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# Cellvizio® News

by **MKT** Mauna Kea Technologies

**JULY 2008**

## DDW / ATS Edition

Cellvizio had a strong scientific presence at the 2008 Digestive Disease Week (DDW) and American Thoracic Society (ATS) annual conferences. In this *Cellvizio News*, we reveal study highlights from the meetings.

DDW also marked the successful commercial debut of our new CholangioFlex miniprobe that enables the Cellvizio system to be used with ERCP to image pancreatic and biliary structures, which previously have been difficult to visualize.

This is exciting and useful information, and we look forward to keeping you updated on additional advances with this innovative technology in future newsletters.

**Sacha Loiseau PhD,**  
President, CEO  
and Founder



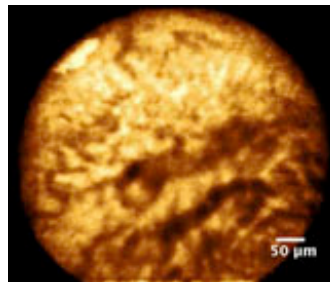
## Upcoming Events

**October 4-8, 2008** **European Respiratory Society Annual Congress**  
Messe Berlin GmbH,  
Berlin, Germany

**October 18-22, 2008** **United European Gastroenterology Week**  
Austria Center  
Vienna

**October 25-30, 2008** **CHEST**  
Pennsylvania  
Convention Center

## Video Spotlight: Normal Bile-Duct Epithelium



This *in vivo* cellular-level Cellvizio image obtained with a CholangioFlex miniprobe shows normal bile-duct epithelium characterized by reticular arrangement of dark-grey bands on a light-grey background.

**Click here** for the unique, real time Cellvizio video.

*Image courtesy of PD. Dr. Alexander Meining, Klinikum rechts der Isar, Technical University of Munich*

## New Study Highlights from Digestive Disease Week®

### Cellvizio Proves its Value in Diagnosing Range of GI Diseases

#### Colorectal Polyps: A 98% negative predictive value

Using Cellvizio during colonoscopy allows GIs to immediately distinguish normal polyps from lesions with a high chance of turning cancerous (Dr. Michael Wallace and colleagues, Mayo Clinic, Jacksonville, Florida; 26 patients). Compared with histopathology, Cellvizio predicted the presence of premalignant, advanced colorectal lesions and malignant lesions with **a high accuracy of 86.5%** and had **a negative predictive value of 98% for 5 mm pale polyps**, the kind most likely to be hyperplastic

#### Ulcerative Colitis Surveillance: 97% specificity

**Cellvizio may help eliminate unnecessary biopsies** for many ulcerative colitis patients (Dr. Frank J van den Broek and colleagues at the Academic Medical Center in Amsterdam; 9 patients, 57 colonic areas). "Typically, their neoplasia is difficult to see during colonoscopy and random biopsies are needed," Dr. van den Broek said. "Cellvizio potentially avoids this by showing histological features *in vivo*."

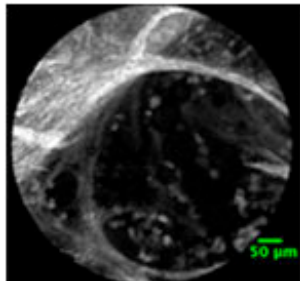
#### Barrett's Esophagus: 98.8% Negative Predictive Value

Cellvizio may aid in the detection of cancer in Barrett's esophagus patients and is highly effective at identifying which Barrett's patients do not have advanced growth of precancerous cells in their

2008 Convention Center, Philadelphia

ATS Conference

**New Study Shows Standard Ways to Interpret Cellvizio Lung Images Being Developed**



Live Cellvizio microscopic image of the alveoli, obtained during a standard bronchoscopy.

Standard ways to interpret Cellvizio *in vivo* microscopic lung images are now being developed (Dr. David Ost, N.Y. University; 8 patients). Physician reviewers agreed on certain lung image characteristics generated by Cellvizio during bronchoscopy and were able to differentiate between images of non-smokers and smokers.

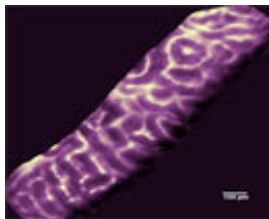
*"These are valuable findings because they suggest Cellvizio could be used to detect lung diseases that affect respiratory bronchioles,"* Dr. Ost said.

CORPORATE NEWS



Welcome to a familiar face in GI.  
**Brian Tinkham joins us as Vice President of Marketing in the U.S**  
 He comes from Boston

esophagus, with a negative predictive value of 98.8 percent (Drs. Heiko Pohl, VA Medical Center, White River Junction, Vermont, USA; Thomas Roesch, Charite University Hospitals, Germany; and Alexander Meining, Technical University of Munich, Germany; 38 patients).



Cellvizio mosaic image of Barrett's esophagus, obtained with unique feature that allows for live reconstruction of large patches of tissue.

A second Barrett's study found that Cellvizio guided endoscopic mucosal resections **significantly increase the detection rate of dysplasia in high risk Barrett's patients** and appear to be especially useful in identifying difficult-to-find dysplasia in flat Barrett's mucosa (Dr. Rami J. Badreddine and colleagues, Mayo Clinic, Rochester, Minnesota; 62 patients).

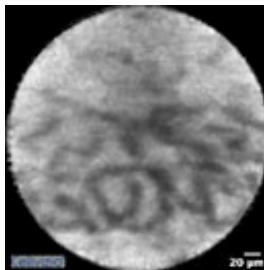
**Cholangiocarcinoma: Improves Detection**

Cellvizio is a promising and reproducible imaging approach for detecting biliary duct cancer (Dr. Alexander Meining, Technical University of Munich, Germany; 14 patients). It predicted biliary tract cancer with an accuracy of 91.7%, superior to the 76.9% accuracy rate of histopathological analysis of biopsies, and Cellvizio had a negative predictive value of 88% vs. a typical 50% for histopathological analysis.

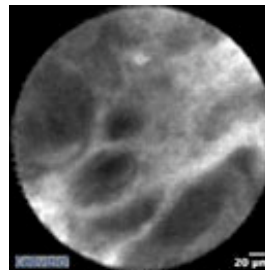
*"This new tool could be of utmost importance as cholangiocarcinoma is difficult to diagnose and one of the cancers with the poorest prognosis,"* said Dr. Meining.

Late Breaking News

**Cellvizio's ERCP Benefits Demonstrated Live at Brussels Workshop**



Normal "reticular" bile duct epithellum Cellvizio image



Cellvizio image of abnormal bile duct epithellum showing gland openings seen on the stricture

**Cellvizio's power, speed and ease of use to help improve the detection and diagnosis of cholangiocarcinoma** were seen first hand by more than 800 GIs at the first ever live Cellvizio ERCP demonstration, performed June 16 by Dr. Marc Giovannini, Paoli-Calmettes Institute, Marseille, France, and PD. Dr. Alexander Meining, Technical University of Munich, Germany, at the Annual Gastroenterology and Endotherapy Workshop in Brussels. During the procedure, Drs. Giovannini and Meining immediately were able to obtain relevant information to characterize normal vs abnormal mucosa in the bile duct.

Scientific, where he spent the last seven years in endoscopy sales and marketing, and brings a wealth of market savvy, clinical knowledge and strong physician relationships.

In a separate lecture, Professor Horst Neuhaus, University of Dusseldorf, Germany, discussed Dr. Meining's Cellvizio ERCP study results from DDW, emphasizing its major advantages over standard ERCP histology or cholangioscopic examination in Negative Predictive Value (88% vs. 50 %) and sensitivity (83% vs. 56%).

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