Press release – For immediate release
May 5th, 2022 – 5:45 pm CEST

Median Technologies is moving forward with the FDA interactions for its iBiopsy® Lung Cancer Screening CADe/CADx Software as Medical Device

- Median has received the FDA's feedback following the 513(g) regulatory submission for its iBiopsy® LCS CADe/CADx Software as Medical Device.
- Median will proceed through a 510(k) submission to obtain an FDA device clearance and market authorization, targeted for end 2023.
- On May 2, 2022, Median initiated a Q-submission process, composed of several submissions, to request feedback from the FDA on various topics such as the pivotal study protocols.

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

The aim of the 513(g) submission was to determine the relevant product classification and choose between the De Novo or the 510(k) regulatory pathways[2] for iBiopsy® LCS CADe/CADx SaMD. The FDA has stated that the Median's iBiopsy® LCS CADe/CADx falls within 21 CFR 892.2090 (Radiological Computer Assisted Detection And Diagnosis Software), a Class II type device, which requires the submission of a 510(k) in order to obtain the FDA clearance prior to marketing.

As next regulatory steps, Median Technologies is preparing several Q-submissions for Q2 and Q3, 2022. The first Q-sub has been submitted for FDA review on May 2, and focuses mostly on reviewing pivotal study protocols and possible predicate devices. A meeting will be scheduled with the FDA experts at their earliest convenience.

"*After this first regulatory feedback of the FDA on the 513(g), we want to keep having frequent and fruitful interactions with the Agency in order to better tailor our device to the US market",* Fredrik Brag, CEO and founder of Median Technologies said. *"The design of the pivotal studies will be a key part of showing the unique performance of our iBiopsy® CADe/CADx Software as Medical Device and how it could have an impact on saving patients' lives by identifying lung cancer onsets at their earliest stage",* 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 innovative AI/ML-based Software as Medical Device, to be used in several indications for which there are

[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] 510(k) and De Novo pathways are the only regulatory pathways available to bring a device of low to moderate risk level on the US market. Compared to the traditional 510(k), the De Novo classification is a risk-based classification process which is allowed for devices which have not filled the conditions to be submitted via a 510(k). *Source: FDA*

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 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

Contacts

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