

Press release – For immediate release

October 17, 2023 – 5:45 pm CEST

First results of Median Technologies' iBiopsy® HCC detection AI model developed on the PHELICAR Clinical Data Registry, to be presented at the ESMO Congress (Oct 20-24, 2023, Madrid, Spain)

- Results are the first data released on the development of an AI model which will be integrated into Median's iBiopsy® AI/ML tech-based CADe/CADx SaMD for Hepatocellular Carcinoma (HCC) early diagnosis.
- Initial results show an HCC lesion detection sensitivity of 92% of Median's iBiopsy® AI model, versus a sensitivity of 69% observed among radiologists without AI-based computer-aided detection.
- Results will be presented by Pr. Olivier Lucidarme, La Pitié-Salpêtrière, AP-HP Hospital, Paris, France, at the ESMO 2023 Congress, during an oral session on Sunday, 22 October at 9:10 am.
- The Median iBiopsy® team will be at booth #522, Hall 5, from October 20 to 23 (exhibition dates) to discuss the study results as well as iBiopsy® advancements.

Sophia Antipolis, France - Median Technologies (ALMDT:PA) announces today that the first results of its iBiopsy® HCC detection AI model developed on the PHELICAR clinical data registry will be presented during the annual congress of the European Society for Medical Oncology (ESMO), taking place from Oct 20 to 24, in Madrid, Spain.

The study, conducted using data from the PHELICAR clinical data registry (CDR), was led by Pr. Olivier Ludicarme, Head of Specialty, and Emergency Imaging Department at the Pitié-Salpêtrière AP-HP Hospital, Paris, France, and his team as well as teams from the Beaujon and Paul-Brousse AP-HP Hospitals. The primary focus of this study was on the evaluation of Median's iBiopsy® AI model for the detection of Hepatocellular carcinoma (HCC), ultimately targeting the early diagnosis of HCC.

HCC constitutes more than 90% of primary liver cancers, ranking as the third leading cause of death by cancer worldwide¹. Notably, the 5-year survival rate of liver cancer patients is only between 3% to 13% if the cancer is diagnosed at advanced stage (C) yet rises significantly to 36% when diagnosed at early stage (A) and even higher when diagnosed at very early stage (0)².

Results presented at the ESMO 2023 Congress under the abstract **Computer-Aided HCC Lesion Detection Based on Deep Learning and CT Images** (abstract [1209MO](#)) describe the first development step of a model slated for integration into Median's AI/ML tech-based end-to-end CADe/CADx³ Software as Medical Device (SaMD) for HCC early diagnosis, on multiphase CT images (Arterial and Portal phase). This initial work is centered on the detection features of Median's future iBiopsy® HCC

¹ Global Cancer Observatory: <https://gco.iarc.fr/today/data/factsheets/cancers/11-Liver-fact-sheet.pdf>

² ASCO Cancer.net: <https://www.cancer.net/cancer-types/liver-cancer/statistics>

³ 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



CADe/CADx SaMD and is based on a cohort of 753 patients from AP-HP, suffering from chronic liver disease and HCC. For the study, data from 561 patients were used for the algorithm's training & tuning, whereas data from 192 patients were used for its testing.

Median's iBiospy® AI model, designed to detect HCC lesions as small as 10 mm in diameter, showcased promising results, achieving an impressive sensitivity rate of 92% on the test set. This notable achievement significantly surpasses the average sensitivity of 69%⁴ observed among radiologists without AI/ML tech-based computer aided detection. The next phase of research will focus on the small-size lesions to improve the diagnosis of very early stage (0) and early-stage (A) HCC.

Study results will be presented during the session Basic Science & Translational Research (ID 81), to be held on Sunday 22 October, session time: 8:30 – 10:05 am CEST, oral presentation time: 9:10 am CEST, Santander Auditorium - Hall 9.

As a reminder, PHELICAR is part of a large research collaboration agreement signed in March 2020 between AP-HP and Median Technologies, aiming at carrying out studies to be used for the development and validation of Median's iBiospy® AI/ML tech-based algorithms. More specifically, PHELICAR is a large-scale clinical data registry (CDR) to accurately identify the specific tumor phenotypes to better diagnose and predict patient outcome in HCC and supports the ongoing rise of predictive and personalized medicine.

The Median iBiospy® team will attend the ESMO 2023 Congress and be at booth #522, Hall 5, from October 20 to 23 (exhibition dates) to discuss the study results as well as iBiospy® advancements.

About iBiospy®: iBiospy® is based on the most advanced technologies in Artificial Intelligence (AI) and Data Science (DS), benefiting from Median's expertise in medical image processing. iBiospy® 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. iBiospy® currently focuses on Lung Cancer, Liver Cancer (HCC) and Liver Disease (NAFLD/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 iBiospy®, our AI/ML tech-based suite of software as medical devices (SaMD) 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.medianttechnologies.com

⁴ Roberts, Lewis R. et al. *Roberts, Lewis R. et al. Imaging for the diagnosis of hepatocellular carcinoma: A systematic review and meta-analysis. Hepatology 67(1):p 401-421, January 2018*



Contacts

Median Technologies Emmanuelle Leygues Head of Corporate Marketing & Financial Communications +33 6 10 93 58 88 emmanuelle.leygues@mediantechnologies.com	Press - ALIZE RP Caroline Carmagnol +33 6 64 18 99 59 median@alizerp.com	Investors - ACTIFIN Ghislaine Gasparetto +33 6 21 10 49 24 gasparetto@actifin.fr
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------