Press release – For immediate release
February 9, 2026 – 7:00 am CET

Median Technologies receives FDA 510(k) clearance for eyonis® LCS, the first AI tech-based detection and diagnosis device for lung cancer screening

- eyonis® LCS aims to redefine lung cancer screening by supporting diagnosis at early, curable stages, while reducing false positives to avoid unnecessary follow-up procedures, and has the potential to help save hundreds of thousands of lives in the US alone
- eyonis® LCS is the only device capable of both detecting and characterizing lung cancer in low-dose CT scans, with 93.3% sensitivity, 92.4% specificity, and 99.9% Negative Predictive Value
- eyonis® LCS' U.S. market authorization will boost large-scale deployment of lung cancer screening programs for the 14.5 million eligible individuals nationwide
- Existing NT-APC 1508 code enables a predictable reimbursement pathway that will accelerate adoption of eyonis® LCS

Sophia Antipolis, France: Median Technologies *(FR0011049824, ALMDT, "Median" or the "Company")*, developer 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, today announced it has received FDA 510(k) clearance for eyonis® LCS, its AI/ML-powered computer-aided detection and diagnosis (CADe/CADx) Software as a Medical Device intended for lung cancer screening.

Lung cancer is the leading cause of cancer death in the United States, and patient outcomes are substantially improved when cancer is identified at early stages. Curable stage 1 lung cancer can be diagnosed through Low-Dose CT (LDCT) screening, yielding ~80% long-term survival versus ≈15% 5-year survival in symptom-detected disease.

By supporting detection and characterization of parenchymal pulmonary nodules on LDCT scans, eyonis® LCS is designed to help clinicians identify suspicious findings earlier, reduce inter-reader variability and improve the efficiency and consistency of lung cancer screening programs.

CEO Statement

"This FDA 510(k) clearance for eyonis® LCS is a major milestone for Median Technologies and an important step toward expanding access to AI-assisted lung cancer screening in the United States. eyonis® LCS is the first end-to-end detection and diagnosis device FDA cleared, specifically targeting lung cancer screenings. We believe eyonis® LCS will prove to be a game changer for clinical teams as they manage rising screening volumes and help healthcare systems deliver high-accuracy and timely lung cancer diagnosis for eligible patients. We are now fully positioned to execute our go-to-market strategy and deploy eyonis® LCS at scale to potentially help save hundreds of thousands of lives in the U.S. alone in the coming years," said **Fredrik Brag, CEO and Founder of Median Technologies.**

"Lung cancer screening combined with eyonis® LCS has the capacity to deliver one of the most impactful advances in cancer care by identifying cancer at a stage where it can be cured. eyonis® LCS will empower US clinicians to significantly transform lung cancer patient outcomes. We will now continue leveraging our AI expertise to expand into additional cancer indications — including Incidental Pulmonary Nodules, HCC (liver cancer), pancreatic, colon and prostate cancer— always with the same objective: finding cancer at a stage where it can be cured," Brag added.

eyonis® LCS establishes a new paradigm in lung cancer screening

eyonis® Lung Cancer Screening (LCS) is designed to analyze imaging data generated from LDCT scans and assist radiologists in detecting and characterizing parenchymal pulmonary nodules, supporting clinical decision-making and patient follow-ups. By enabling earlier identification of suspicious lesions, eyonis® LCS supports diagnosis at stages where patient outcomes can be significantly improved.

In manufacturer performance testing on a lung cancer screening reference population, eyonis® LCS demonstrated 93.3% sensitivity, 92.4% specificity, and a 99.9% Negative Predictive Value (NPV).

The high Negative Predictive Value (NPV) of eyonis® LCS, demonstrates a very low level in false positives (1 per 1,000), which provides clinicians with a high level of diagnostic confidence, enabling them to identify individuals who can remain in standard screening pathways versus those requiring recall, avoiding unnecessary follow-up procedures.

In addition to performance, eyonis® LCS is engineered to integrate seamlessly into existing healthcare workflows, enhancing diagnosis accuracy, and reducing routine workload. eyonis® LCS can be directly integrated into hospital Picture Archiving and Communication Systems (PACS).

eyonis® LCS will help improve adherence to screening programs, enabling healthcare systems to deliver more consistent, high-quality patient care.

Approximately 14.5 million people are currently eligible for lung cancer screening in the United States, and eyonis® LCS benefits from an established reimbursement framework, creating a highly favorable environment for rapid scale.

The USPSTF eligible population for lung cancer screening using LDCT in the United States includes adults aged 50 to 80 years with a 20-pack-year smoking history. Based on current eligibility criteria, 14.5 million individuals qualify for screening, and this population is expected to increase over time as screening guidelines expand.

Median Technologies believes that eyonis® LCS can play a major role in helping healthcare systems expand access to screening, reduce operational burden, and support more standardized parenchymal nodule evaluation, particularly as screening volumes grow amid a worsening shortage of radiologists.

This opportunity is supported by an existing reimbursement framework: AI-driven CT tissue characterization is reimbursed under Category III CPT codes 0721T and 0722T, both assigned to New Technology APC 1508, with Medicare payments ranging from $601–$700. These codes provide a

predictable payment pathway that accelerates adoption of advanced AI medical devices among U.S. imaging providers. eyonis® LCS is positioned to leverage this established reimbursement pathway, generating immediate economic value for imaging providers and accelerating nationwide adoption.

Median plans to commercialize eyonis® LCS in the United States through a combination of direct enterprise sales, strategic distribution partnerships, and integration into existing clinical environments. Median will utilize the current CMS reimbursement framework, including applicable New Technology APC pathways, while working toward broader, long-term insurance coverage.

The Company will provide further details regarding the commercial launch in the coming weeks.

Alongside its U.S. rollout, the Company continues to advance the European regulatory pathway and expects CE marking in Q2 2026, expanding access to this technology to hundreds of thousands of patients in Europe.

About Median Technologies: Pioneering innovative software as a medical device and imaging 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.

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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.