

MAJOR STEP FOR OPTICAL BIOPSY: MAUNA KEA TECHNOLOGIES RECEIVES REGULATORY APPROVAL FOR CELLVIZIO IN JAPAN

- *Approval covers use of Cellvizio in various medical specialties*
- *Second largest market for medical device and the global leading country for innovation in endoscopy now open to Cellvizio*

PARIS, April 28, 2014 – Mauna Kea Technologies (NYSE Euronext: MKEA, FR0010609263), leader in the optical biopsy market, announced today it received regulatory approval in Japan for the company's Cellvizio flagship product. The approval by Japan's Ministry of Health, Labor and Welfare (MHLW) includes a Class 1 authorization for the Cellvizio technology as well as a Class 2 designation, known as NINSHO approval, covering the use of Cellvizio probes in endoscopic use. The approval applies to all current Cellvizio indications including gastrointestinal, urologic, and respiratory.

The Japanese medical device market is the second largest worldwide after the United States and is worth about €24 billion. It continues to grow through social health insurance system and the aging of the Japanese population, which remains the fastest in the world today¹. Regarding endoscopy procedures, Japan is a leading market with one of the highest per capita rates of endoscopy use in the world. Currently the rate of endoscopy procedures in Japan represents about 20% of the global endoscopy market. Japan is also an internationally recognized center for technology and techniques in endoscopy; many of the leading clinical innovators in endoscopy are based in Japan.

At Fujita Health University, a leading medical center in the Chubu region, Cellvizio is already shared by multiples departments, including Gastroenterology and Hepatology, Interventional Pulmonology and Urology.

"We already have Cellvizio at Fujita Health University and have seen firsthand the significant advantages that this advanced endomicroscopy technology provides to both clinicians and patients. We are very pleased that MHLW has announced regulatory clearance of Cellvizio, and we look forward to working with clinicians throughout Japan to bring this important technology to all of the patients who can benefit from it as quickly as possible," said Pr. Ichiro Hirata, chairman and professor in the Division of Gastroenterology, Fujita Health University. Pr. Hirata is also the incoming president of the Japan Gastroenterological Endoscopy Society (JGES).

"Cellvizio represents a great potential for the management of patients with peripheral, potentially cancerous nodules and diffuse lung diseases", added Pr. Kazuyoshi Imaizumi, Professor in the Division of Respiratory Medicine and Clinical Allergy, Department of Internal Medicine, Fujita Health University, "We look forward to performing ground-breaking work in Japan where the need for better pulmonary care is important".

Last week, Cellvizio had a strong presence at the 18th World Congress of Bronchology and Interventional Pulmonology in Kyoto, Japan, with 7 presentations on the latest results obtained with Cellvizio in pulmonary indications given by American, French and Chinese investigators.

For more information on the presentations, [click here](#)

To support the most efficient market penetration, Mauna Kea Technologies announced a distribution agreement for Cellvizio in Japan with AMCO, Inc. back in June 2013. AMCO has more than 60 years of experience as a distributor in Japan for foreign medical devices with eight regional offices and 80 sales representatives in Japan. AMCO and Mauna Kea Technologies will now diligently work together to fully launch Cellvizio in Japan.

"Japan represents a critically important market for Cellvizio. This approval is a key milestone in our goal to make optical biopsy standard of care and to expand access to Cellvizio for the millions of patients who need it in Japan and in other countries around the world. We very much look forward to working with the clinicians and innovators in endoscopy throughout Japan who will be using Cellvizio in the years ahead," said Sacha Loiseau, founder and CEO of Mauna Kea Technologies.

¹ Source Ubifrance



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 during digestive, pulmonary and urologic endoscopy procedures, including pancreatic and biliary endoscopic explorations as well as fine needle aspiration procedures. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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