

LungLife Al

Early-stage lung cancer diagnostics

LungLife AI is a medical diagnostics company focused on the development of AI-supported blood-based tests for the early detection of lung cancer. It has identified a significant medical need for non-invasive, sensitive and specific tests in early-stage lung cancer. The company's core technology, the LungLB test, seeks to detect circulating tumour cells (CTCs) to identify malignant lung nodules. It aims to apply machine learning/AI (ML/AI) to derive algorithms to increase test accuracy. Following a 2021 pilot study showing 76% sensitivity and 71% specificity, LungLife AI is currently planning a large-scale validation study, with the aim of commercialising in 2023.

Early diagnosis is an unmet medical need

According to the World Health Organization, lung cancer accounted for 1.8 million deaths worldwide in 2020. Diagnosis and treatment at an early stage has a significant effect on lung cancer survival rates. Low-dose computed tomography (LDCT) scans are the standard method for lung cancer screening; however, these return a high rate of false positives when assessing indeterminate lung nodules. Consequently, a high percentage of lung biopsies are conducted on benign nodules, increasing the cost and the risk of adverse events. The alternative 'wait-and-see' approach results in delayed treatment, significant anxiety for the patient and a potentially worse prognosis.

FISH-ing for CTCs

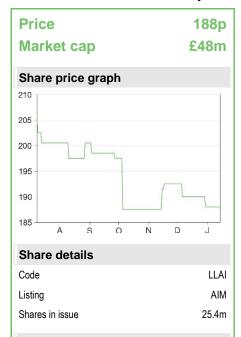
The LungLB test uses a patient's blood sample, which is shipped to the company's Clinical Laboratory Improvement Amendments (CLIA) approved lab. Red cells and some white blood cells are removed from the sample and the remaining cells are stained with fluorescence in situ hybridization (FISH) probes, allowing the identification of cancerous DNA markers, if present. A computer-controlled microscope takes pictures and sorts the images of cancerous cells based on these FISH signals. Subsequently a technician reviews the images before the results are sent back to the physician. LungLife AI aims to develop and implement ML/AI-derived algorithms to increase the accuracy of the image sorting. The full process takes approximately five days.

Clinical validation trials planned

LungLife AI completed a pilot study of 149 participants with biopsy-confirmed cancerous and non-cancerous lung nodules. The LungLB test demonstrated a sensitivity of 76%, a specificity of 71% and a positive predictive value of 89%, leading to the company listing on the AIM section of the London Stock Exchange in July 2021. After raising £17m in July 2021, the company now intends to conduct a multi-centre, large-scale (425-participant) clinical validation study. If positive, a clinical utility study will follow to support reimbursement from US insurers. LungLife AI hopes this cash will take it to commercialisation in 2023. However, any delays may mean that it needs to raise extra capital.

Healthcare

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Business description

LungLife AI is a medical diagnostic company focused on the application of AI in the early-stage detection of lung cancer. Its LungLB blood test uses CTCs as biomarkers to provide physicians with information to avoid unnecessary biopsies or risky 'wait-and-see' approaches in lung cancer diagnosis. The company is planning for a large-scale clinical validation study following results from its 2021 pilot study.

Bull

- Unmet medical need for early diagnosis in lung cancer.
- Clinical development supported by scientific expertise at Mount Sinai
- Quick, non-invasive diagnostic tool.

Bear

- Early-stage product carries significant R&D risk.
- Lung cancer diagnostics is a large and competitive market.
- Delays to trials and/or commercialisation could necessitate a further capital raise.

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