

Press release – For immediate release February 28, 2023 – 5:45 pm CET

## Median Technologies to present new and breakthrough results for its iBiopsy<sup>®</sup> Lung Cancer Screening CADe/CADx Software as Medical Device at the European Congress of Radiology, taking place March 1-5 2023 in Vienna, Austria

- New results, obtained on a very large cohort of 9,863 patients show drastically improved performance of the iBiopsy<sup>®</sup> LCS CADe/CADx Software as Medical Device (SaMD) with a sensitivity of 96.5% at a specificity of 97.2%.
- Further to the completion of the Q-Submission phase with the FDA announced on Feb. 27, 2023, these new performance results have set Median's trajectory for execution of the upcoming pivotal studies of this device with an aim at obtaining 510(k) clearance in the first half of 2024.
- Results will be presented at the European Congress of Radiology (ECR, Vienna, Austria) on March 1<sup>st</sup> at 4:00 pm CET and on March 2<sup>nd</sup> at 1:30 pm CET during the AIX Theater and at Median's booth #AI-35 from March 1 to 4 (ECR exhibition dates).

**Sophia Antipolis, France** – Median Technologies (ALMDT:PA) today announces new and breakthrough results for its iBiopsy<sup>®</sup> Lung Cancer Screening (LCS) AI/ML tech-based CADe/CADx<sup>1</sup> Software as Medical Device (SaMD) to characterize malignant lung nodules in low dose CT scans (LDCT).

New results released today demonstrate considerable increase of Median's proprietary algorithms performance with a sensitivity<sup>2</sup> of 96.5% for a specificity<sup>3</sup> of 97.2% on end-to-end lung nodule detection and malignancy characterization. These results complement the results released previously (March 22, 2022), which were based on a cohort of 1,760 patients and showed a 94.7% sensitivity at a 93.3% specificity. New results are calculated on a much larger cohort of 9,863 patients corresponding to 195,943 nodules (vs. 16,789 lung nodules in March 2022). Consistent with previously released results, the performance corresponds to end-to-end detection and characterization at nodule level.

"On February 27, 2023 we announced the completion of the Q-Submission phase with the FDA regarding clinical protocols pre-submission, a major milestone in the roadmap of our iBiopsy® LCS CADe/CADx SaMD. Our pivotal study protocols are now finalized and ready for study execution. Today, with the release of our improved performance results, we are more than ever confident for the next steps which will drive our iBiopsy® LCS CADe/CADx SaMD to the FDA clearance. Our next milestone is now the execution of the pivotal studies, based on imaging and clinical data we started to collect at the end of 2022 from very prestigious clinical sites and cancer centers in the US and Europe", highlights Fredrik Brag, CEO and founder of Median. "Subsequent to this breakthrough performance, we recently filed two patents", Brag added.

<sup>&</sup>lt;sup>1</sup> A radiological CADe device is "intended to identify, mark, highlight or otherwise direct attention to portions of an image that may reveal abnormalities during interpretation of images by the clinician." A CADx device is "intended to provide information beyond identifying abnormalities, such as an assessment of disease." Source: FDA

<sup>&</sup>lt;sup>2</sup> Sensitivity is the ability to correctly generate positive results for cancer patients.

<sup>&</sup>lt;sup>3</sup> Specificity is the ability to correctly generate negative results for non-cancer patients



Results will be presented at the European Congress of Radiology (ECR) AIX Theater, on Wednesday, 1 March, at 4:00 pm CET and on Thursday, 2 March at 1:30 pm CET. Median's team will be available at booth #AI-35 for the duration of the technical exhibition (March 1-4).

The European Congress of Radiology (ECR) organized by the European Society of Radiology (ESR) is the premier European event in radiology and the second largest in the world. The congress conveys more than 20,000 with a split of more than 10,000 professional delegates (radiologists, technologists etc.), and ~8,000 industry participants (imaging modalities, PACS etc.). Radiology professionals from Europe and beyond attend to gather knowledge through educational courses, to see the latest innovations presented by technical exhibitors, and to discover groundbreaking research from scientific paper presentations. More about the ECR: https://www.myesr.org/congress/about-ecr

**About iBiopsy®:** iBiopsy® is based on the most advanced technologies in Artificial Intelligence (AI) and Data Science (DS), benefiting from Median's expertise in medical image processing. iBiopsy® targets the development of AI/ML tech-based Software as Medical Devices (SaMD), to be used in several indications for which there are unmet needs regarding early diagnosis, prognosis and treatment selection in the context of precision medicine. iBiopsy® currently focuses on Lung Cancer, Liver Cancer (HCC) and Liver Disease (NAFLD/NASH)

Forward-looking statements: This press release contains express or implied information and statements that may be considered forward-looking information and statements about Median Technologies. They are not historical facts. Such information and statements include financial projections that are based on certain assumptions and assessments made by Median Technologies' management in light of its experience and perception of historical trends, current economic and industry conditions, expected future developments and other factors it deems relevant. These forward-looking statements include statements that generally use conditional verbs and contain words such as "expects", "anticipates", "believes", "intends", "plans" or "estimates" and variations and conjugations thereof and words of similar import. Although Median Technologies' management believes that the forward-looking statements and information are reasonable, Median Technologies' shareholders and other investors are cautioned that the realization of these expectations is inherently subject to various known and unknown risks and uncertainties that are difficult to predict and generally beyond the control of Median Technologies. These risks could cause actual results and developments to differ materially from those expressed, implied or projected in the forward-looking statements. This press release contains only summary information and should be read in conjunction with the public information filed by Median Technologies with the AMF and that are available on Median Technologies' website. Other than as required by applicable law, Median Technologies is issuing this press release as of the date hereof and does not undertake to update or revise any forward-looking information or statements.



**About Median Technologies:** Median Technologies provides innovative imaging solutions and services to advance healthcare for everyone. We harness the power of medical images by using the most advanced Artificial Intelligence technologies, to increase the accuracy of diagnosis and treatment of many cancers and other metabolic diseases at their earliest stages and provide insights into novel therapies for patients. Our iCRO solutions for medical image analysis and management in oncology trials and iBiopsy<sup>®</sup>, our AI-powered software as medical device help biopharmaceutical companies

and clinicians to bring new treatments and diagnose patients earlier and more accurately. This is how we are helping to create a healthier world.

Founded in 2002, based in Sophia-Antipolis, France, with a subsidiary in the US and another one in Shanghai, Median has received the label "Innovative company" by the BPI and is listed on Euronext Growth market (Paris). FR0011049824– ticker: ALMDT. Median is eligible for the French SME equity savings plan scheme (PEA-PME). For more information: <u>www.mediantechnologies.com</u>



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