



Press release – For immediate release

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eyonis™ LCS, Median Technologies' AI-powered Software as a Medical Device for lung cancer screening, confirmed efficacy and safety in RELIVE pivotal study

- All secondary endpoints required to support eyonis™ LCS' intended use and desired marketing claims achieved in RELIVE
- eyonis™ LCS previously met primary endpoint, achieving statistically significant superiority compared to state of the art in RELIVE
- U.S. FDA 510(k) filing is on track for May 2025, and filing for CE marking expected in June 2025
- Preparing U.S. commercial launch of eyonis™ LCS in Q4 2025

Sophia Antipolis, France – Median Technologies (*FR0011049824, ALMDT, PEA/PME scheme eligible, "Median" or "The Company"*), manufacturer of eyonis™, a suite of artificial intelligence (AI) powered Software as a Medical Device (SaMD) for early cancer diagnosis, and a globally leading provider of AI-based image analyses and central imaging services for oncology drug developers, disclosed today pivotal study RELIVE's final results, which confirm and complement the top-line results released [on February 3, 2025](#).

This successfully concludes the pivotal studies of Median's AI/ML-based computer aided detection and diagnosis (CADe/CADx) SaMD, eyonis™ Lung Cancer Screening (LCS), a key requirement for regulatory submissions in the US and Europe.

The US FDA filing is on track for formal submission in May 2025, shortly followed by filing for CE marking in Europe in June. Consequently, given normal review times, Median expects eyonis™ LCS' FDA 510(k) clearance in Q3 2025 and CE marking in Q1 2026, as previously communicated.

The eyonis™ LCS SaMD was developed for the following intended use: firstly, to allow early detection and characterization of probably benign, suspicious or very suspicious lung nodules in order to aid cancer diagnosis and to drive the clinical management of patients; secondly, to aid radiologists in the detection, localization, characterization and assessment of pulmonary nodules from medical images by generating a proprietary result report that highlights lung nodules as "probably benign" or "suspicious" or "very suspicious" and scores nodules individually; and, thirdly, to aid the identification of tumor at its earliest stage, to allow better patient care while reducing the number of unnecessary tests, procedures and healthcare costs.

Based on a highly enriched cohort, RELIVE study final results show that Median's eyonis™ LCS SaMD met all key endpoints, demonstrating statistically significant performance, superior to state of the art, as well as device safety and efficacy.

The results support the intended use for which eyonis™ LCS was developed, which was shared with the EU Notified Body and discussed with the FDA during the Q-submission phase. Device efficacy and



safety in line with intended use are mandatory requirements for obtaining marketing authorizations from regulatory bodies in the US and Europe.

“We have achieved the efficacy and safety goals that we set for the intended use and marketing of eyonis™ LCS to aid diagnose lung cancer - this is a tremendous achievement and good news for patients, health professionals and our shareholders,” said Fredrik Brag, CEO of Median Technologies. “Now, our team at Median is working with confidence to prepare the regulatory submissions for marketing authorizations in U.S. and Europe. In parallel, we are already preparing for a successful commercial launch of eyonis™ LCS in the US and Europe.”

Median Technologies intends to present pivotal study results including RELIVE study data, at upcoming ad-hoc medical and scientific conferences and submit scientific papers in peer-reviewed publications in the coming quarters.

If caught early, lung cancer can most often be cured. AI-based Software as Medical Device will facilitate the scalability of lung cancer screening programs worldwide. Median Technologies has developed eyonis™ LCS as a unique artificial intelligence based SaMD to scale up Low Dose CT lung cancer screening programs in the United States, Europe and the rest of the world in order to save people’s lives, support medical professionals in completing more screening procedures and reduce healthcare costs.

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-based computer aided detection and diagnosis (CADe/CADx) system, or Software as a Medical Device (SaMD) that uses machine learning to help analyze imaging data generated with low dose computed tomography (LDCT) to aid radiologists in diagnosis of 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 ([Clinicaltrials.gov ID: NCT06576232](https://clinicaltrials.gov/ct2/show/study/NCT06576232)) and RELIVE ([Clinicaltrials.gov ID: NCT06751576](https://clinicaltrials.gov/ct2/show/study/NCT06751576)), both of which have been successfully completed. Regulatory filings including these pivotal data are scheduled to be submitted for FDA 510(k) clearance and CE marking in Q2 2025.

About eyonis™ pivotal studies: The first pivotal study, **REALITY**, with results communicated in August 2024, is based on an enriched cohort of retrospectively collected imaging and clinical data from 1,147 patients. REALITY evaluated eyonis™ LCS’ standalone ability to diagnose and characterize cancerous vs non-cancerous patients (i.e. “performance at patient level”) and detect and characterize probably benign, suspicious or very suspicious nodules using LDCT lung screening scans. The objective of the second pivotal study **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 16 radiologists, that eyonis™ LCS can aid 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 patient management and avoid unnecessary follow-up procedures. RELIVE cohort corresponded to a highly enriched cohort. RELIVE final results were disclosed in March 2025. RELIVE and REALITY studies were both performed using enriched and



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 Median Technologies: Pioneering innovative imaging solutions and Software as a Medical Device, 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.

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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.