Mauna Kea Technologies Receives 510(k) Clearance for the Cellvizio® Needle-Based AQ-Flex™ 19 Confocal Miniprobe™ Enabling Peripheral Lung Nodule Targeting and Imaging

The Cellvizio® AQ-Flex probe is cleared for use with transbronchial needles through existing bronchoscopes and bronchoscopic accessories

Paris and Boston, February 25, 2019 – 5.45 PM CET – Mauna Kea Technologies (Euronext: MKEA,) inventor of Cellvizio®, the multidisciplinary probe-based 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 use of the Cellvizio AQ-Flex™ 19 Confocal Miniprobe™ through existing bronchoscopes, transbronchial needles and other bronchoscopic accessories. This marks the 16th U.S. FDA 510(k) clearance of the Cellvizio® p/nCLE platform.

"Our pioneering team has demonstrated that real-time imaging and identification of benign and malignant cellular structures inside pulmonary nodules and lymph nodes with needle-based Confocal Laser Endomicroscopy is not only feasible but highly reproducible." said Pr. J. T. Annema, M.D., Ph.D., chairman of the Department of Respiratory Medicine, Amsterdam University Medical Centers. *"The availability of nCLE inside the lungs has clear potential to have a major impact on the diagnostic accuracy for peripheral nodules, one of the most elusive challenges in the battle against lung cancer."*

Current navigation products provide advanced minimally invasive access to peripheral nodules but with limited ability to achieve direct visualization outside the airways. The Cellvizio AQ-Flex™ 19 Confocal Miniprobe™ can be used through the working channel of existing navigation products to provide direct "through the needle" visualization inside peripheral lesions.

"This is an important regulatory milestone for the Company and, more importantly, we believe this clearance formalizes our market development strategy: to evaluate the potential commercial opportunity for our Cellvizio technology in the interventional pulmonology market," said Robert L. Gershon, Chief Executive Officer of Mauna Kea Technologies. *"We believe our Cellvizio AQ-Flex™ 19 Confocal Miniprobe™ unlocks a new era in interventional pulmonology, paving the way toward more precise guidance to identify the optimal area for sampling, and potentially as a real-time feedback technique for diagnostic, staging and treatment procedures in lung lesions."*

Mr. Gershon continued: *"We have an established presence in the U.S. GI market, and expect our commercial strategy in the U.S. GI market to be the primary driver of revenue growth in 2019. With more than 240,000 annual lung biopsy procedures in the U.S. alone[1], interventional pulmonology represents a compelling market opportunity for Mauna Kea's next clinical indication for commercial focus. We look forward to sharing our plans to evaluate this opportunity on our 2018 full year results conference call on March 20, 2019."*

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

[1] Source: American Cancer Society *Cancer Facts & Figures 2018*, internal analysis

United States
Mike Piccinino, CFA
Westwicke, an ICR Company
443-213-0500

France and Europe
NewCap - Investor Relations
Valentine Brouchot
+33 (0)1 44 71 94 94
maunakea@newcap.eu

Disclaimer

This press release contains forward-looking statements concerning Mauna Kea Technologies and its activities. Such forward looking statements are based on assumptions that Mauna Kea Technologies considers to be reasonable. However, there can be no assurance that the anticipated events contained in such forward-looking statements will occur. Forward- looking statements are subject to numerous risks and uncertainties including the risks set forth in the registration document of Mauna Kea Technologies registered by the French Financial Markets Authority (Autorité des marchés financiers (AMF)) on April 27, 2018 under number R.18-0429 and available on the Company's website (www.maunakeatech.com), and to the development of economic situation, financial markets, and the markets in which Mauna Kea Technologies operates. The forward-looking statements contained in this release are also subject to risks unknown to Mauna Kea Technologies or that Mauna Kea Technologies does not consider material at this time. The realization of all or part of these risks could lead to actual results, financial conditions, performances or achievements by Mauna Kea Technologies that differ significantly from the results, financial conditions, performances or achievements expressed in such forward-looking statements. This press release and the information it contains do not constitute an offer to sell or to subscribe for, or a solicitation of an order to purchase or subscribe for, Mauna Kea Technologies shares in any country.