# MAUNA KEA TECHNOLOGIES ANNOUNCES RECORD 50 CELLVIZIO® STUDIES PUBLISHED THIS YEAR SO FAR

- Number of studies published in 2012 already equals total for all of 2011. Over 190publications total on Cellvizio have been published to date
- Data highlights include breakthroughs in the detection and treatment of cancer of the bile duct, esophagus and bladder, and inflammatory bowel disease (IBD) -

PARIS, August 23, 2012 – Mauna Kea Technologies (NYSE Euronext: MKEA), leader in the endomicroscopy market and developer of Cellvizio® imaging, the fastest way to see cancer, today announced that clinicians have published more than 50 new scientific publications showing Cellvizio's clinical utility already in 2012, equal to the number of studies that were published during all of 2011. This new body of evidence brings the total number of Cellvizio publications to 190 and the total number of publications on endomicroscopy to 353.

Link to Online Bibliography: <a href="http://www.maunakeatech.com/healthcare-professionals/445/bibliography">http://www.maunakeatech.com/healthcare-professionals/445/bibliography</a>

These new studies support the use of real-time cellular-level imaging with Cellvizio to help physicians immediately confirm or rule out cancer or other diseases throughout the body so they can make informed treatment decisions at the patient's bedside. Data highlights include breakthroughs in the detection and treatment of cancer of the bile duct, esophagus and bladder, and inflammatory bowel diseases (IBD) like Crohn's disease and ulcerative colitis.

Physicians worldwide use Cellvizio images to generate optical biopsies that are microscopic, real-time, and non-invasive. The information that Cellvizio provides allows physicians to make more informed treatment decisions on the spot. Disease can be ruled out immediately with high accuracy and the need for unnecessary, random biopsies is eliminated.

"A growing body of important evidence confirms the benefit of using real-time cellular level imaging to diagnose and treat patients with a range of cancers more effectively and efficiently," said Sacha Loiseau, CEO and Founder of Mauna Kea Technologies. "We are working with leaders across medical specialties to increase the understanding of the positive impact that access to cellular level imaging with Cellvizio can have on improving patient outcomes and lowering long-term healthcare costs."

#### Clinical Publication Highlights

## **Bile Duct Cancer**

Physicians have identified a set of visual features in Cellvizio images that can be used to confirm or rule out early signs of cancer in the bile ducts (cholangiocarcinoma), a highly lethal form of cancer. By using this set of pre-defined criteria, different physicians who viewed Cellvizio images reached similar conclusions about the patient's condition, showing that these criteria could be systematically and reliably applied by a group of physicians to confirm or rule out cancer.

"Standard diagnostic procedures to identify or exclude bile duct cancer are notoriously inaccurate, missing up to half of the cancers," said Adam Slivka, MD, PhD, Associate Chief of the Division of Gastroenterology, Hepatology and Nutrition at the University of Pittsburgh Medical Center (UPMC). "With the miniaturized Cellvizio probes and this set of pre-defined criteria, we are able to visualize the lining of the bile ducts and understand the images so we can differentiate malignant tissue from inflammation in a majority of cases. This is a significant step forward in the diagnosis of this very dangerous disease that is often missed or caught too late."

Final results of a multicenter, prospective, randomized, controlled study were published in the March 2012 issue of *Endoscopy*, the premier journal for information on the latest technologies and international developments in gastrointestinal endoscopy.

## **Esophageal Cancer**

New data also show that Cellvizio is an effective tool to improve how physicians monitor and treat patients with Barrett's esophagus, a condition that arises from chronic gastroesophageal reflux disease (GERD) that can lead to esophageal cancer.

Previously, when physicians saw signs of Barrett's esophagus, they had to take random biopsies to identify pre-cancerous tissue. If they ultimately found early forms of cancer, the patient would often have to undergo surgery to remove the esophagus. Cellvizio was designed to help physicians guide those treatments more effectively so patients can avoid major surgery and unnecessary biopsies.

A study published in the May 2012 issue of *Case Reports in Gastroenterology*, showed Cellvizio can be used prior to endoscopic therapy to identify areas of concern, guide targeted biopsies and target additional therapy to that area in Barrett's esophagus patients. Post treatment, Cellvizio can be used to assess the accuracy and completeness of each minimally invasive endoscopic therapy, such as endomucosal resections (EMR) and radio-frequency ablation (RFA) procedures.

In a separate 100-patient study published in the August 2012 issue of *Digestive Disease and Science*, adopting the pCLE technique in Barrett's Esophagus surveillance programs was found to result in earlier diagnoses of early esophageal cancer. Replacing standard tissue biopsies with in-vivo, real time tissue characterization using Cellvizio also extended the intervals required for patients to undergo endoscopies and ultimately improved the cost-effectiveness of Barrett's Esophagus surveillance programs.

# **Inflammatory Bowel Diseases**

Inflammatory bowel disease (IBD) is a group of inflammatory conditions of the colon and small intestine. The major types of IBD are Crohn's disease and ulcerative colitis. The Center for Disease Control and Prevention estimates that as many as 1.4 million people in the United States suffer from these diseases. According to a study published in the June 2012 issue of *International Journal of Clinical Experimental Pathology*, Cellvizio in combination with other techniques can successfully detect early signs of Crohn's disease.

In a separate review article published in the March 2012 issue of *Gastroenterology Research and Practice*, Cellvizio allowed physicians to detect early signs of IBD and also monitor how well patients react to therapies. According to the review article, Cellvizio can help rule out unnecessary biopsies and allow at-the-bedside management decisions and surveillance.



#### **Bladder Cancer**

A study out of Stanford University shows that, as an adjunct to white light cystoscopy (WLC), Cellvizio offers the potential for real time bladder cancer characterization. It is estimated that nearly 73,000 new cases of bladder cancer will be diagnosed in the USA in 2012 alone and nearly 15,000 people will die from the disease. There are over 520,000 bladder cancer survivors in the United States. Because of its high recurrence rate of approximately 50-80% and the need for lifelong surveillance, bladder cancer is the most expensive cancer to treat on a per patient basis.

Physicians found a 100% accuracy rate for detection of low grade bladder cancer with white light cystoscopy (WLC) combined with Cellvizio in the 57-patient study published in the February 2012 issue of *Photonic Therapeutics and Diagnostics VIII*.

### **About Mauna Kea Technologies**

Mauna Kea Technologies is a global medical device company and leader in the endomicroscopy market. The company researches, develops and markets innovative tools to visualize and detect abnormalities in the gastro-intestinal and pulmonary tracts. 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 and pulmonary tracts.

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

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