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Press release – For immediate release
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Median Technologies files FDA 513(g) regulatory submission for iBiopsy® Lung Cancer Screening CADe/CADx Software as Medical Device

- 513(g) submission is a key milestone that marks the initiation of Median's interactions with the FDA.
- 513(g) submission will allow Median Technologies to determine the best FDA regulatory pathway for iBiopsy® LCS CADe/CADx Software as Medical Device.
- Median aims to obtain a full device approval and market authorization by the end of 2023, and proceed with subsequent commercialization.
- iBiopsy® LCS CADe/CADx SaMD could significantly contribute to eliminating barriers to the widespread adoption of lung cancer screening programs and save the lives of millions of patients.

Sophia-Antipolis, France - Median Technologies (ALMDT) announces today that the company has filed a 513(g) submission on Feb. 17, 2022 to the United States Food and Drug Administration (FDA) for its iBiopsy® Lung Cancer Screening (LCS) AI/ML technology-based end-to-end CADe/CADx[1] Software as Medical Device (SaMD).

The 513(g) submission will allow Median Technologies to determine the best product classification and choose between the De Novo or the 510(k) regulatory pathways for iBiopsy® LCS CADe/CADx SaMD. The FDA is expected to review the 513(g) submission and provide feedback within 60 calendar days.

As next regulatory steps, Median Technologies is preparing several Q-submissions for Q2, 2022.

"This first regulatory submission marks the beginning of our interactions with the FDA. The FDA's feedback will help us determine the shortest and most efficient way to bring our product onto the US healthcare market", Fredrik Brag, CEO and founder of Median Technologies said. *"Lung cancer is the deadliest cancer, and being able to detect it very early is of critical importance for patients. Our innovative iBiopsy® AI/ML-based technology could have a huge impact on saving patients' lives by identifying lung cancer onsets at their earliest stage, and could significantly improve the accuracy, consistency, and adoption of lung cancer screening programs worldwide".*

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 innovative AI/ML-based Software as Medical Device, 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 fibrosis (NASH).

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[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*

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), is part of the Enternext® PEA-PME 150 index and has been awarded the Euronext European Rising Tech label. For more information: www.mediantechnologies.com

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