Press release – For immediate release
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Median Technologies files European application for Class IIb CE marking of its AI-based Software as a Medical Device for Lung Cancer Screening, eyonis® LCS

- Class IIb CE marking is a prerequisite for Median's eyonis® LCS Software as a Medical Device marketing in Europe
- Lung cancer screening programs are already implemented in several European countries, and will be gathering pace across the continent,
- Eligible population in Europe is estimated at 20 million people
- Median previously submitted U.S. application for FDA 510(k) clearance of eyonis® LCS in May 2025 for marketing in U.S.
- On track for U.S. commercial launch before year-end and European launch in H1 2026, pending regulatory authorizations

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, announced today it has filed an application for Class IIb CE marking of eyonis® LCS (Lung Cancer Screening), its AI/ML tech-based Software as a Medical Device (SaMD) for computer aided detection and diagnosis (CADe/CADx) of lung cancer in screening programs. Concurrently to CE marking, Median has also applied for ISO 13485 certification for the Quality Management System supporting the manufacturing of eyonis ® LCS.

Median Technologies applied for 510(k) clearance of eyonis® LCS with the U.S. Food and Drug Administration (FDA) on May 2025.

Both regulatory filings confirm that timetables for eyonis® LCS are on track, towards commercial launch as soon as year-end 2025 in the U.S., pending FDA 510(k) clearance expected end Q3 2025, and in H1 2026 in Europe, pending Class IIb CE marking expected in Q1 2026.

"Filing for CE marking of eyonis® LCS is yet another important step forward for Median, leveraging the Median eyonis® strong technology, clinical development and regulatory capabilities," said **Fredrik Brag, CEO and Founder of Median Technologies**. *"Our regulatory submissions are built on a significant volume of positive clinical data demonstrating eyonis® LCS' safety and efficacy in REALITY and RELIVE successful pivotal studies. We are looking forward to continuing and finalizing our constructive discussions with market stakeholders, in both the U.S. and Europe, as we aim to bring eyonis® LCS to patients eligible for lung cancer screening in existing and future screening programs. Thanks to multiple institutions visits and major medical congresses attendance, our eyonis® team confirms the strong support of lung cancer key opinion leaders belonging to the pulmonology, oncology and radiology scientific bodies and societies in the U.S. and Europe. We are truly blessed with an exceptional appreciation of our highly differentiated technology, which contributes to establishing a powerful brand equity for eyonis® LCS. Additionally, our device market access strategy is already*

developed, ready for execution in the U.S. and tailored for specific payers to ensure maximum market penetration".

Based on SOLACE project data, the overall eligible population in the EU is about 20 million people. Currently, Croatia and Poland have national Low Dose Computed Tomography (LDCT)-based lung cancer screening programs and many other European countries are conducting promising pilot programs.

On June 23, 2025, LDCT-based lung cancer screening received green light in Germany for eligible people covered by statutory health insurance providers, with the policy due to go into effect in April 2026. Other European countries are moving toward lung cancer screening programs implementation, including France.

In the U.S., the market opportunity includes a population of 14.5 million people, currently eligible for a LDCT lung cancer screening exam, with an existing potential reimbursement of $650 per exam with a SaMD postprocessing for characterization of malignant vs benign nodules. The eligible U.S. patient number is expected to rise in the coming years, driven by the planned broadening of the eligibility criteria.

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 has been the subject of two pivotal studies required for marketing approvals in the U.S. and Europe: REALITY (Clinicaltrials.gov ID: NCT06576232) and RELIVE (Clinicaltrials.gov ID: NCT06751576), both of which have been successfully completed. Based on these pivotal data, Median Technologies submitted U.S. application for 510(k) clearance of eyonis® LCS on May 13th, 2025, and European application for CE mark on June 30th, 2025.

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.