Press Release – For immediate release
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iBiopsy®: promising results on a preliminary study to evaluate the risk of tumor recurrence in patients with primary liver cancer

- Encouraging preliminary results about the iBiopsy® clinical development plan on liver cancer and the technological methods therein
- Development of a fibrosis biomarker from CT scan imaging
- A better performing biomarker compared to existing imaging biomarkers

Sophia Antipolis, France – Median Technologies (ALMDT), The Imaging Phenomics Company®, announces today the results of a preliminary retrospective study on the evaluation of the risk of recurrence for patients with primary liver cancer (HCC – hepatocellular carcinoma) based on a non-invasive biomarker. The iBiopsy® imaging biomarker discovery platform, which integrates advanced technologies in artificial intelligence has produced these results on one of the three indications on which it is positioned. Bearing in mind, the various clinical development plans for iBiopsy® were communicated on April 20, and relate to (1) the evaluation of severity of hepatic fibrosis in non-alcoholic fatty liver disease (NASH - Non Alcoholic Steatohepatitis), (2) the identification of responders/non-responders to certain immunotherapies in oncology, and finally (3) the detection, characterization and prognosis of primary liver cancer (HCC).

The level of hepatic fibrosis[1] is of great prognostic value and helps inform therapeutic intervention with regard to liver disease. The diagnosis of fibrosis is classically based on the anatomo-pathological examination of a fragment of liver collected by a hepatic puncture, a painful invasive act, presenting risks for the patient and which turns out to be expensive.

There was a two-fold objective for the preliminary retrospective study: first, to accurately quantify liver fibrosis on CT images, and second, to correlate the score of fibrosis with the risk of recurrence in post-operative patients with HCC.

Therefore, a learning algorithm was used on the pre-operative CT scans of 94 patients that were separated in two sets (training and validation) in order to model the relationship between image features of liver, spleen and hepatic fibrosis characterized by histological METAVIR scoring system (F0-F4). The performance of iBiopsy® testing characterized by the area under the curve (AUROC) is 0.91 with a specificity of 1 for the diagnosis of severe fibrosis (F3-F4). Using this quantification methodology, iBiopsy® non-invasive fibrosis biomarker permits the stratification of pre-operative patients at high-risk of tumor recurrence (HR = 4.1 (CI: [1.2,13.9], p-value<0.01). Such knowledge can positively impact the therapeutic approach in patients to undergo hepatic resection.

Based solely on the threshold values of advanced fibrosis, the iBiopsy® fibrosis test would avoid biopsy in 100% of cases, unlike other imaging techniques such as ultrasonic elastography and elasto-MR which have lower specificity and sensitivity values. These very encouraging first results need to be confirmed in larger independent patient cohorts. This will be one of the objectives of the Liver iBiopsy

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[1] Hepatic fibrosis is the result of most of chronic liver diseases, and is characterized by the excessive deposition of **extracellular matrix** (ECM) in the **hepatic parenchyma**

study, conducted in collaboration with the AP-HP, as part of the AP-HP Median partnership announced on March 2.

"These initial results are exciting and show the relevance of our approach. With the integration of the AI technologies, cloud computing and our data science expertise, we are positioning iBiopsy® as a platform for the discovery of imaging biomarkers, on which we will deploy our entire non-invasive biomarkers portfolio, " said Fredrik Bragg, CEO and co-founder of Median.

"In this first study, the success of the quantification of HCC-related fibrosis via routine scanner imaging opens the prospective to the evaluation of the severity of fibrosis on NASH patients using the same modality. Our objective is to exploit the information content of the images widely used in clinical routine and clinical trials. iBiopsy® allows for the comprehensive analysis of features of images on whole organ, which permits a true evaluation of the entire tumoral landscape and increases the amount of information that we can extract from images, and thus the performance of the biomarkers we calculate," he added.

About iBiopsy®: Based on the most advanced AI technologies and with expertise in data science, Median's iBiopsy® proprietary imaging platform allows for the extraction of non-invasive imaging biomarkers, which are the disease "signatures". These biomarkers, obtained from standard medical imaging modalities are used both in the field of clinical development and clinical routine in which medical needs regarding disease detection, treatment options and follow-up of patients are still unmet and have yet to foster the promise of predictive and precision medicine.

Median's iBiopsy® development program is supported by the European Investment Bank (EIB) through a financial loan of €35 million under the Juncker Plan, the European Fund for Strategic Investments, which aims to support research and innovation projects developed by companies with high growth potential.

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 Euronext Growth market (ISIN: FR0011049824, ticker: ALMDT). For more information: www.mediantechnologies.com

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