## MAUNA KEA TECHNOLOGIES ANNOUNCES CE MARK FOR USE OF CELLVIZIO® IN MINIMALLY INVASIVE SURGERY

 Broad scope of EU regulatory approval supports broader integration of Cellvizio technology in many surgical and interventional image guided platforms in oncology

**PARIS, France – 18 May, 2015 –** Mauna Kea Technologies (Euronext: MKEA, FR0010609263), inventor of Cellvizio®, the multidisciplinary confocal laser endomicroscopy platform, announced today CE mark for the use of Cellvizio in minimally invasive laparoscopic surgical indications. This regulatory milestone positions Cellvizio for useful imaging support in a wide range of oncologic surgical procedures, many of which have already been investigated successfully in several clinical studies throughout Europe.

Cellvizio brings real-time visualization of tissue at the microscopic level, representing a major advance in image-guided surgery. In this setting, the *Celioflex* Cellvizio probe can be delivered laparoscopically through a trocar and manipulated in the surgical field with standard laparoscopic hand-held instruments. Usage of the Cellvizio probe with robotic instruments will be accessible in the near future. Access to real-time visualization of tissue may provide a range of benefits to surgeons and patients such as improved frozen section sampling, more accurate tumor margin detection and improved surgical planning. In addition, Cellvizio is compatible and synergistic with macroscopic optical fluorescent imaging systems currently used in a range of surgical applications.

Dr Silvana Perretta, from IRCAD-EITS, University of Strasbourg, France said, "Cellvizio is able to provide important digital information in real time while overcoming the physical barrier of the OR. The ability to bring this new level of knowledge and precision into the surgical field is a significant advantage as the global focus on evidenced-based medicine continues to expand."

Sacha Loiseau, CEO and founder of Mauna Kea Technologies said, "While we view this achievement as an important regulatory milestone for the company, it is also the next step in our ongoing effort to position this technology to transform how surgery is performed in the years ahead. Based on a rapidly growing body of clinical evidence, Cellvizio is the ideal technology for integration into many surgical and interventional imageguided platforms. Based on versatility and ease-of-use, we feel confident that adoption and use of this landmark technology will continue to expand rapidly in the EU and around the world."

## **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

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