Press release – For immediate release
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Median Technologies submits U.S. application for 510(k) clearance of eyonis® LCS

- Submission based on positive data from two pivotal studies, which both met their primary endpoints
- U.S. clearance expected in Q3 2025 based on average observed review timelines for radiological medical devices

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, today announced it has filed an application to the U.S. Food and Drug Administration (FDA) for 510(k) clearance of eyonis® LCS, its AI/ML tech-based SaMD for computer aided detection and diagnosis (CADe/CADx) in lung cancer screening.

The submission is based on positive data from the two pivotal studies of eyonis® LCS, REALITY and RELIVE, both of which met their primary endpoints. This data demonstrated that eyonis® LCS provides robust diagnostic performance for early detection and characterization of lung nodules in high-risk lung cancer populations, with significant potential to impact patients' clinical outcomes. Additionally, Median's eyonis® LCS SaMD confirmed safety and efficacy in RELIVE, the second and last pivotal study.

"*eyonis® LCS' FDA filing is a major milestone for Median and a testament to our R&D and clinical programs' strength,*" **said Fredrik Brag, CEO and Founder of Median Technologies.** *"RELIVE and REALITY pivotal studies met their primary endpoints and confirmed the device's safety and efficacy. This shows that eyonis® LCS has the potential to be a game-changer in lung cancer screening. By providing early detection and characterization at scale, eyonis® LCS can significantly improve high-risk patient outcomes. Based on average observed review regulatory timeframes, we would expect an eyonis® LCS' clearance in the U.S. in Q3 this year."*

Results from REALITY released in August 2024, showed that eyonis® LCS can accurately detect and characterize lung nodules, with exceptional results of an area under the curve (AUC) value of 0.904 versus the minimum value set as a primary endpoint for REALITY of an AUC of 0.80. Results from RELIVE released in March 2025, showed that radiologists aided by eyonis® LCS achieved statistically significant improved performance over radiologists alone (p=0.027) and can thus improve clinicians' diagnostic accuracy in analyzing low dose computed tomography (LDCT) lung cancer screening scans. In addition, importantly, the Company believes that eyonis® LCS can increase efficiency of LDCT scans analyses, so that healthcare professionals can process many more patients through lung cancer screening with greater confidence in diagnostic accuracy.

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. The market opportunity includes a population of 14.5 million people in the U.S. alone, currently eligible for a lung cancer screening exam, with an existing potential reimbursement of $650 per exam with a SaMD postprocessing for

characterization of malignant vs benign nodules. This represents a total addressable annual market of over $10bn. The eligible U.S. patient number is expected to rise in the coming years, driven by planned broadening of the eligibility criteria. Similarly, new lung screening program deployments are planned in Europe and Asia.

In the US alone, the direct medical costs of cancer patients care were estimated to be nearly $230 billion in 2023[1]. The vast majority of cancer care costs are incurred in treating advanced cancer patients, versus preventive care such as screening that save patients' lives.

About eyonis™ LCS: eyonis® Lung Cancer Screening (LCS) is an artificial intelligence AI-based computer aided detection and diagnosis (CADe/CADx) 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) and RELIVE (Clinicaltrials.gov ID: NCT06751576), both of which have been successfully completed.

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.

Contacts

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

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

U.S. media & investors - COHESION BUREAU
Chris Maggos
+41 79 367 6254
chris.maggos@cohesionbureau.com

Press – ULYSSE COMMUNICATION
Bruno Arabian
+33 6 87 88 47 26
barabian@ulysse-communication.com
Nicolas Entz
+33 6 33 67 31 54
nentz@ulysse-communication.com

[1] American Cancer Society.

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.