FDA Grants Mauna Kea Technologies 510(k) Clearance to Market AQ-Flex(TM) 19 Miniprobe for Fine Needle Aspiration Procedures

The Associated Press

Mauna Kea Technologies (NYSE Euronext: MKEA), leader in the optical biopsy market and developer of Cellvizio®, the fastest way to see cancer, today announced that the U.S. Food and Drug Administration (FDA) has cleared the AQ-Flex 19 miniprobe to provide real-time optical biopsies during endoscopic ultrasound-guided fine needle aspiration (EUSFNA) procedures in the digestive tract. This represents the sixth U.S. regulatory clearance for Mauna Kea Technologies' Cellvizio or one of its dedicated miniprobes, which already obtained the CE mark in Europe.

"With needle-based optical biopsies, we now have access to absolutely unique real-time dynamic views of the cellular and vascular structures of previously unreachable areas such as pancreatic cysts. While many of these lesions are benign, some cysts are pre-cancerous and even cancerous and need to be surgically removed. With current imaging and sampling techniques, it remains difficult to confirm which patient has the high risk or cancerous type of cyst and whether surgery is strongly advised," said Kenneth J. Chang, M.D., Professor and Chief of the Division of Gastroenterology and Executive Director of the H.H. Chao Comprehensive Digestive Disease Center at the University of California Irvine, School of Medicine. "Needle-based optical biopsies may provide the missing information needed to separate the high risk versus low risk cysts and impact patient management as demonstrated by initial data generated in U.S. and international centers, including ours. This could result in a more efficient and cost-effective way to manage these patients."

A growing number of pancreatic cysts are being diagnosed as a result of the estimated 70 million scans being performed in the U.S. every year. Data from a large retrospective analysis showed that pancreatic cysts were present in 2.4% of asymptomatic patients who underwent CT scans of the abdomen for non-pancreatic issues(1). However, the relatively low sensitivity of standard procedures to characterize pancreatic cysts as benign or cancerous means there is a significant need for effective, low-cost, non-invasive diagnostic techniques that can significantly improve patient outcomes and lower overall treatment cost.

"The AQ-Flex 19 miniprobe, at only 0.8 mm in diameter, exemplifies Mauna Kea Technologies' dedication to consistent innovation of optical biopsy technology," said Sacha Loiseau, Ph.D., CEO of Mauna Kea Technologies. "This U.S. regulatory clearance represents a significant business milestone for the company and extends the application of optical biopsies into new clinical areas only reachable with fine needles where there is a significant unmet medical need for more efficient and accurate diagnoses. We believe leading U.S. centers in this field can achieve greater

benefits for patients and avoid repeat costly and complication-prone procedures through adoption of this new technique."

The AQ-Flex miniprobe is compatible with all Cellvizio 100 series systems currently marketed by Mauna Kea Technologies and will be immediately made available in the U.S. through our direct sales force. Mauna Kea Technologies is also exploring other commercial partnerships in order to accelerate its market reach.

About Pancreatic Cancer
Pancreatic cancer is one of the rare cancers for which chemotherapy and radiotherapy have disappointing results. The best patient outcomes are achieved with surgery in which the surgeon must remove all the cancerous cells, including those in the primary tumor, as well as those hidden in the surrounding pancreatic tissue and lymph nodes. The American Cancer Society (ACS) estimates that approximately 43,920 people (22,090 men and 21,830 women) will be diagnosed with pancreatic cancer this year and about 37,390 people (18,850 men and 18,540 women) will die of the disease. Since 2004, rates of pancreatic cancer have continued to steadily increase by 1.5% each year, according to the ACS.

About Mauna Kea Technologies
Mauna Kea Technologies is a global medical device company dedicated to the advent of optical biopsy. The company researches, develops and markets innovative tools to visualize and detect cellular abnormalities during endoscopic procedures. Its flagship product, Cellvizio®, a probe-based Confocal Laser Endomicroscopy (pCLE) system, provides physicians and researchers high-resolution cellular views of tissue inside the body. Large, international, multicenter clinical trials have demonstrated Cellvizio's ability to help physicians more accurately detect early forms of disease and make treatment decisions immediately. Designed to improve patient outcomes and reduce costs within a hospital, Cellvizio can be used with almost any endoscope. Cellvizio has 510(k) clearance from the U.S. Food and Drug Administration and the European CE-Mark for use in the GI tract, biliary and pancreatic ducts and lungs.

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

(1) Laffan TA, Horton KM, Klein AP, et al. Prevalence of unsuspected pancreatic cysts on MDCT. AJR Am J Roentgenol. 2008;191(3):802-7.

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