Press release – For immediate release
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Median Technologies' eyonis® LCS Obtains CE Marking

- European marketing authorization follows U.S. FDA clearance of eyonis® LCS, Median's AI-based Software as a Medical Device designed to aid in the detection and diagnosis of lung cancer in screening programs
- CE marking enables the commercial launch of eyonis® LCS across the European Union
- eyonis® LCS' unique technology and performance will empower lung cancer screening programs to enable earlier diagnosis, as screening initiatives continue to expand across Europe

Sophia Antipolis, France: Median Technologies *(FR0011049824, ALMDT, "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, today announced eyonis® LCS has obtained CE marking as a Class IIb medical device, under the new European Medical Device Regulation (MDR 2017/745), enabling commercialization across the European Economic Area.

The CE marking, granted by the French notified body GMED demonstrates compliance with the highest European standards for patient safety and clinical efficacy.

This marks a major achievement for eyonis® LCS, the Company's AI/ML-powered SaMD. eyonis® LCS helps clinicians both detect lung parenchymal nodules on LDCT scans and characterize them as probably benign, suspicious or very suspicious, thus supporting early cancer diagnosis, patient risk stratification, improved patients' clinical management, and ultimately enabling lung cancer screening programs implementation at scale.

Following February 2026's clearance of eyonis® LCS by the U.S. Food and Drug Administration (FDA), the CE marking further expands access to Median's AI-based SaMD designed to address the biggest clinical unmet needs in lung cancer screening: the false positives and false negatives, which significantly hamper existing screening programs.

Lung cancer screening programs across the European Union (EU)

Across the EU, an estimated 25 to 30 million individuals[1] may be eligible for lung cancer screening under current high-risk criteria, representing a substantial and largely untapped addressable market for early diagnostic solutions.

[1] Estimate derived from country-level modelling extrapolated to the EU population, and consistent with published epidemiological data on smoking prevalence and high-risk screening criteria.

Lung cancer screening programs across Europe are gaining momentum. While only a limited number of countries have established national programs—such as England, Poland and Croatia—Europe is entering an acceleration phase, illustrated by the launch of Germany's nationwide screening program in April 2026.

At the same time, major countries including France are advancing large-scale pilot initiatives designed to assess the feasibility of organized lung cancer screening in real-world settings. In France, the national IMPULSION study has been launched as a large-scale pilot program to evaluate the feasibility of implementing organized lung cancer screening using low-dose CT in a real-world setting, targeting approximately 20,000 high-risk individuals and combining screening with smoking cessation support.

Italy also stands out as one of the most advanced European countries in lung cancer screening, with a nationwide network-based approach (RISP) and multiple large-scale pilot programs already underway, providing a real-world foundation for the future expansion of organized screening.

The key growth drivers for lung cancer screening in the EU are the transition from pilot programs to national deployment, increasing pressure on radiology capacity, and the progressive integration of standardized, AI-enabled workflows, which will create a strong foundation for scalable, technology-driven solutions such as eyonis® LCS.

"*Receiving CE marking is a critical step in our mission to make earlier, more accurate lung cancer diagnosis accessible to more patients eligible for lung cancer screening in Europe,*" said **Fredrik Brag, Founder and CEO of Median Technologies**.

"*Several European nations have already launched lung cancer screening programs and our AI-based eyonis® LCS SaMD was developed to aid earlier detection and diagnosis of lung cancer, when treatment is more likely to be successful, helping patients gain faster access to potentially life-saving therapies. The CE marking of eyonis® LCS - which follows the recent FDA 510(k) clearance for the US market - positions us as a key player in Europe, well-suited to support healthcare systems in scaling screening programs with enhanced accuracy, efficiency, and clinical confidence,"* **Fredrik Brag added.**

Ability to find lung cancer early is critical

Lung cancer is the leading cause of cancer death in the EU, accounting for 20% of the total number of cancer deaths[2]. Early detection dramatically changes the prognosis of lung cancer. Data from the International Early Lung Cancer Action Program (I-ELCAP) show a 20-year survival rate of 81% for lung cancers diagnosed through annual CT screening and 92% for Stage I cancers resected within two months of diagnosis[3], compared with an estimated 5-year survival rate of only 10–12% for metastatic lung cancer[4].

[2] European Commission Joint Research Center – 2024 estimates of cancer cases and death in the EU, February 2026

[3] Henschke CI, Yip R, et al. A 20-Year Follow-Up of Participants with Lung Cancer Diagnosed in the International Early Lung Cancer Action Program (I-ELCAP). Radiology. 2023 and International Early Lung Cancer Action Program (I-ELCAP). Research Summary.

[4] American Cancer Society/SEER survival statistics

eyonis® LCS features a unique and strongly differentiated positioning

Unlike existing AI-based solutions primarily focused on either lung nodule detection or lung cancer diagnosis outside of screening pathways, eyonis® LCS is the first in the world to combine computer-aided detection (CADe) and computer-aided diagnosis (CADx) embedded directly within the diagnostic care pathway of LDCT lung cancer screening.

By enabling the characterization of pulmonary parenchymal nodules during screening, Median's SaMD has the potential to reduce unnecessary downstream workups while supporting earlier and more confident cancer identification by clinicians.

As more European countries implement national lung cancer screening programs, the CE marking of eyonis® LCS positions Median as a key player in Europe, well-suited to support healthcare systems in scaling screening programs with enhanced accuracy, efficiency, and clinical confidence.

Industry-Leading Performance: Accuracy, Reliability, False Negatives (FN) and False Positives (FP)

eyonis® LCS' manufacturer values have demonstrated 93.3% sensitivity (finding cancer when present), and 92.4% specificity (ruling out cancer when not present). By contrast, traditional lung cancer screening by unaided radiologists demonstrated 80.3% sensitivity and 76.4% specificity[5], positioning eyonis® LCS' performance at a significant clinical advantage.

eyonis® LCS has demonstrated a 68% reduction of False Positives (FP)[6], greatly helping clinicians to focus on the actual nodules of interest, preventing avoidable follow-up procedures, including potentially harmful invasive ones, reducing overwhelming patient anxiety, and lowering excessive workload for clinical teams amid ongoing workforce shortages.

eyonis® LCS has demonstrated a 66% reduction of False Negatives (FN)[7], avoiding missed cancers, upgrading patient management and saving lives.

[5] Jonas DE, et al. Screening for Lung Cancer with Low-Dose Computed Tomography: Updated Evidence Report and Systematic Review for the US Preventive Task Force. JAMA. 2021 Mar 9;925(10):971-987

[6] Estimated from Jonas DE, et al. Screening for Lung Cancer with Low-Dose Computed Tomography: Updated Evidence Report and Systematic Review for the US Preventive Task Force. JAMA. 2021 Mar 9;925(10):971-987

[7] Estimated from Jonas DE, et al. Screening for Lung Cancer with Low-Dose Computed Tomography: Updated Evidence Report and Systematic Review for the US Preventive Task Force. JAMA. 2021 Mar 9;925(10):971-987

About Median Technologies: Pioneering innovative Software as a Medical Device (SaMD) 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 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.