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Recruiting

Phase III Trial of SYS6010 Versus Platinum-based Chemotherapy for EGFR-mutated NSCLC (SYNSTAR01)

ClinicalTrials.gov ID NCT06927986

Sponsor CSPC Megalith Biopharmaceutical Co.,Ltd.

Information provided by CSPC Megalith Biopharmaceutical Co.,Ltd. (Responsible Party)

Last Update Posted 2025-11-17

Study Details Tab

Study Overview

Brief Summary

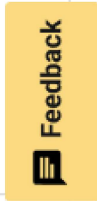
To evaluate the efficacy and safety of SYS6010 versus platinum-based chemotherapy in participants with EGFR-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC)

Detailed Description

This is a randomized, open-label, multi-center, phase III clinical study, aiming to evaluate the efficacy and safety of SYS6010 versus platinum-based chemotherapy in participants with EGFR-mutated locally advanced or metastatic NSCLC who have failed EGFR TKI therapy.

Official Title

A Randomized, Open-label, Multi-center, Phase III Clinical Study Comparing SYS6010 With Platinum-based Chemotherapy in the Treatment of EGFR-mutated Locally Advanced or Metastatic Non-small Cell Lung Cancer After Failure of EGFR TKI Treatment



Conditions ⓘ

EGFR-mutated Locally Advanced or Metastatic NSCLC

Intervention / Treatment ⓘ

- Drug: SYS6010
- Drug: Pemetrexed
- Drug: Cisplatin
- Drug: Carboplatin

Other Study ID Numbers ⓘ

- SYS6010-011

Study Start (Actual) ⓘ

2025-03-30

Primary Completion (Estimated) ⓘ

2026-07-30

Study Completion (Estimated) ⓘ

2026-08-30

Enrollment (Estimated) ⓘ

380

Study Type ⓘ

Interventional

Phase ⓘ

Phase 3

Resource links provided by the National Library of Medicine

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (https://dailymed.nlm.nih.gov/dailymed/) available for:

[Pemetrexed](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Pemetrexed) (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Pemetrexed)

[Cisplatin](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Cisplatin) (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Cisplatin)

[Carboplatin](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Carboplatin) (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Carboplatin)

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>).

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).

Study Contact

Name: Clinical Trials Information Group officer

Phone Number: 86-0311-69085587

Email: ctr-contact@cspc.cn

This study has 1 location

China

Shanghai Municipality Locations

 Shanghai, Shanghai Municipality, China,
200030

Recruiting

Shanghai Chest Hospital

Contact : Lu Shun, Ph.D

2200000-3123

shunlu_shchest@sina.com

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies \(https://clinicaltrials.gov/study-basics/learn-about-studies\)](https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

1. Aged 18-75 (inclusive) years old, male or females;
2. Patients with pathologically confirmed locally advanced or metastatic NSCLC, including those with stage IIIB or IIIC based on 8th edition of the AJCC staging system who are not suitable for surgical resection or radical chemoradiotherapy, or those with stage IV NSCLC. Patients with EGFR-mutated locally advanced or metastatic NSCLC who have failed EGFR TKI therapy, whereas patients progressed on first- or second-generation EGFR-TKIs must have also progressed on third-generation EGFR-TKIs if T790M mutation was detected as positive status.
3. Presence of at least one EGFR-sensitive mutation;
4. At least one measurable lesion confirmed by CT or MRI scan according to RECIST v1.1 criteria;
5. ECOG performance status of 0-1;
6. Life expectancy \geq 3 months;
7. Major organ function must meet the following criteria within 7 days prior to randomization (No component transfusion, G-CSF, TPO, IL-11, or EPO within 2 weeks prior to randomization):

Hematology: Absolute neutrophil count (ANC) $\geq 1.5 \times 10^9/L$; Platelet count (PLT) $\geq 100 \times 10^9/L$; Hemoglobin (HGB) $\geq 100g/L$. Renal function Cr: $\leq 1.5 \times$ upper limit of normal (ULN) and creatinine clearance ≥ 50 mL/min; Liver function Serum total bilirubin (TBIL) : $\leq 1.5 \times$ ULN, $\leq 3 \times$ ULN for patients with Gilbert syndrome/metastases to liver Alanine aminotransferase (ALT) and aspartate aminotransferase (AST): $\leq 2.5 \times$ ULN, $\leq 5 \times$ ULN for patients with metastases to liver Coagulation function Coagulation function Activated partial thromboplastin time (APTT) and international normalised ratio (INR): $\leq 1.5 \times$ ULN
8. Women of childbearing potential must have a negative blood pregnancy test within 7 days prior to randomization. Participants must agree to use effective contraception from the time of signing the informed consent form until 7 months after the last dose; during this period, women should not be breastfeeding, and men should avoid donating sperm;
9. Voluntarily participate in this clinical study, understand the study procedures, and be able to sign a written informed consent form.

Exclusion Criteria:

1. Histologically or cytologically confirmed combined small cell lung cancer, squamous cell carcinoma, neuroendocrine carcinoma, or carcinosarcoma
2. Patients with meningeal metastasis, brainstem metastasis, spinal cord metastasis and/or compression, or active CNS metastasis. Patients with supratentorial and/or cerebellar

metastasis (i.e., without mesencephalon, pons, or medulla involvement) who have received local treatment, have achieved stability for at least 2 weeks prior to randomization (imaging shows no new brain metastasis or enlargement of existing brain metastasis, and all neurologic symptoms have stabilized or returned to normal), and do not require corticosteroid therapy or are receiving prednisone at a daily dose of ≤ 10 mg or equivalent doses of other corticosteroids, can participate in the study;

3. Patients with a history of other malignant tumors within 3 years prior to randomization, except for the following conditions: cured skin basal cell carcinoma or squamous cell carcinoma, superficial bladder cancer, prostate carcinoma in situ, and cervical carcinoma in situ, etc.;
4. Patients who are known to be allergic to any component of SYS6010 or to humanized monoclonal antibody products; allergic to carboplatin, cisplatin, or pemetrexed, or have contraindications for their use;
5. AEs caused by prior anti-tumor treatment have not recovered to \leq Grade 1 (excluding Grade 2 alopecia, peripheral neurotoxicity, and other toxicities judged by the investigator to have no safety risk) according to NCI-CTCAE v5.0;
6. Previously received systemic anti-tumor therapy for locally advanced or metastatic non-squamous NSCLC other than EGFR TKI; patients who have previously received adjuvant/neoadjuvant chemotherapy and experienced disease progression more than 12 months after the end of treatment are allowed to be included;
7. Patients who have not met the corresponding washout period requirements for the following medications or treatments should be excluded:
 1. Major surgery (excluding needle biopsy): At least 4 weeks
 2. Small molecule targeted drugs, traditional Chinese medicines with anti-tumor indications, palliative radiation or local therapy: At least 2 weeks
 3. intravenous injection of antibiotics, antifungals, or antivirals: At least 2 weeks
 4. Investigational product and Live attenuated vaccine: At least 4 weeks
 5. Strong CYP3A4 inducers or inhibitors, OATP1B1 and OATP1B3 inhibitors: At least 2 weeks
8. History of severe cardiovascular or cerebrovascular disease within 6 months prior to randomization, including but not limited to:
 1. Presence of severe cardiac rhythm or conduction abnormalities, such as ventricular arrhythmia requiring clinical intervention, third-degree atrioventricular block, Fridericia-corrected QT interval > 470 ms (Fridericia formula: $QTcF = QT/RR^{0.33}$, $RR = 60/\text{heart rate}$);
 2. History of myocardial infarction, unstable angina pectoris, aortic dissection, angioplasty, or coronary artery bypass;
 3. NYHA class II or higher cardiac failure, LVEF $<50\%$ at screening;
 4. Stroke or other Grade 3 or higher cardiovascular and cerebrovascular events;
 5. Pulmonary embolism;

9. Imaging examination suggests tumor invasion of the cervical, thoracic, and abdominal great vessels; and the investigator assessed that there was no risk of bleeding.
10. Patients who have a history of ILD/non-infectious pneumonitis treated with corticosteroids in the past, currently have ILD/non-infectious pneumonitis, for whom imaging examinations at screening cannot rule out ILD/non-infectious pneumonitis, or whose pulmonary function test indicates severe ventilatory dysfunction and/or decreased diffusion capacity;
11. Presence of severe infections within 4 weeks prior to randomization, including but not limited to bacteraemia requiring hospitalisation, severe pneumonia, active pulmonary tuberculosis infection, etc.; presence of active infections requiring systemic antibiotics within 2 weeks prior to randomization;
12. Previous permanent discontinuation of EGFR-targeted therapy due to skin toxicity, or currently have skin diseases requiring oral or intravenous medication;
13. History of ulcerative colitis or Crohn's disease;
14. Pleural effusion or pericardial effusion requiring clinical intervention within 2 weeks prior to randomization;
15. Active HBV or HCV infection (hepatitis B surface antigen and/or hepatitis B core antibody positive and HBV DNA copies $\geq 1 \times 10^4$ copies/mL or ≥ 2000 IU/mL, HCV antibody positive and HCV RNA above the lower limit of detection of the analytical procedure). Note: For HBsAg-positive patients, it is recommended to start antiviral therapy before randomization, nucleoside analogues are recommended, such as entecavir, tenofovir disoproxil;
16. History of immunodeficiency (including positive HIV test, other acquired or congenital immunodeficiency diseases), history of allogeneic stem cell or organ transplant;
17. Other conditions that the investigator deems unsuitable for participation in this clinical study (such as mental disorders, macular cystoid oedema, severe corneal disorders, uncontrolled or poorly controlled hypertension and diabetes mellitus).

Ages Eligible for Study ⓘ

18 Years to 75 Years (Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : Randomized

Interventional Model ⓘ : Parallel Assignment

Interventional Model Description: SYS6010,Q3W This is a randomized, open-label, multi-center, phase III clinical study, aiming to evaluate the efficacy and safety of SYS6010 versus platinum-based chemotherapy in participants with EGFR-mutated locally advanced or metastatic NSCLC who have failed EGFR TKI therapy. Approximately 380 participants are planned to be enrolled, who will be randomly assigned in a 1:1 ratio to the experimental group: SYS6010, and the control group: pemetrexed + cisplatin/carboplatin. Randomization stratification factors include: presence of brain metastasis (yes or no), received third-generation EGFR TKI treatment before (yes or no)

Masking ⓘ : None (Open Label)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: SYS6010	Drug: SYS6010 <ul style="list-style-type: none"> • SYS6010,Q3W
Active Comparator: Platinum-containing chemotherapy Pemetrexed injection 500 mg/m ² + cisplatin 75 mg/m ² or carboplatin (AUC=5, Calvert formula) administered via intravenous infusion, Q3W	Drug: Pemetrexed <ul style="list-style-type: none"> • Pemetrexed injection 500 mg/m² administered via intravenous infusion, Q3W Drug: Cisplatin <ul style="list-style-type: none"> • Cisplatin 75 mg/m² administered via intravenous infusion, Q3W Drug: Carboplatin <ul style="list-style-type: none"> • Carboplatin (AUC=5, Calvert formula) administered via intravenous infusion, Q3W

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame

Progression-free survival (PFS) assessed by independent review committee (IRC)	Defined as the time from randomisation until the date of objective disease progression or death was assessed by IRC according to RECIST 1.1	Up to approximately 1.5 years
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Secondary Outcome Measures 

Outcome Measure	Measure Description	Time Frame
Investigator-assessed PFS	Defined as the time from randomisation until the date of objective disease progression or death was assessed by investigator according to RECIST 1.1	Up to approximately 1.5 years
Disease Control Rate (DCR)	Defined as the percentage of subjects who have a best overall response of CR or PR or SD based on IRC and investigator according to RECIST 1.1	Up to approximately 2 years
Objective response rate (ORR)	: Defined as the proportion of patients with response (including CR and PR) assessed by the investigator and the IRC according to RECIST v1.1.	Up to approximately 1.5 years
Overall Survival (OS)	Defined as the time from randomization until death from any cause	Up to approximately 2 years

Incidence of adverse events (AEs)	AEs graded by CTCAE version 5.0	Up to approximately 2 years
Serious adverse events (SAEs)	SAEs graded by CTCAE version 5.0	Up to approximately 2 years
EORTC QLQ-LC13 questionnaire	EORTC QLQ-LC13 incorporates one multi-item scale to assess dyspnoea, and a series of single items assessing pain, coughing, sore mouth, dysphagia, peripheral neuropathy, alopecia, and haemoptysis.	Up to approximately 2 years
EORTC QLQ-30 questionnaire	EORTC QLQ-C30 is designed to measure cancer patients' physical, psychological and social functions.	Up to approximately 2 years
Plasma concentrations of toxin-bound antibodies	Tests are conducted after single and continuous administration of SYS6010.	Up to approximately 2 years
Plasma concentrations of total antibodies	Tests are conducted after single and continuous administration of SYS6010.	Up to approximately 2 years
Plasma concentrations of free toxin (JS-1)	Tests are conducted after single and continuous administration of SYS6010.	Up to approximately 2 years

anti-SYS6010
antibodies
(ADA)

Incidence of SYS6010 anti-drug antibodies

Up to
approx-
imately
2 years

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

CSPC Megalith Biopharmaceutical Co.,Ltd.

Investigators ⓘ

- Principal Investigator: Shun Lu, Doctor, Cancer Institute and Hospital, Chinese Academy of Medical Sciences

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2025-03-12

First Submitted that Met QC Criteria ⓘ

2025-04-07

First Posted ⓘ

2025-04-15

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2025-11-13

Last Update Posted (Estimated) ⓘ

2025-11-17

Last Verified ⓘ

2025-08

More Information

Terms related to this study

Additional Relevant MeSH Terms

Carcinoma, Bronchogenic
Bronchial Neoplasms
Lung Neoplasms
Respiratory Tract Neoplasms
Thoracic Neoplasms
Neoplasms by Site
Neoplasms
Lung Diseases
Respiratory Tract Diseases
Carcinoma, Non-Small-Cell Lung
Guanine
Hypoxanthines
Purinones
Purines
Heterocyclic Compounds, 2-Ring
Heterocyclic Compounds, Fused-Ring
Heterocyclic Compounds
Glutamates
Amino Acids, Acidic
Amino Acids
Amino Acids, Peptides, and Proteins
Amino Acids, Dicarboxylic
Chlorine Compounds
Inorganic Chemicals
Nitrogen Compounds
Platinum Compounds
Coordination Complexes

Organic Chemicals

Pemetrexed

Cisplatin

Carboplatin

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

No