# Mauna Kea Technologies Announces New Data Supporting Clinical Utility of Cellvizio(R)

The Associated Press

Mauna Kea Technologies (NYSE Euronext: MKEA) leader in the optical biopsy market and developer of Cellvizio®, the fastest way to see cancer, today announced that more than nine presentations at the American College of Gastroenterology Annual Scientific Meeting (ACG) continue to validate the role of optical biopsy to speed and direct treatment decisions for digestive diseases including pancreatic, stomach, rectal cancers and Barrett's Esophagus. Physicians also reported that Cellvizio may play an important role in the diagnosis of irritable bowel syndrome (IBS). ACG took place in Las Vegas from October 19 to 24.

Clinical Highlights

Pancreatic Cancer

In an oral presentation on October 24, Kenneth J. Chang, M.D., Professor and Chief of the Division of Gastroenterology and Executive Director of the H.H. Chao Comprehensive Digestive Disease Center at the University of California, Irvine School of Medicine, announced updated results of the DETECT (Diagnosis of Pancreatic Cysts: Endoscopic Ultrasound, Through the Needle Confocal Laser-induced Endomicroscopy and Cystoscopy Trial) (i) study designed to evaluate the safety and effectiveness of using the new Cellvizio miniprobe designed for imaging solid organs through a needle.

Dr. Chang reported that using the miniprobe is safe and may help physicians more accurately differentiate benign and cancerous pancreatic cysts to determine with more certainty if the patient needs immediate surgery.

"A growing body of clinical data with this new miniprobe shows that optical biopsies help gastroenterologists confirm and rule out pancreatic cancer in real time so we can make more informed, immediate, targeted treatment decisions for our patients," said Dr. Chang. "If larger studies confirm these promising early results, we expect this to lead to a significant change in how physicians manage their patients for this disease, which is probably the most dangerous digestive cancer."

Pancreatic cysts are abnormal pockets of fluid on or within the pancreas. While most of these lesions are benign, some pancreatic cysts, particularly those deemed to be "mucinous", need to be surgically removed because the risk of harboring or developing a malignancy is important. Pancreatic cancer is associated with high mortality rates, due largely to late diagnosis and to its resistance to chemotherapy and radiation therapy.

This new miniprobe is known as the AQ-Flex 19. It has received the European CE

Mark and clearance in Israel earlier in 2012. The company is working to obtain FDA clearance in the U.S.

In a separate poster presentation on October 22, investigators from Weill Cornell Medical College reported that when using another type of Cellvizio miniprobe, which views the inside of the ducts that lead to and from the pancreas, they were able to more effectively differentiate malignant from inflamed tissue and plan surgeries for patients with suspected pancreatic cancer.(ii)

Stomach Cancer

In another oral presentation, Dr. Chang also presented the results of one of the first studies to investigate the benefits of adding optical biopsies to endoscopies to diagnose gastric intestinal metaplasia(iii) (GIM), a pre-malignant condition that can lead to stomach cancer. Currently, physicians use endoscopes and random tissue biopsies to diagnose the condition, but sampling errors are very common and beleaguer accurate diagnosis.

Dr. Chang and his colleagues first defined the key cellular structures associated with the pre-cancerous condition in the Cellvizio videos. In the second part of the study, they prospectively showed that when one or both of the features were present, optical biopsies are an effective way to diagnose GIM on the spot during an endoscopy. When using several features identified, sensitivity reached 92.7% and specificity was 97.2% ($p$-value $< 0.001$).

With GIM, the normal lining of the stomach is replaced with cells that closely resemble the cells that usually line the intestine. GIM is a precursor for stomach cancer. The American Cancer Society estimates that about 21,320 cases of stomach cancer will be diagnosed in 2012 and that about 10,540 Americans will die from this type of cancer. Stomach cancer is even more common in other parts of the world, particularly in Asia.

Rectal Cancer

In a poster session on October 22, Georgetown University Hospital physicians presented the results of a study showing that optical biopsies can successfully aid in the management of residual or reoccurring colorectal cancer. Optical biopsies with Cellvizio helped them pinpoint the presence of adenomas in all patients, resulting in a 100% accuracy rate. The utilization of optical biopsies in endoscopic resections of lower rectal adenomas can also prevent future unnecessary repeat procedures and interventions, they concluded.(iv)

The ACS estimates that 40,290 new cases of rectal cancer will be diagnosed in the U.S. during 2012. Mortality rates from both colon and rectal cancer are improving with widespread screening programs.

Barrett's Esophagus

Barrett's esophagus is a potentially pre-cancerous condition that arises from chronic

gastro-esophageal reflux disease (GERD). New advanced endoscopic tools have made it possible for physicians to perform endoscopic treatment of the esophagus to remove dangerous tissue, but these patients must undergo surveillance to ensure that the condition doesn't return. Currently, most physicians use imprecise random tissue sampling techniques to look for residual cancer.

In a poster session on October 22, physicians from the Cleveland Clinic reported that optical biopsies for surveillance, biopsy targeting, and resections in patients who had undergone previous therapy for Barrett's Esophagus were a less-invasive, quicker alternative to the current reference technique.(v)

The ACS estimates that about 17,460 new esophageal cancer cases diagnosed during 2012 and that 15,070 Americans will die from the disease this year.

IBS

There is currently no single test to diagnose patients with Irritable Bowel Syndrome (IBS), so physicians take information from numerous sources and consider the patient's symptoms. Researchers at University of Alberta in Canada hypothesized that intestinal barrier dysfunction in IBS patients may be caused by increased extrusion of epithelial cells. In healthy patients, dying cells are replaced by new cells in equal numbers, but an imbalance may occur in IBS patients.

In a prospective, controlled cohort study of 17 IBS patients and 18 healthy controls(vi), Julia Liu, MD, MSc., and colleagues used Cellvizio to measure gaps, or the spaces in the lining of the gut. She found that these gaps occurred in about two-thirds (64 percent) of patients with IBS, while 90 percent of the healthy patients had no evidence of these gaps. These findings suggest that a patient with a positive test has a 73 percent chance of having IBS.

Dr. Liu presented the results of her study during the ACG's press conference on new technologies advancing the treatment of gastrointestinal disorders on Oct. 22.

"These findings add to the large body of data showing the increasing impact that Cellvizio and optical biopsies are having on the diagnosis and treatment of many of the most pervasive diseases and cancers," said Sacha Loiseau, CEO and Founder of Mauna Kea Technologies. "We will continue to work with leaders in endoscopy and surgery to expand indications for this ground-breaking technology and to inform our research and development initiatives to most effectively meet their needs as clinicians for better, faster diagnostic tools."

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 about Mauna Kea Technologies, visit www.maunakeatech.com

(i) Chang, K., et al. Diagnosis of Pancreatic Cysts: Endoscopic Ultrasound, Through the Needle Confocal Laser-induced Endomicroscopy and Cystoscopy Trial (DETECT Study). Program No.58. ACG 2012 Annual Scientific Meeting Abstracts. Las Vegas, NV: American College of Gastroenterology

(ii) Kahaleh, M., et al. Probe-Based Confocal Laser Endomicroscopy in the Pancreatic Duct Provides Direct Visualization of Ductal Structureds and Aids in Clinical Management. Program No. P652. ACG 2012 Annual Scientific Meeting Abstracts. Las Vegas, NV: American College of Gastroenterology

(iii) Chang, K., et al. In-Vivo Diagnosis of Gastric Intestinal Metaplasia Using Probe-Based Confocal Laser-Induced Endomicroscopy (pCLE). Program No. 61. ACG 2012 Annual Scientific Meeting Abstracts. Las Vegas, NV: American College of Gastroenterology.

(iv) Al-Kawas FH, et al. Does pCLE Have a Role in the Post Endoscopic Resection Follow-Up of Sessile Rectal Adenomas?. Program No. P1032. ACG 2012 Annual Scientific Meeting Abstracts. Las Vegas, NV: American College of Gastroenterology.

(v) Jang, SN, et al. Comparison of Probe-based Confocal Endomicroscopy to Standard Endoscopy with Biopsies for Patients who Underwent Endoscopic Mucosal Resection for Barrett's Esophagus-related Dysplasia or Intramucosal Adenocarcinoma. Program No. P1047. ACG 2012 Annual Scientific Meeting Abstracts. Las Vegas, NV: American College of Gastroenterology.

(vi) Liu, J, et al. Confocal Laser Endomicroscopy Findings Of The Small Intestine In Irritable Bowel Syndrome (IBS). Program No. 52. ACG 2012 Annual Scientific Meeting Abstracts. Las Vegas, NV: American College of Gastroenterology.

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