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LungLife AI, Inc.
(the “Company” or “LungLife”)

First patient enrolment for LungLB® validation study

LungLife AI (AIM: LLA), a developer of clinical diagnostic solutions for lung cancer announces it has enrolled its first patient in its pivotal clinical study to evaluate the LungLB® test in subjects presenting with indeterminate lung nodules.

The multi-centre clinical study will be used to validate the LungLB® test performance, looking to repeat the high performance already observed in the pilot study completed earlier in the year. The study will enrol 425 participants across multiple US sites, including MD Anderson Cancer Center and Mount Sinai Hospital in New York City, involving participants who present with indeterminate lung nodules that would otherwise be scheduled for needle biopsy.

It is estimated over 5m chest CT scans are performed in the US each year with over 1.5m of them showing indeterminate lung nodules, requiring further imaging or potentially unnecessary and risky biopsy to determine whether they are cancerous.

This first patient enrolment confirms that the Company is on track to enrol patients over the next 14 months, with study completion expected in Q1 2023 and in-line with expectations. Study completion is key to offering the test commercially through LungLife AI’s CLIA-certified laboratory, in addition to supporting the Company’s desire to pursue FDA submission.

Paul Pagano, Chief Executive Officer of LungLife, said: *“I am delighted that we remain on track with this key validation study and first patient enrolment. This is an important milestone on our journey towards the successful commercial roll-out of our blood-based diagnostic test, which we believe is set to become a driving force in the early detection of lung cancer.”*

LungLB® is an AI-enhanced, blood-based test to stratify cancerous and benign lung nodules identified by CT scan, and is designed to support a physician’s decision to biopsy or to monitor non-invasively using additional imaging. The test utilises well-established FISH (*Fluorescence in situ hybridization*) techniques to identify rare target cells isolated from whole blood.

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About Lunglife AI

LungLife AI is a developer of artificial intelligence-enhanced clinical diagnostic solutions designed to make a significant impact in the early detection of lung cancer, the deadliest cancer globally. Using a minimally invasive blood draw, the Company’s LungLB® test is designed to deliver additional information to clinicians who are evaluating indeterminate lung nodules suspicious for lung cancer. For more information visit www.lunglifeai.com