

## MAUNA KEA TECHNOLOGIES RECEIVES REGULATORY APPROVAL FOR THE AQ-FLEX 19 MINIPROBE IN JAPAN

**Approval provides significant support for broader adoption of Cellvizio's needle-based confocal laser endomicroscopy solution in a leading global market for endoscopy**

**PARIS, France – 6 July, 2015** – Mauna Kea Technologies (Euronext: MKEA, FR0010609263), inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy platform, announced today it has obtained approval from Japan's Ministry of Health, Labor and Welfare (MHLW) for its unique needle-base Confocal Laser Endomicroscopy solution, the AQ-Flex 19 miniprobe.

Used during endoscopy procedures, the Cellvizio AQ -Flex™ 19 miniprobe is comprised of a fiber-optic microscope that is small enough to thread through a needle. It provides real-time microscopic imaging of pancreatic cysts during endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) procedures, making it possible to see the cyst wall down to a cellular level to help physicians find and identify features of each type of cyst that can drive treatment decisions.

"The use of needle-based Confocal Laser Endomicroscopy in pancreatic lesions has been shown in a range of clinical studies to provide essential information that can help doctors make more accurate and faster treatment decisions," said Pr. Kenji Yamao, director of the Division of Gastroenterology, Aichi Cancer Center, "The approval of this ground-breaking technology in Japan is a major advantage for physicians and pancreatic surgeons who manage a growing number of patients with these pathologies".

The AQ-Flex 19 Miniprobe was awarded a CE Mark in the EU in 2012 and was cleared by the US Food and Drug Administration in 2013.

"Japan represents the second largest market for endoscopic equipment in the world, with high demand for GI screening and interventional procedures due to an aging population and other factors. We are seeing growing awareness and support for Cellvizio from Key Opinion Leaders in Japan and throughout Asia, which represents an important market for us in the years ahead," said Sacha Loiseau, founder and CEO of Mauna Kea Technologies.

### **About Mauna Kea Technologies**

Mauna Kea Technologies is a global medical device company focused on leading innovation in endomicroscopy and optical biopsy. The company designs, develops and markets innovative tools to visualize and detect cell abnormalities in real time during standard gastrointestinal and pulmonary endoscopy procedures. The company's flagship product, Cellvizio®, a probe needlebased Confocal Laser Endomicroscopy (pCLE/nCLE) system, provides physicians and researchers with high-resolution cellular imaging of internal tissues. Large-scale, international, multi-center clinical trials have demonstrated Cellvizio's ability to help physicians to more accurately detect early forms of diseases and make immediate treatment decisions. Designed to help physicians in their diagnoses, provide patients with better treatment and reduce hospital costs, the Cellvizio system can be used with virtually any endoscope. Cellvizio has 510(k) clearance from the United States Food and Drug Administration and CE Marking in the European Union for use in the gastrointestinal tract and the urinary and respiratory systems, for endoscopic exploration of the biliary and pancreatic ducts and for fine-needle aspiration procedures. Cellvizio has also obtained SFDA regulatory approval in China and MHLW approval in Japan.

For further information on Mauna Kea Technologies, visit [www.maunakeatech.com](http://www.maunakeatech.com)

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