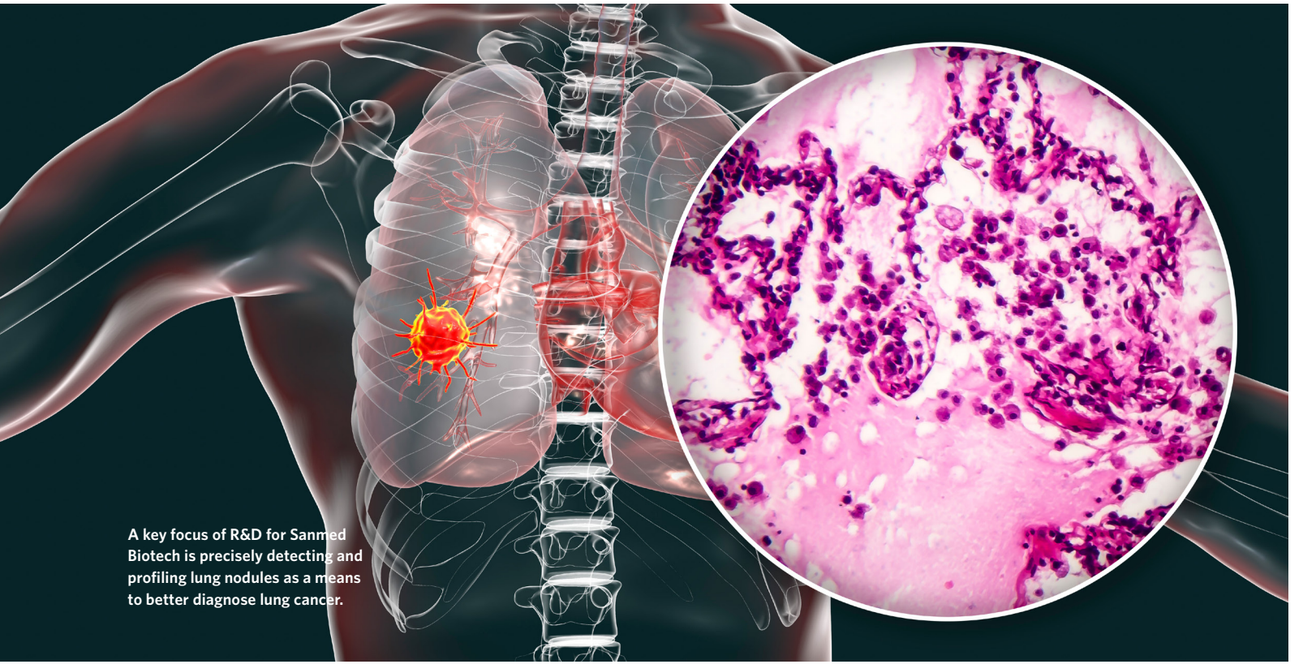

A key focus of R&D for Sanmed Biotech is precisely detecting and profiling lung nodules as a means to better diagnose lung cancer.

Katerina Kon/Science Photo Library/Getty

# USING PRECISION DIAGNOSTICS FOR EARLY DETECTION OF LUNG CANCER

Sanmed Biotech's comprehensive solution for **LIQUID TUMOUR BIOPSY** seeks to improve patient survival.

**Lung cancer is the second most common type of cancer** and the leading cause of cancer deaths worldwide. Early-stage lung cancer is often asymptomatic, meaning patients are typically diagnosed at an advanced stage, where tumours are growing rapidly and the prognosis is grave. A cross-disciplinary team at Sanmed Biotech, a precision medicine innovation firm founded in 2016, is hoping to improve the outlook for lung cancer through new solutions for early diagnosis.

"The survival rate of stage 1A lung cancer at 10 years is over 90%. Yet for late-stage lung cancer patients, the survival drops significantly and only the 5-year survival rate is calculated," says Frank Shi, CEO of Sanmed Biotech. "Early diagnosis of lung cancer is critical in reducing the mortality rate and prolonging survival."

As Shi explains, the company has its roots in Cynvenio Biosystems, a global pioneer in liquid biopsy technology founded in 2008 by Nobel-winning physicist and chemist, Alan J. Heeger, and company Zhuhai Livzon Diagnostics, one of China's first in vitro diagnostic products manufacturing enterprises. Powered by this legacy, Sanmed Biotech aims to leverage its expertise in liquid biopsy to offer early diagnosis options for lung cancer patients.

## DIFFERENTIATING CANCEROUS NODULES

The research and development priority at Sanmed Biotech is to precisely detect and profile lung nodules — small lumps of tissue that can be benign, precancerous or metastatic tumours. Low dose computed tomography (LDCT) screening is the recommended test to detect and measure nodules, but it's fraught with challenges.

"Where nodules are found to be 15 or even 20 millimeters, clinicians may propose further testing, such as a positron emission tomography scan, bronchoscopy or tissue biopsy," says Xin Ye, product development director of Sanmed Biotech. "However, LDCT has proven difficult to accurately profile smaller suspect nodules, presenting a major diagnostic challenge for clinicians to determine whether the nodule is malignant or benign, or whether an invasive biopsy or immediate surgical resection is necessary."

An effective, non-invasive, early detection test is needed to improve the diagnostic efficacy of LDCT, and Sanmed Biotech's proprietary liquid biopsy technology, fits the bill, says Ye.

Sanmed's liquid biopsy assay uses a novel multiplex fluorescence in-situ hybridization (FISH) test to detect chromosomal aberrant cells (CACs) in peripheral blood: a technique developed in 2010 by Ruth Katz. In 2020, refinements of this technique by Katz's team led to improved diagnosis of benign and malignant lung nodules by detecting chromosomal abnormalities in the peripheral blood genome through a simple, safe, effective, non-invasive test.

Sanmed's test contrasts with other liquid biopsy technologies that detect 'antigen-dependent' circulating tumour cells (CTC): these may lose sensitivity if the tumour cells alter the antigen profile by leaking into the bloodstream. Sanmed's liquid biopsy assay can distinguish between benign and malignant lung nodules by identifying individual cells bearing gains and/or loss of specific chromosomal loci that are labeled with distinct fluorophores.

## TOWARDS GREATER DIAGNOSTIC CERTAINTY

Early lung cancer diagnosis is also impeded by the absence of standardized methods for interpreting LDCT images. Due to imaging anomalies and human error, doctors may reach different diagnostic conclusions on the same scan. So, Sanmed Biotech has invested globally in specialized high-throughput computation and image recognition algorithms to automate the LDCT image and data analysis.

One outcome is the SANMED Target Call Lung Nodule Analysis Platform, which is built on deep convolutional neural networks and machine learning algorithms trained on a massive dataset of around 300,000 annotated pulmonary nodules. This platform can automatically reconstruct, segment, and analyse the LDCT images and label the lung nodules with the relevant parameter values indicating malignancy risks.

In 2022, Sanmed Biotech published its preliminary findings in *Frontiers in Oncology*. This study proposed a machine-learning-based prediction model, which integrates clinical characteristics (age and smoking history) and radiological profiles of nodules with the artificial intelligence (AI) analysis of LDCT data and Sanmed's liquid biopsy assay results. In a sample of 728 subjects, the model achieved optimal diagnostic performance, outperforming any approaches conducted alone.

## RAMPING UP WITH APPLICATIONS

Sanmed has established a sound intellectual property protection system and its technological advantage has stretched to far-reaching applications and collaborations. At present, the products are in clinical use in more than 20 leading hospitals in China.

Furthermore, the company's comprehensive solution in early detection of lung cancer attracted a specialist in respiratory diseases. Chunxue Bai, chair of the Chinese Alliance against Lung Cancer and vice president of the Chinese Respiratory Association, plans to partner with the company to conduct a multi-center clinical study of AI-assisted Sanmed's liquid biopsy assay diagnosis of benign and malignant lung nodules in China, enrolling more than 10 hospitals and 100,000 participants.

**"WE STRIVE TO OFFER CUTTING-EDGE PRODUCTS TO MAXIMIZE BENEFITS FOR BOTH PATIENTS AND PHYSICIANS."**

"We strive to offer cutting-edge products to maximize benefits for both patients and physicians," says Ye. "We believe our non-invasive option will be a useful complementary tool for clinicians in assessing early lung cancer. It could help to improve early lung cancer diagnosis and treatment in patients with malignant nodules while sparing those with benign entities from unnecessary and potentially harmful surgery." ■

SANMED BIOTECH

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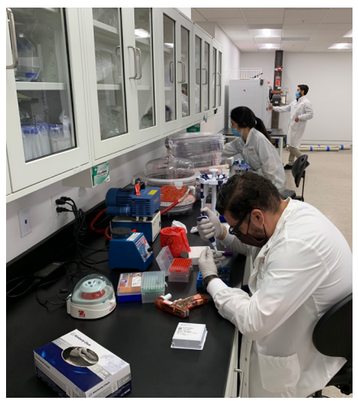

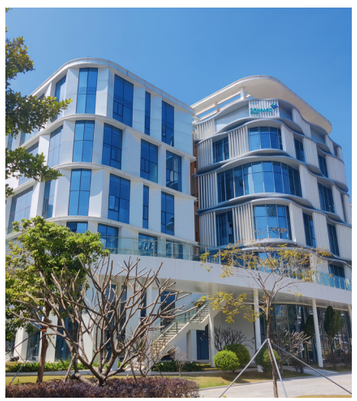



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