

Mauna Kea Technologies Announces New Study Shows Optical Biopsy Is More Accurate Than Conventional Endoscopic Biopsy in Detecting Stomach Cancer

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, reported a new study showing that a Cellvizio optical biopsy can overcome the limitations of standard tissue biopsies in accurately diagnosing cancerous stomach tumors. The study was completed at the Soonchunhyang University Hospital Gastrointestinal Cancer Center in Seoul, Korea. The study findings(i) were published online in the March Issue of Gastrointestinal Endoscopy.

In Asia, stomach cancer is the second most prevalent kind of cancer and the leading cause of cancer in men according to the World Health Organization. An estimated 736,000 people die from stomach cancer each year, making it the second largest cause of cancer death worldwide(ii).

"Histological examination of gastric lesions via forceps biopsy is known to be of limited(iii) accuracy and does not fully portray the severity and extent of a stomach lining lesion. Therefore, there is a risk for missing carcinomas," said Joo Young Cho, M.D., Ph.D., Director of the Korea NOTES Research Group and Director of the Gastrointestinal Cancer Center at Soonchunhyang University Hospital. "Cellvizio optical biopsies offer a way for gastroenterologists to accurately characterize many more spots in the stomach and get a more comprehensive view of the patient's stomach tissue, in real time."

Patients enrolled in the study underwent an optical biopsy prior to endoscopic resection of the cancerous tissue in the stomach lining previously diagnosed by endoscopic biopsy. The overall accuracy of the optical biopsy diagnosis was compared with endoscopic resection.

54 lesions consisting of three benign lesions, 19 pre-cancerous lesions and 32 adenocarcinomas were imaged and resected. Optical biopsies were found to have a higher overall rate of accuracy of diagnosis for cancerous lesions than conventional biopsies. The overall accuracy for the diagnosis of cancerous lesions in the stomach lining was 91.7% for optical biopsies and 85.2% for conventional biopsies. The combined accuracy of conventional endoscopic biopsies and optical biopsies was 98.1%.

The study also showed that optical biopsy findings are highly reproducible between physicians, with excellent overall agreement amongst physician observers for optical biopsies (kappa statistic $k=0.824$) as compared to the conventional biopsy

(k=0.617).

"These results confirm the value of Cellvizio for stomach cancer and show that optical biopsy is a reliable method that provides a better diagnostic solution than the current standard of care. This is a very exciting clinical development for the Asian market, where stomach cancer is a highly pervasive disease," said Sacha Loiseau, CEO and Founder of Mauna Kea Technologies. "We are continuing our efforts to expand and deepen our footprint in the Asian market and expect important studies like this to help facilitate utilization of optical biopsies across the world's most populated continent."

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

(i) Hyun Bok, G et al. (2013) The accuracy of probe-based confocal endomicroscopy versus conventional endoscopic biopsies for the diagnosis of superficial gastric neoplasia. *Gastrointestinal Endoscopy*. Published online 08 March 2013.

(ii) GLOBOCAN 2008 (IARC) Section of Cancer Information (22/1/2013)

(iii) Park, JS. (2013) Early-stage gastric cancers represented as dysplasia in a previous forceps biopsy: the importance of clinical management. *Digestive Liver Disease*. 2013 Feb;45(2):170-5. doi: 10.1016/j.dld.2012.09.008.

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