

A Study of SI-B001+SI-B003± Chemotherapy in the Treatment of Locally Advanced or Metastatic Non-small Cell Lung Cancer

NCT05949606

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Sichuan Baili Pharmaceutical Co., Ltd.
Enrollment	160 participants

Plain Language Summary

This study is testing a combination of two experimental antibody drugs (SI-B001 and SI-B003), with or without chemotherapy, in people with locally advanced or metastatic non-small cell lung cancer (NSCLC). These drugs target proteins on cancer cells to help the immune system fight the cancer.

****You may be eligible if...****

- You are 18 to 75 years old with confirmed advanced or metastatic NSCLC
- You have at least one measurable tumor
- Your overall health and organ function meet required levels
- You are willing to provide a tumor tissue sample
- You have not received prior anti-cancer treatment for this advanced disease (for Phase II patients)

****You may NOT be eligible if...****

- You have certain known genetic mutations in your tumor (tested before enrollment)
- You have active or symptomatic brain metastases
- You have a history of severe interstitial lung disease
- You have active autoimmune disease or have been on immunosuppressants recently
- You are HIV positive or have active hepatitis B or C
- You are pregnant or breastfeeding
- You have had another cancer in the past 5 years (with some exceptions)

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (15)

- Voluntarily sign the informed consent form and comply with the protocol requirements;
- No gender restrictions;
- Age ≥18 years and ≤75 years;
- Expected survival time ≥3 months;
- Subjects must agree to complete ctDNA testing during the screening period;
- ... and 10 more (see full listing online)

Exclusion (26)

- Prior to signing the informed consent form, relevant genetic alterations were indicated;
- For patients enrolled in Phase II, any of the following conditions apply: a) Patients suitable for and willing to undergo local therapy; b) Patients who have received systemic chemotherapy;
- Symptomatic brain parenchymal or leptomeningeal metastases, deemed ineligible by the investigator;
- Participation in any other clinical trial within 4 weeks prior to the administration of this trial's investigational product (based on the last dose date);

<https://clinicaltrials.gov/study/NCT05949606>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

- Use of chemotherapy, biologic therapy, immunotherapy, etc., within 4 weeks or 5 half-lives prior to the first dose, or palliative radiotherapy, small-molecule targeted therapy, or other antitumor treatments within 2 weeks before the first dose;
- ... and 21 more (see full listing online)

Locations (1 total)

Shanghai Pulmonary Hospital, Shanghai, Shanghai Municipality, China