Mauna Kea Technologies Receives FDA 510(k) Clearance of Cellvizio® with a Fluorescent Dye, Fluorescein, as Drug Device Combination

The Cellvizio® 100 series system with all its different Confocal Miniprobes™ is now cleared for use with the fluorescein dye to image blood flow in the microvasculature and capillaries

Paris and Boston, January 27, 2020 – 6.00 PM CET – Mauna Kea Technologies (Euronext: MKEA) inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (pCLE/nCLE) platform, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the Cellvizio® 100 series and all associated Confocal Miniprobes™ for the additional indication of visualization of blood flow when used in conjunction with a fluorescent dye, fluorescein, as a drug device combination. This marks the 17th U.S. FDA 510(k) clearance of the Cellvizio® p/nCLE platform.

The Mauna Kea Technologies Cellvizio *in vivo,* real-time endomicroscopic visualization technology platform is intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells and vessels and their organization or architecture. The endomicroscopy system is used in the fields of gastroenterology, pulmonology, and urology during endoscopic procedures, laparoscopic and robot-assisted surgeries, and image-guided percutaneous procedures. FDA clearance of the endomicroscopy system in combination with a fluorescent dye, fluorescein, and the addition of the indication for imaging blood flow in vascular areas, including microvasculature and capillaries, represents a pivotal milestone for the Company. Real-world data, published in multiple peer-reviewed medical journals by leading investigators, paved the way for this new FDA clearance. Cellvizio has, for sometime, been an important adjunct to traditional biopsy and histopathological examination. Nine years ago, in 2011, Wallace et al.[1] reported that "*this technology has the further advantage of visualizing a dynamic process on a microscopic level for monitoring and determination of blood flow in various conditions, […] making it a useful tool for detection of neo-angiogenesis*."

"*This new FDA clearance of our Cellvizio platform in combination with a fluorescent dye is a major regulatory milestone for Mauna Kea Technologies. It validates the wealth of data that have been published over the past decade that demonstrates its important clinical contribution. This FDA clearance will greatly facilitate our commercial development in United States by allowing the fluorescein dye to be directly supplied with Cellvizio*" commented Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. "*This clearance is another step for Mauna Kea Technologies in an accelerated development of drug-device combination indications, enabling the clinical use of Cellvizio with highly specific molecular imaging markers.*"

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company focused on eliminating uncertainties related to the diagnosis and treatment of cancer and other diseases thanks to real-time *in vivo* microscopic visualization. The Company's flagship product, Cellvizio®, has received clearance/approval in a wide range

[1] Wallace, M. *et al.* Miami classification for probe-based confocal laser endomicroscopy. *Endoscopy* **43**, 882–891 (2011)

of applications in more than 40 countries, including the United States, Europe, Japan, and China. For more information on Mauna Kea Technologies, visit www.maunakeatech.com

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