On Target Laboratories and Mauna Kea Technologies Demonstrate Intraprocedural Targeted Detection of Lung Cancer with a Molecular Imaging Agent

Study published in Nature Communications finds cancer-targeted molecular imaging agent with needle-based confocal laser endomicroscopy system achieved rapid, highly sensitive and specific detection of cancer cells during biopsy procedures, with excellent diagnostic accuracy and reproducibility

West Lafayette, Paris, and Boston, May 18, 2022 – 5:45 pm CEST – On Target Laboratories, Inc. ('On Target') a privately-held biotechnology company developing intraoperative molecular imaging agents to target and illuminate cancer during surgery and **Mauna Kea Technologies (Euronext: MKEA, 'Mauna Kea')** inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announced publication of a study entitled "**Targeted Detection of Cancer at the Cellular Level During Biopsy by Near-Infrared Confocal Laser Endomicroscopy**"[1] in the peer-reviewed scientific journal *Nature Communications*.

The proof-of-concept study, conducted at University of Pennsylvania School of Medicine in Philadelphia, evaluated the use of On Target's intraoperative molecular imaging agent, CYTALUX™ (pafolacianine) injection, paired with Mauna Kea's U.S. FDA 510(k) cleared Cellvizio® platform for intralesional visualization of cells that have taken been up by CYTALUX™ during biopsy of pulmonary nodules.

A Molecular Image-guided Procedure (MIP) conducted with near-infrared needle-based confocal laser endomicroscopy (NIR-nCLE) may allow for real-time detection of cancer in smaller, difficult to visualize lung nodules with improved diagnostic yield during pulmonary nodule biopsy, all during a minimally invasive bronchoscopy.

The study demonstrated this new approach can identify small volumes of cancer, including a single cancer cell among one thousand normal cells, in a type of pulmonary nodule known as a ground glass opacity (GGO), which is particularly challenging to identify and diagnose with existing technology. Furthermore, the study showed that NIR-nCLE can deliver easily interpretable images in real time which allow the user to accurately distinguish between cancerous and non-cancerous tissue during bronchoscopic biopsy, with an overall sensitivity and specificity of 100% and 92%, respectively, and very high inter- and intra-observer agreements.

"This study marks an important milestone in the development of needle-based confocal laser endomicroscopy for its application in lung cancer. In assessing the use of Cellvizio with CYTALUX, we've demonstrated the potential for the first ever real-time endoluminal molecular imaging technology for lung cancer," stated Nicolas Bouvier, interim CEO of Mauna Kea Technologies. "These results signal that Molecular Image-guided Procedures conducted with near-infrared needle-based confocal laser endomicroscopy have the potential to be a must-have in the bronchoscopy suite."

"We are thrilled about the results of this study," said Chris Barys, Chief Executive Officer of On Target Laboratories. "We look forward to continuing our collaboration with Mauna Kea and working towards extending our intraoperative molecular imaging agents to more patients."

About the Study Principal Investigators
Sunil Singhal, MD, is the Chief of the Division of Thoracic Surgery, the William Maul Measey Associate Professor in Surgical Research, and director of the Center for Precision Surgery, Abramson Cancer Center at the University of Pennsylvania.
Gregory Kennedy, MD, is a resident in General Surgery at the University of Pennsylvania.

About Lung Cancer
Lung cancer is the world's leading cause of cancer deaths claiming over 1.8 million lives every year — more than colorectal, breast, and prostate cancers combined[2]. Its diagnosis remains challenging, despite significant advancements in diagnostic and treatment technologies. As a result, nearly half of lung cancer cases are diagnosed late stage when the survival rate is only 6%[3]. The number of lung nodules identified on chest CTs continues to rise with one study estimating that, in the U.S. alone, nearly 1.6 million people who underwent a chest CT had a pulmonary nodule identified[4]. Determining if a suspicious pulmonary nodule is malignant or benign can be challenging and time-consuming, often requiring multiple biopsy attempts and/or invasive procedures which can result in inconclusive results, increased risk of complications, and higher anxiety for patients. One study reported it can take up to 6 months to diagnose a lung nodule and the majority were diagnosed at advanced stages of the disease, underscoring the need for earlier and more accurate diagnoses[5].

About On Target Laboratories
On Target Laboratories discovers and develops targeted intraoperative molecular imaging agents to illuminate cancer during surgery. Their molecular imaging technology, based on the pioneering work of Philip S. Low, PhD, Purdue University's Presidential Scholar for Drug Discovery and the Ralph C. Corley Distinguished Professor of Chemistry, is comprised of a near-infrared dye and a targeting molecule, or ligand, that binds to receptors overexpressed on cancer cells. The imaging agents illuminate the cancerous tissue, which may enable surgeons to detect cancer that otherwise may have been left behind. For more information visit www.ontargetlabs.com.

Media Contacts
On Target Laboratories, Inc.
Jessica Todd
Phone: 513-325-5706
jtodd@ontargetlabs.com

Syneos Health
Danielle Kirsch
Phone: 201-693-3197
danielle.kirsch@syneoshealth.com

About Mauna Kea Technologies
Mauna Kea Technologies is a global medical device company that manufactures and sells Cellvizio®, the real-time in vivo cellular imaging platform. This technology uniquely delivers in vivo cellular visualization which enables physicians to monitor the progression of disease over time, assess point-in-time reactions as they happen in real time, classify indeterminate areas of concern, and guide surgical interventions. The Cellvizio platform is used globally across a wide range of medical specialties and is making a transformative change in the way physicians diagnose and treat patients. For more information, visit www.maunakeatech.com.

Investor Relations – Mauna Kea Technologies
NewCap
Thomas Grojean
+33 (0)1 44 71 94 94
maunakea@newcap.eu

Disclaimers

CYTALUX Indication

CYTALUX is an FDA-approved optical imaging agent indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions.

Important Safety Information

Infusion-Related Reactions
Adverse reactions consisting of nausea, vomiting, abdominal pain, flushing, indigestion, chest discomfort, and itching were reported during the administration of CYTALUX. Your doctor may treat you with antihistamines and/or anti-nausea medication.

Pregnancy
CYTALUX may cause fetal harm when administered to a pregnant woman. There are no available human data to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Contact your healthcare provider with a known or suspected pregnancy.

Folate Supplement Usage
Folic acid may reduce the detection of cancerous tissue with CYTALUX. Patients should stop taking folate, folic acid, or folate-containing supplements 48 hours before administration of CYTALUX.

Risk of Misinterpretation
Errors may occur with the use of CYTALUX. Sometimes cells may light up even if they are not cancerous or those that are cancerous may not light up. Also, cancerous or non-cancerous cells from other areas may light up, such as areas of the bowel, kidneys, lymph nodes, and inflamed tissue.

Adverse Reactions
The most common side effects of CYTALUX reported in clinical trials were nausea, vomiting, abdominal pain, flushing, indigestion, chest discomfort, itching, and allergic reaction during administration or infusion.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of CYTALUX. For more information, ask your healthcare provider.

Call your doctor for medical advice about side effects. You may report side effects to On Target Laboratories at 1-844-434-9333 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Click here to see full Prescribing Information.

Mauna Kea Technologies

This press release contains forward-looking statements concerning Mauna Kea Technologies and its activities. All statements other than statements of historical fact included in this press release, including, without limitation, those regarding Mauna Kea Technologies' financial condition, business, strategies, plans and objectives of management for future operations are forward-looking statements. 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 Chapter 3 of the 2020 Universal Registration Document of Mauna Kea Technologies registered by the French Financial Markets Authority (Autorité des marchés financiers (AMF)) on June 17, 2021 under number D-21-0566 and the amendment to the 2020 Universal Registration Document filed with the AMF on September 17, 2021, which are both available on the Company's website (www.maunakeatech.com), and risks relating the 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 jurisdiction in which such an offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction. The distribution of this document may, in certain jurisdictions, be restricted by local regulations. Persons who come into possession of this document are required to observe all applicable local regulations relating to this document

1. DOI: 10.1038/s41467-022-30265-z
2. International Agency for Research on Cancer, World Health Organization. Cancer fact sheet: all cancers. http://gco.iarc.fr/today/data/factsheets/cancers/39-All-cancers-fact-sheet.pdf. Accessed May 2020.
3. American Lung Association; State of Lung Cancer 2020 Report. Accessed online May 2022. https://www.lung.org/getmedia/381ca407-a4e9-4069-b24b-195811f29a00/solc-2020-report-final.pdf
4. Gould MK, Tang T, Liu IL, Lee J, Zheng C, Danforth KN, Kosco AE, Di Fiore JL, Suh DE. Recent Trends in the Identification of Incidental Pulmonary Nodules. Am J Respir Crit Care Med. 2015 Nov 15;192(10):1208-14. doi: 10.1164/rccm.201505-0990OC. PMID: 26214244.
5. Gildea TR, DaCosta Byfield S, Hogarth DK, Wilson DS, Quinn CC. A retrospective analysis of delays in the diagnosis of lung cancer and associated costs. Clinicoecon Outcomes Res. 2017;9:261-269. doi.org:10.2147/CEOR.S132259