MAUNA KEA TECHNOLOGIES RECEIVES 510(K) REGULATORY CLEARANCE FROM U.S. FDA FOR NEW CELLVIZIO SYSTEM FUNCTIONING IN A NEAR-INFRARED WAVELENGTH

- ***Cellvizio 785 nm opens new possibilities for microscopic imaging inside the human body***
- ***New clearance is an important step on the company's product roadmap***

PARIS, July 29, 2014 – Mauna Kea Technologies (NYSE Euronext: MKEA, FR0010609263), a leader in the optical biopsy market, announced today it has received 501(k) regulatory clearance from the United States Food and Drug Administration ("FDA") (510(k) #K133466) for a new Cellvizio system functioning at a near-infrared wavelength of 785 nanometers.

Optical biopsy with endomicroscopy works by using the properties of light to enable the operator to make a real-time tissue assessment inside the body. Obtaining FDA regulatory clearance of a near-infrared version of its Cellvizio endomicroscopy technology will allow Cellvizio to be utilized to perform a broader range of microscopic tissue analysis. In, particular, it may facilitate the use of Cellvizio in conjunction with macroscopic imaging systems in future surgical indications, as near-infrared is a wavelength of light that is widely used by other leading commercially available imaging technologies, notably with robotic systems.

Sacha Loiseau, CEO and Founder of Mauna Kea Technologies, added: "The FDA clearance of the 785nm wavelength is a key milestone in our long-term product roadmap that is the result of years of technical and pre-clinical development. We anticipate that the Cellvizio system operating at this new wavelength will open new imaging possibilities that were previously unexplored and are of particular relevance for many potential applications. We are also excited about the new clinical research avenues and commercial developments this FDA clearance will provide the medical community."

With this new version of its unique confocal endomicroscopy solutions, Mauna Kea Technologies is again demonstrating its versatility and adequation to the needs of different constituencies of physicians, surgeons and researchers, like ultra-sound using multiple frequencies for different applications.

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-based Confocal Laser Endomicroscopy (pCLE) 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 practically all endoscopes. 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 also obtained SFDA regulatory approval in China and MHLW approval in Japan.

For further information on Mauna Kea Technologies, visit www.maunakeatech.com

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