



## **Cellvizio® Confocal Microscopy Improves ERCP Bile Duct Cancer Detection, According to New Study Presented at DDW**

### **- Mauna Kea Technologies Debuts Cellvizio® ERCP Miniprobe -**

**SAN DIEGO – May 18, 2008 --** Doctors may now be able to better diagnose cancer of the bile ducts, one of the most difficult cancers to detect and treat, according to a new study presented today at the Digestive Disease Week® (DDW) 2008 conference.

The 14-patient clinical trial (Abstract S1161) evaluated the ability of Mauna Kea Technology's Cellvizio® confocal microscopy system to detect cancer in biliary tract tissue by examining tissue at the cellular level during Endoscopic Retrograde Cholangiopancreatography (ERCP), a procedure used to diagnose cancer of the bile ducts and pancreas.

Dr. Alexander Meining and colleagues of the Technical University of Munich conducted the study and found that Cellvizio predicted cancer with an accuracy rate of 91.7%, which was superior to the 76.9% accuracy rate of histopathological analysis of biopsied tissue taken from strictures. Usually, the preoperative diagnosis of cancer of the bile ducts, medically known as cholangiocarcinoma, is associated with a low accuracy rate.

"Cellvizio represents a promising diagnostic imaging approach for the detection of cancer even in small ducts such as the biliary system," Dr. Meining said. "This new tool could be of utmost importance as cholangiocarcinoma remains one of the cancers with the poorest prognosis. We believe the potential for improved accuracy of diagnosis is due to the real-time, cellular-level images the technology provides on benign and malignant biliaro-pancreatic strictures."

At the conference, Mauna Kea debuted a specially designed miniprobe enabling its Cellvizio® GI System to be used with ERCP. Sacha Loiseau, Ph.D., president and CEO of Mauna Kea Technologies, said: "We now offer mini probes that can enable in vivo microscopy in virtually all segments of the gastrointestinal tract. We have received significant interest from the medical community in our ERCP probe and look forward to working closely with leading experts in the field to expand the body of data validating its utility in improving detection of pancreatic and bile duct cancer."

Cellvizio is the first and only confocal microscopy system that is compatible with most endoscopes. It can also be used with various advanced endoscopic modalities, such as narrow band imaging and autofluorescence imaging, and has 510(k) clearance from the Food & Drug Administration and the European CE-Mark for use in the gastrointestinal and pulmonary tracts. Over 1,000 Cellvizio procedures have been completed to date.

#### **About Cholangiocarcinoma**

Cholangiocarcinoma is a cancer of the bile ducts, which drain bile from the liver into the small intestine. With an annual incidence rate of one to two cases per 100,000 in the Western world, this disease has been steadily increasing over the past several decades. Risk factors include inflammation of the bile ducts and liver malfunctions. Symptoms include jaundice, weight loss and generalized itching. This disease is diagnosed through a combination of blood tests, imaging, endoscopy and sometimes surgical exploration. To date, surgery is the only potentially curative treatment.

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



Mauna Kea Technologies leads the growing in vivo cellular imaging market enabling physicians to visualize, diagnose and treat pathologies that can not be seen using other imaging techniques. Mauna Kea Technologies' flagship Cellvizio system provides microscopic visualization of mucosal tissue and promises to improve clinical outcomes by increasing the diagnostic yield of existing endoscopic procedures. Mauna Kea Technologies is currently focused on the gastroenterology and pulmonology markets. The company plans to expand into other markets in the future. The company also has a distribution agreement with Leica Microsystems to sell products for the Small Animal Imaging market in Europe, the U.S. and Japan. For more information about Mauna Kea Technologies: [www.maunakeatech.com](http://www.maunakeatech.com).

#### **About Digestive Disease Week 2008**

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 17-22, 2008, at the San Diego Convention Center, San Diego, CA. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit [www.ddw.org](http://www.ddw.org).

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### ABSTRACT

#### **EMBARGOED UNTIL SUNDAY, MAY 18, 2008 / 8:00 A.M. PACIFIC TIME**

#### **S1161**

Detection of Cholangiocarcinoma in-Vivo Using Miniprobe-Based Confocal Microscopy  
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Background: The preoperative diagnosis of cholangiocarcinomas is associated with a low accuracy. To overcome these limitations, a new imaging modality was developed and evaluated to detect neoplasia in vivo in the biliary tract. Methods: Mucosal imaging was performed with a confocal laser scanning miniprobe after intravenous injection of fluorescein 1%. After an initial feasibility study performed in two pigs, 14 patients with biliary strictures were examined in vivo with a specially designed miniaturized confocal laser probe thin enough to be inserted through the accessory channel of a peroral cholangioscope. Results: Presence of irregular vessels was the laser microscopic hallmark able to predict neoplasia with an accuracy of 91.7%. Confocal microscopy was thereby superior to histopathology of biopsy specimens taken from strictures (accuracy: 76.9%). Mean signal-to-noise-ratio of laser microscopic images acquired from

malignant strictures differed significantly from those of benign origin ( $p=0.003$ ). Figure shows confocal laser scanning microscopic images in patients with benign (a, b) or malignant strictures (c, d). Field of view is  $240 \times 240 \mu\text{m}$ . Benign findings are characterized by reticular arrangement of dark-grey bands on a light-grey background. In contrast, malignancy is characterized by a black/dark-grey-background with irregular large white streaks (blood vessels filled with fluorescein). Conclusions: The methodology described represents a promising and reproducible diagnostic imaging approach for the detection of cancers even in small ducts such as the biliary system. This new tool could be of utmost importance as cholangiocarcinoma remains one of the cancers with the poorest prognosis.

