchoscopy, using both Cellvizio and the Monarch® Platform from Auris Health, Inc., a subsidiary of Ethicon, Inc., part of the Johnson & Johnson Medical Devices Companies, to assess the capability of nCLE to accurately confirm needle position for the diagnosis of peripheral lung nodules (Clinicaltrials.gov: NCT05231278).

The primary objective of this study, named CLEAR (Confocal Laser Endomicroscopy nodule locAlization by Robotic Bronchoscopy), is to evaluate the ability of nCLE to confirm successful navigation of the biopsy needle ("tool-in-lesion") during peripheral lung nodule procedures, as confirmed by cone beam CT. The secondary objectives are to evaluate the reproducibility of using nCLE across multiple facilities and to evaluate the ability of nCLE to diagnose malignancy vs. non-malignancy, including exploring diagnostic yield at the index procedure. This study will include up to 75 patients with peripheral lung nodules in at least 3 U.S. centers.

"I am very excited to start the CLEAR study, which combines two breakthrough technologies," said Sandeep Bansal, MD, Medical Director of The Lung Center and Interventional Pulmonology at Penn Highlands Healthcare, DuBois, Pennsylvania. "The Monarch Platform is designed to provide vision, precision, and stability during peripheral lung nodule biopsy procedures. With its unique capability to visualize individual cells and structures at the tip of the needle during bronchoscopy, Cellvizio could provide real-time tool-in-lesion confirmation and potentially reduce the current near-miss rate of peripheral lung nodules."

"We are pleased to announce the start of this important clinical study in collaboration with the LCI," said Nicolas Bouvier, interim Chief Executive Officer of Mauna Kea Technologies. "This builds on the recent completion of enrollment of the first in human clinical study combining robotic-assisted bronchoscopy and nCLE for the diagnosis of peripheral lung nodules[2] and we look forward to validating further Cellvizio's role in this critical and strategic indication."

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.

[1] The legal entity of the Lung Cancer Initiative at Johnson & Johnson is Johnson & Johnson Enterprise Innovation, Inc.

[2] Clinicaltrials.gov: NCT04441749

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