



Press release – For immediate release
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Median Technologies announces pivotal REALITY study of its eyonis™ LCS lung cancer diagnostic met all primary and secondary endpoints

- eyonis™ LCS met the primary endpoint for accuracy, achieving an Area Under the Curve (AUC)¹ of 0.90, significantly above the 0.80 set for regulatory clearance.
- eyonis™ LCS met all 9 secondary endpoints in REALITY with statistical significance.
- RELIVE, the second eyonis™ LCS pivotal study, to report top-line data in Q1 2025.
- U.S. & European eyonis™ LCS marketing authorization regulatory filings in H1 2025.

Sophia Antipolis, France: Median Technologies (*FR0011049824, ALMDT, PEA/PME scheme eligible, “Median” or “The Company”*) announces today that eyonis™ LCS, its proprietary Artificial Intelligence (AI)/machine learning (ML) powered Software as Medical Device (SaMD) for lung cancer screening (LCS), met the primary and all secondary endpoints in REALITY, the first of two pivotal studies required for marketing authorizations in U.S. and Europe.

Median’s eyonis™ LCS SaMD is designed for improving the detection and diagnostic accuracy of low-dose computed tomography (LDCT). LDCT imaging is the standard of care globally and is currently the only approved lung cancer screening modality in U.S. and Europe.

Fredrik Brag, CEO of Median Technologies said: *“These data met our ambition for improving the performance of LDCT with eyonis™ LCS. Now, we are even more excited to report the upcoming RELIVE pivotal data and file for marketing authorizations in H1 2025. We believe that broad implementation of LDCT with eyonis™ LCS has the potential to vastly improve early detection and lead to far more cures, dramatically reducing lung cancer mortality.”*

The average five-year survival rate for all lung cancer patients is 18.6 percent because only 16 percent of lung cancers are diagnosed at an early stage². Conversely, Stage 1 lung cancer can be cured when detected, with an 80% survival rate after 20 years, where many die from other causes. For Stage 1A cancers that measure 10 mm or less, the 20-year survival rate has been shown to be 92%.

Consequently, there is tremendous momentum behind efforts in the U.S., Europe and Asia to increase lung cancer screening and improve its accuracy. Enabling the accurate early detection of lung cancer with eyonis™ LCS could dramatically improve lung cancer survival.

¹ The accuracy of a diagnostic test is determined by the balance between true positives and false positives. To calculate the ratio, medical professionals use what is referred to as the receiver operating characteristic (ROC) to generate a statistical plot, or curve; the area under the curve (AUC) scores the diagnostic accuracy and can be used to compare different screening methodologies. For reference, a diagnostic test with no discriminatory power (e.g. to discern cancerous from normal tissue) would have an AUC of 0.5 while a perfect test would have an AUC of 1.

² <https://www.mountsinai.org/about/newsroom/2022/lung-cancer-screening-dramatically-increases-long-term-survival-rate>



Thomas Bonnefont, COO and CCO eyonis™ Business Unit said: *“The high performances of our device can not only save lives but also prevent healthy patients undergoing unnecessary medical procedures. This will avoid unnecessary distress for patients and reduce healthcare costs.”*

Lung cancer screening is recommended by the U.S. Preventive Services Task Force (USPSTF) in adults aged 50 to 80 years who have a 20 pack-year smoking history. The market opportunity includes a population of 14.5 million people in the US alone, currently eligible for a lung cancer screening exam, with an existing potential reimbursement of \$650 per exam with a SaMD postprocessing for characterization of malignant vs benign nodules. This represents a total addressable annual market of over \$9 billion. The eligible U.S. patient number is expected to rise in the coming years, driven by planned broadening of the eligibility criteria. Similarly, new lung screening program deployments are planned in Europe and Asia. Around \$230bn were spent on cancer medical care in 2023 in the US. The vast majority of cancer care costs are incurred in treating advanced cancer patients, versus preventive care such as screening that can save patients' life.

Definitive results from REALITY show that eyonis™ LCS can accurately detect and characterize cancerous nodules. The novel SaMD achieved exceptional results, with an area under the curve (AUC) value of 0.904 at patient level versus an AUC of 0.80 – the minimum value set as a primary endpoint for REALITY. Importantly, 80% of the cancers in the analyzed cohort of REALITY were difficult-to-diagnose Stage 1 cancers. Moreover, the REALITY cohort was enriched compared to real life with small non-spiculated cancers, and large spiculated benign nodules, both of which are challenging for radiologists to diagnose.

The pivotal REALITY study ([Clinicaltrials.gov identifier: NCT0657623](https://clinicaltrials.gov/ct2/show/study/NCT0657623)), initiated in July 2023, collected retrospective imaging and clinical data from 1,147 patients from five major cancer centers and hospitals in the US and Europe and two clinical data providers. REALITY evaluated eyonis™ LCS ability to diagnose lung cancer. The objectives were to assess eyonis™ LCS standalone performance in characterizing cancerous vs non-cancerous patients (i.e. “performance at patient level”), and in detecting and characterizing suspicious versus malignant nodules. The primary endpoint of REALITY was determined after consultation with the U.S. regulatory authorities and the primary endpoint was selected to show that eyonis™ LCS would achieve an AUC superior to 0.8.

The second pivotal trial, RELIVE, is a Multi-Reader Multi-Case (MRMC) study that will offer clinical validation of eyonis™ LCS to complement the analytical validation already achieved and communicated today with REALITY. All the patient recruitment and relevant patient clinical data for the RELIVE study have already successfully been collected from the participating sites. RELIVE is scheduled for completion in the coming months, with an anticipated data read-out in Q1 2025 and regulatory filings in H1 2025.

About eyonis™ LCS: eyonis™ Lung Cancer Screening (LCS) is an artificial intelligence (AI) powered diagnostic tool that uses machine learning (ML) to help analyze imaging data generated with low-dose computational tomography (LDCT) to diagnose cancer at the earliest stages, when it can still be cured in the majority of patients. eyonis™ LCS has been classified by regulators as “Software as Medical Device”, or SaMD, and is the subject of two pivotal studies required for marketing approvals in the U.S. and Europe: REALITY (successfully completed - [Clinicaltrials.gov identifier: NCT0657623](https://clinicaltrials.gov/ct2/show/study/NCT0657623)) and RELIVE (ongoing). Filing applications including these pivotal data are scheduled to be submitted for FDA 510(k) premarket clearance and CE marking in H1 2025. In the interim, eyonis™ technology is being used in at clinical research centers. Separately, Median's AI technology



is being sold and deployed via Median's [iCRO business unit](#), to biopharmaceutical companies performing clinical trials of experimental therapeutics, including the world's leading pharmaceutical companies in cancer.



About Median Technologies: Pioneering innovative imaging solutions and services, Median Technologies harnesses cutting-edge AI to enhance the accuracy of early cancer diagnoses and treatments. Median's offerings include iCRO, which provides medical image analysis and management in oncology trials, and eyonis™, an AI/ML tech-based suite of software as medical devices (SaMD). Median empowers biopharmaceutical entities and clinicians to advance patient care and expedite the development of novel therapies. The French-based company, with a presence in the U.S. and China, trades on the Euronext Growth market (ISIN: FR0011049824, ticker: ALMDT). Median is also eligible for the French SME equity savings plan scheme (PEA-PME). For more information, visit www.mediantechnologies.com.

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Median Technologies' Forward-Looking Statements

This press release contains forward-looking statements. These statements are not historical facts. They include projections and estimates as well as the assumptions on which these are based, statements concerning projects, objectives, intentions, and expectations with respect to future financial results, events, operations, services, product development and potential, or future performance.

These forward-looking statements can often be identified by the words "expects," "anticipates," "believes," "intends," "estimates" or "plans" and any other similar expressions. Although Median's management believes that these forward-looking statements are reasonable, investors are cautioned that forward-looking statements are subject to numerous risks and uncertainties, many of which are difficult to predict and generally beyond the control of Median Technologies, that could cause actual results and events to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements.

All forward-looking statements in this press release are based on information available to Median Technologies as of the date of the press release. Median Technologies does not undertake to update any forward-looking information or statements, subject to applicable regulations, in particular Articles 223-1 et seq. of the General Regulation of the French Autorité des Marchés Financiers.