

Press release – For immediate release
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Median Technologies announces completion of the Q-submission phase with the FDA for its iBiopsy® Lung Cancer Screening CADe/CADx Software as Medical Device

- The Q-submission phase was initiated on May 2, 2022 with the FDA.
- The Q-submission phase aims at clarifying and implementing the FDA's expectations on key topics including pivotal study protocols.
- Further to the Q-submission phase completion, Median's iBiopsy® LCS CADe/CADx SaMD pivotal study protocols are now finalized and ready for study execution.
- Median Technologies aims at starting the execution of the iBiopsy® LCS CADe/CADx SaMD pivotal studies by the end of Q2, 2023 and obtaining 510(k) clearance in the first half of 2024.

Sophia-Antipolis, France – Median Technologies (ALMDT) announces today that the Company has received feedback from the United States Food and Drug Administration (FDA) regarding the Q-submission phase initiated [on May 2, 2022](#) for its iBiopsy® Lung Cancer Screening (LCS) AI/ML tech-based CADe/CADx¹ Software as Medical Device (SaMD) and announces completion of this phase.

The Q-submission phase is a major regulatory step which allows regular and in-depth discussions with the FDA on key topics such as pivotal study protocols. Further to this Q-submission phase, Median's SaMD is better tailored to fit the FDA's expectations and market needs.

As next steps, Median Technologies, having finalized its pivotal study protocols, is now getting ready for pivotal study execution by the end of Q2 2023, as planned, once all imaging and clinical data collection and preparation as well as reader training are completed. Likewise, Median still targets obtaining the FDA 510(k) clearance for its iBiopsy® LCS CADe/CADx SaMD in the first half of 2024, subject to FDA review requirements.

"The Q-submission phase allowed us to have frequent and fruitful interactions with the Agency in order to better tailor our medical device software to the US market", Fredrik Brag, CEO and Founder of Median Technologies said. "But more than that, we had the opportunity to present to the FDA the vision we have for our product, the cutting edge performance we aim for, and our ambition to change the paradigm in the early diagnosis of lung cancer patients", Brag added.

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

¹ 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



of AI/ML tech-based Software of 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®, 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: www.mediantechologies.com

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