# LEADING U.S. PULMONOGISTS TO INVESTIGATE IMPACT OF MAUNA KEA TECHNOLOGIES' CELLVIZIO ON LUNG CANCER DIAGNOSIS

Optical biopsies of lung tissue expected to improve accuracy of bronchoscopy procedures, reducing the need to repeat invasive, expensive diagnostic tests for lung cancer

PARIS (March 21, 2013) — Mauna Kea Technologies (NYSE Euronext: MKEA), leader in the optical biopsy market and developer of Cellvizio®, the fastest way to see cancer, announced today that it has launched a registry study to determine the impact of Cellvizio optical biopsies on the diagnosis of lung cancer, the leading cause of cancer death in the world. Previous studies have shown that Cellvizio's real-time, cellular-level views of distal lung tissue extend the reach and improve the diagnostic accuracy of bronchoscopy procedures, reducing the need to repeat invasive, expensive diagnostic tests.

The registry will include 200 patients enrolled at up to ten leading U.S. lung centers.

"Data from the recently-published National Lung Screening Trial (NLST) suggest that lung cancer screening with low-dose CT chest scans in long-term smokers leads to early detection and improved survival. However, the very high false positive rate associated with CT scans often results in additional diagnostic procedures to evaluate a lesion," said Sandhya Khurana, MD, Associate Professor of Medicine, Pulmonary Diseases, and Critical Care at the University of Rochester Medical Center (URMC). Dr. Khurana is one of the Principal Investigators of the Cellvizio U.S lung registry. "Our goal is to accurately diagnose these lesions by using the least invasive, lowest risk and highest-yield tests."

According to the NLST, a study sponsored by the National Institutes of Health and originally published in the *New England Journal of Medicine*, 96.4 percent of CT scans generated false positives for lung cancer. Based on a recent analysis of the data, 24 out of every 100 patients screened will have lesions and only one of the 24 will eventually be diagnosed with lung cancer. Getting to a final diagnosis can be quite taxing on patients because of the limitations of traditional bronchoscopes and tissue biopsy techniques. Recent studies have found that 31% of lung lesion biopsies need to be repeated<sup>i</sup> due to radiologists and pathologists requesting additional information.

"Cellvizio offers a potential new way for pulmonologists to achieve accurate real-time characterization of tissue as benign or malignant, particularly in areas of the lung not directly accessible to the bronchoscope," Dr. Khurana said. "Using a navigational bronchoscopy system to guide physicians to the suspicious lesions could further enhance diagnostic accuracy of optical biopsies and decrease the need for additional invasive diagnostic procedures. We are excited to be a part of this important trial."

Dr. Khurana and Dr. Michael Nead, study co-investigator, enrolled the first Cellvizio lung registry patient at URMC earlier this month.

The U.S. lung registry study is a prospective observational study which will aim to refine the criteria to differentiate healthy versus diseased tissue in patients with discrete lung lesions. Once these criteria have been refined, the diagnostic parameters and the reproducibility of optical biopsies will be assessed. Investigators will also use the registry to characterize acute

lung rejection in patients with transplanted lungs. The Food and Drug Administration-cleared AlveoFlex™ probe is 1.4 mm in diameter and works with a standard bronchoscope.

Other participating centers include the Mayo Clinic in Jacksonville, FL; the University of Chicago Pritzker School of Medicine/University of Chicago Medical Center; University of Michigan Medical School/University of Michigan Medical Center; and Ohio State College of Medicine/Wexner Medical Center.

"Since receiving its CE mark and FDA clearance for probes used in digestive and pulmonary tracts in 2005, the company has focused its efforts on developing a strong foothold in the endoscopy market. The U.S. lung registry, our first, large multi-center study in pulmonology, will provide key performance data on the value of Cellvizio to separate out benign nodules from malignant nodules," said Sacha Loiseau, PhD, Founder and CEO of Mauna Kea Technologies.

To learn more, please visit http://www.clinicaltrials.gov/ct2/show/NCT01793246.

#### **About Lung Cancer**

According to the American Cancer Society, an estimated 228,190 people in the U.S. will be diagnosed with lung cancer in 2013 and that 159,480 men and women will die of the disease, making it the leading cause of cancer death in the U.S.

#### **About Mauna Kea Technologies**

Mauna Kea Technologies is a global medical device company dedicated to the advent of optical biopsy. The company researches, develops and markets innovative tools to visualize and detect cellular abnormalities during endoscopic procedures. Its flagship product, Cellvizio®, a probe-based Confocal Laser Endomicroscopy (pCLE) system, provides physicians and researchers high-resolution cellular views of tissue inside the body. Large, international, multicenter clinical trials have demonstrated Cellvizio's ability to help physicians more accurately detect early forms of disease and make treatment decisions immediately. Designed to improve patient outcomes and reduce costs within a hospital, Cellvizio can be used with almost any endoscope. Cellvizio has 510(k) clearance from the U.S. Food and Drug Administration and the European CE-Mark for use in the GI tract, biliary and pancreatic ducts and lungs.

For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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<sup>&</sup>lt;sup>1</sup> Ricardi et al. (2008). Accuracy of CT-guided transthoracic needle biopsy of lung lesions: Results of 612 consecutive procedures. *Journal of Clinical Oncology*. Part I. Vol 25, No. 18S (June 20 Supplement), 2007: 18022