Press Release - For immediate release
February 03, 2025 – 7:00 am CET

eyonis™ Lung Cancer Screening (LCS) meets primary endpoint in RELIVE clinical trial, the final pivotal study required for regulatory submissions

- Primary endpoint met with statistical significance (p=0.027) in pivotal RELIVE trial of eyonis™ LCS, Median's AI/ML-based Software as a Medical Device for lung cancer screening
- eyonis™ LCS has now successfully completed its clinical validation, having already met primary and all secondary endpoints in previous pivotal study, REALITY
- eyonis™ LCS filings for U.S. FDA 510(k) clearance and EU CE marking submission targeted for Q2 2025
- eyonis™ LCS FDA clearance is expected as early as Q3, 2025, with subsequent commercial launch in U.S.

Fredrik Brag, CEO of Median Technologies, will host two webcasts on February 4, 2025
"New Horizons in Fighting Lung Cancer: eyonis™ LCS RELIVE study results and next steps towards marketing authorizations"

- *February 4, 2025 – 2:00 pm CET (French): Sign-up Link*
- *February 4, 2025 – 4:00 pm CET / 10:00 am EDT (English): Sign-up Link*

Webcast replays will be available on Median's corporate website shortly after the live sessions.

Sophia Antipolis, France: Median Technologies (*FR0011049824, ALMDT, PEA/PME scheme eligible, "Median" or "The Company")* announces today that eyonis™ LCS, its wholly owned proprietary AI/ML-based CADe/CADx Software as a Medical Device (SaMD) for lung cancer screening, met the primary endpoint in RELIVE. Top-line data from RELIVE shows that eyonis™ LCS together with radiologist achieved statistically significant improvement over radiologist alone (p=0.027). RELIVE is the second of two pivotal studies required for marketing authorization in U.S. and Europe.

By meeting primary endpoint in RELIVE, eyonis™ LCS has successfully completed its clinical validation and confirmed the analytical validation previously achieved in REALITY, a standalone pivotal study which results were announced in August 2024. Successful pivotal studies are a key prerequisite of regulatory submissions both in the US and in EU. Consequently, eyonis™ LCS regulatory filings are now being prepared for U.S. FDA 510(k) filing and EU CE marking and will be submitted in Q2 2025.

Median's eyonis™ LCS AI/ML-based CADe/CADx SaMD is designed to improve diagnostic accuracy of radiologists in analyzing low dose computed tomography (LDCT) scans for lung cancer screening.

Lung cancer is the number one killer of all cancers. A recent study showed that only 16% of lung cancers are diagnosed at an early stage and, because most were detected too late, the average five-year survival rate for all lung cancer patients is 18.6%[1]. Conversely, Stage 1 lung cancer can be cured, with an 80% survival rate after 20 years. For Stage 1A cancers that measure 10 mm or less, the 20-year survival rate has been shown to reach 92%.

[1] https://www.mountsinai.org/about/newsroom/2022/lung-cancer-screening-dramatically-increases-long-term-survival-rate

"This is truly the most important milestone that Median eyonis™ has achieved yet; with RELIVE successfully meeting primary endpoint, we confirm the game-changing potential of our AI/ML-based Software as a Medical Device for lung cancer screening. We are confident that eyonis™ LCS will contribute to accelerate efforts in the U.S. and Europe by making lung cancer screening more accurate and efficient, especially for early-stage lung cancers" said **Fredrik Brag, CEO and Founder of Median Technologies**. *"Broad implementation of LDCT screening procedures with eyonis™ LCS has the potential to dramatically improve lung cancer diagnosis accuracy, address the bottlenecks of complexity and time required for analyzing LDCT images, and, most importantly, save lives and reduce the need for healthcare spending on late-stage lung cancer treatment.*

"We believe timely screening of the high-risk populations using eyonis™ LCS can enable doctors to save more lives while further reducing medical costs," **Brag** continued. *"Furthermore, using eyonis™ LCS can not only save lives but also prevent healthy patients from undergoing unnecessary medical procedures. This will avoid unnecessary distress for patients and afford payers tremendous cost savings on unnecessary procedures in addition to obviating the even greater costs of palliative care required for late- stage lung cancer management.".*

The primary objective of RELIVE, a *multi-reader multi-case* (MRMC) trial conducted on a cohort of 480 patients at high-risk of developing lung cancer, was to demonstrate, through a superiority test run by a set of 16 radiologists, that eyonis™ LCS can improve clinicians' diagnostic accuracy in analyzing LDCT lung cancer screening scans, by helping in the detection localization and characterization of lung nodules, by reducing false positives and by driving clinical management to avoid unnecessary follow-up procedures. Top-line data from RELIVE shows that eyonis™ LCS achieved statistically significant improvement over radiologist alone (p=0.027). This finding demonstrates that eyonis™ LCS may save lives of patients, time for healthcare professionals as well as reduce cancer costs for payers.

Additional RELIVE data, including multiple secondary endpoints, are being analyzed and will be reported in the coming weeks. RELIVE data will be shared in future Median Technologies communications and at upcoming medical and scientific conferences. More information regarding RELIVE study can already be found on ClinicalTrials.gov, study ID NCT06751576.

The first pivotal study, REALITY, initially communicated in August 2024, collected retrospective imaging and clinical data from 1,147 patients. REALITY evaluated eyonis™ LCS' ability to diagnose and characterize cancerous vs non-cancerous patients (i.e. "performance at patient level"), and detect and characterize suspicious versus malignant nodules using LDCT lung screening scans.

Both RELIVE and REALITY studies were performed using retrospectively collected imaging and clinical data from patients from five major cancer centers and hospitals in the US and in EU, along with two US data providers.

About lung cancer screening in the U.S.: 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 and covered by Medicare; the eligible population is currently of 14.5 million people.

There already is an existing reimbursement of $650 per SaMD procedure creating a substantial commercial opportunity to improve patient care in this addressable market. Furthermore, the eligible patient number is expected to rise in the coming years, driven by planned broadening of the eligible U.S. population by USPSTF. Similarly, new lung screening program deployments are planned in Europe and Asia.

About eyonis™ LCS: eyonis™ Lung Cancer Screening (LCS) is an artificial intelligence AI/ML-enabled Software as a Medical Device that uses machine learning to help analyze imaging data generated with low dose computed tomography (LDCT) to aid to diagnose lung cancer at the earliest stages, when it can still be cured in many patients. eyonis™ LCS is the subject of two pivotal studies required for marketing approvals in the U.S. and Europe: REALITY (successfully completed - Clinicaltrials.gov ID: NCT06576232) and RELIVE (primary endpoint successfully achieved, secondary endpoints analysis on-going - Clinicaltrials.gov ID: NCT06751576). Filing applications including these pivotal data are scheduled to be submitted for FDA 510(k) clearance and CE marking in Q2 2025.

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 a Medical Device (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.

Contacts

Median Technologies
Emmanuelle Leygues
VP, Corporate Marketing & Financial Communications
+33 6 10 93 58 88
emmanuelle.leygues@mediantechnologies.com

U.S. media & investors
Chris Maggos
Cohesion Bureau
+41 79 367 6254
chris.maggos@cohesionbureau.com

Investors – SEITOSEI ACTIFIN
Ghislaine Gasparetto
+33 6 21 10 49 24
ghislaine.gasparetto@seitosei-actifin.com

Press - ALIZE RP
Caroline Carmagnol
+33 6 64 18 99 59
median@alizerp.com

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, including the risks set forth in the annual financial report of the Company published on April 25, 2024, which is available on the Company's website (https://mediantechnologies.com/). The occurrence of all or parts of such risks 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.