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Median Technologies announces outstanding lung nodule detection (CADe¹) performance for iBiopsy® Lung Cancer Screening

- iBiopsy® Lung Cancer Screening (LCS) detection performance reaches 94.9% sensitivity for a false positive rate of 1 per CT scan, a performance superior to that of lung CADe systems currently on the market.
- The particularly high sensitivity of iBiopsy® LCS is a prerequisite for implementing a reliable detection and diagnosis (CADe/CADx) solution for lung cancer screening programs.
- After detection (CADe), the diagnostic component (CADx) of iBiopsy® LCS characterizes
 nodules as malignant or benign. Its sensitivity/specificity levels were announced in
 2021 and are still unparalleled today.

Sophia Antipolis, France – Median Technologies (ALMDT:PA) announces outstanding performance for its iBiopsy[®] Lung Cancer Screening (LCS) CADe algorithm in detecting potentially cancerous lung nodules.

When screening for lung cancer, the entire lung must be scanned, which can generate hundreds of images for each patient to detect very small lung nodules. Time constraints and the very large numbers of images to review render it difficult for radiologists to exhaustively detect lung nodules without an automation tool. Without such automation tools, diagnostic errors may result when radiologists are dealing with fatigue. Automated detection tools can help radiologists read images and must offer high sensitivity to minimize false negatives and avoid missing nodules. These tools should also minimize the number of false positives to ensure that radiologists do not focus their attention and time on regions that are not clinically relevant, and will help to avoid lung biopsies as well as unnecessary follow up procedures for the patients.

iBiopsy® LCS offers an integrated detection/diagnosis approach (CADe/CADx). The first step is detecting, as thoroughly as possible, all lung nodules in the CT scan images with minimal false negatives and false positives per scan. After automated detection, the diagnostic component (CADx) of iBiopsy® LCS aims to reach high levels of sensitivity and specificity, accurately characterizing the presence of cancer while minimizing the false positive rate. False positives are one of the major barriers to adopting screening programs globally. It bears recalling that the outstanding characterization results of iBiopsy® CADx were published on September 6, 2021 (performance characterizing cancerous nodules at all stages) and on November 23, 2021 (focus on stage 1 cancers).

The results released today by Median Technologies specifically focus on the lung nodule detection function, which applies Median's proprietary deep learning algorithms to low-dose computed tomography (LDCT). They are based on a cohort of 888 patients from the LIDC/IDRI² public database. The 10-fold cross-validation method was used for training (800 train/88 test patients). The overall

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 Lung Imaging Database Consortium/Image Database Resource Initiative: https://www.cancerimagingarchive.net/



result, obtained by aggregating the ten test fold results, showed a sensitivity of 94.9% for a false positive rate of 1 per CT scan.

According to publicly available data on the performance of lung CADe devices currently on the market, iBiopsy® detection algorithms show the best combination of sensitivity/false positives per CT scan.

"After announcing iBiopsy®'s first outstanding results for malignant vs. benign lung nodule characterization in 2021, we are proud to announce our detection algorithm's performance," highlights Fredrik Brag, CEO and founder of Median. "These results give us reason to be optimistic as we enter the final phase of iBiopsy® Lung Cancer Screening's technological risk mitigation. We are now working on combining detection and diagnosis modules to determine integrated performance. We believe it is only by integrating these two functions in the same software as a medical device (SaMD) that we can remove the current barriers to implementing lung cancer screening programs. Large international trials have already shown the major impact of LDCT lung screening programs on mortality. In parallel, as demonstrated by studies such as the IASLC staging project and an I-ELCAP cohort study respectively, detecting and diagnosing the disease at its earlier stage, when lung nodules are still very small and manageable is key to drastically increasing the patient 5-year and 15-year overall survival rates, saving the lives of patients suffering from lung cancer," 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 of AI digital biomarkers, 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 (NASH).



About Median Technologies: Median Technologies provides innovative imaging solutions and services to advance healthcare for everyone. We leverage the power of Imaging Phenomics to provide insights into novel therapies and treatment strategies. Our unique solutions for medical image analysis and management in oncology trials and iBiopsy® for imaging phenotyping, together with our global team of experts, are advancing the development of new drugs and diagnostic tools to monitor disease and assess response to therapy. Median Technologies supports biopharmaceutical sponsors

and healthcare professionals around the world to quickly and precisely bring new treatments to patients in need. 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 the Euronext Growth market. FR0011049824— ticker: ALMDT. Median is eligible for the French SME equity savings plan scheme (PEA-PME), 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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