Press release – For immediate release
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Median Technologies announces design completion of its iBiopsy® Lung Cancer Screening end-to-end CADe/CADx Software as Medical Device (SaMD) with outstanding sensitivity & specificity performance

- iBiopsy® Lung Cancer Screening (LCS) CADe/CADx[1] outstanding performance reaches 94.7% sensitivity[2] at 93.3% specificity[3], based on a cohort of 1,760 patients
- With such performance, iBiopsy® LCS CADe/CADx SaMD positions itself to dramatically increase the efficacy of lung cancer screening programs worldwide, which would facilitate saving the lives of millions
- Median has started the regulatory engagement and the design of the pivotal clinical studies for iBiopsy® LCS CADe/CADx SaMD, and aims to obtain a US FDA approval and market authorization by the end of 2023

Sophia Antipolis, France - Median Technologies (ALMDT:PA) announces outstanding performance of its iBiopsy LCS AI/ML tech-based end-to-end CADe/CADx Software as Medical Device, intended to enable early detection and characterization of lung cancer nodules and improve clinical management of patients.

Median's iBiopsy® LCS SaMD offers a unique end-to-end detection/diagnosis approach (CADe/CADx) based on AI/ML technologies. Median aims at drastically improving the ability to detect and characterize lung cancers at their earliest stages, enabling a better patient care while avoiding unnecessary medical tests and procedures, and reducing healthcare costs. No product is currently approved for both lung cancer detection and diagnosis in the US or Europe. With this breakthrough innovation, Median's iBiopsy® LCS SaMD brings a unique AI-powered solution for clinicians to fight lung cancer, the deadliest cancer worldwide.

Results released today show unrivalled performance for Median's end-to-end detection/diagnosis approach for lung cancer screening.

The study was based on a cohort of 1,760 patients from the National Lung Screening Trial (NLST) consisting of a total of 16,789 lung nodules. The training set was composed of a subset of 1,289 patients with 12,108 nodules and the test set represented 471 patients with a total of 4,681 nodules.

[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*

[2] Sensitivity is the ability to correctly generate positive results for cancer patients.

[3] Specificity is the ability to correctly generate negative results for non-cancer patients

The performance of iBiopsy® LCS CADe/CADx SaMD to detect and characterize lung cancer nodules achieves an AUC of 0.976 and an outstanding sensitivity of 94.7% for a specificity of 93.3%.

"*We are thrilled to announce our performance. These results pave the way for a disruptive approach in lung cancer screening management*", Fredrik Brag, CEO and founder of Median Technologies said. "*We have already initiated our interactions with the FDA with the recent 513(g) submission, which will allow us to determine the best FDA regulatory pathway for our iBiopsy® LCS SaMD. Our next step will be to integrate the FDA's comments in the protocols of the pivotal clinical studies that we will launch in the second half of 2022. In parallel, we are reviewing our regulatory pathway to the CE-Mark in Europe",* Brag added.

Median Technologies aims to obtain a device approval and market authorization by the end of 2023.

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).

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 France and is listed on Euronext Growth market (ISIN: FR0011049824, ticker: ALMDT). Median is eligible for the French SME equity savings plan scheme (PEA-PME), is listed on 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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