

# Clinical Trial of SYS6010±SYH2051 Versus Chemotherapy in Advanced Breast Cancer and Other Solid Tumors

ClinicalTrials.gov ID ⓘ NCT06775236

Sponsor ⓘ CSPC Megalith Biopharmaceutical Co.,Ltd.

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

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## Study Details

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## Study Overview

### Brief Summary

The study consists of two phases. Phase 1b and Phase 2. Phase 1b aims to evaluate the safety, tolerability, and preliminary efficacy of SYS6010 as a monotherapy and in combination with SYH2051, and to determine the recommended Phase 2 dose (RP2D) for subsequent Phase 2 studies. Phase 2 aims to assess the efficacy and safety of SYS6010 monotherapy or in combination with SYH2051 compared to investigator-selected chemotherapy in patients with EGFR-expressing, unresectable locally advanced or metastatic advanced breast cancer.

### Detailed Description

#### Phase Ib Design:

Group A (SYS6010 3.2 mg/kg, Q2W):

Monotherapy Cohort: Planned enrollment of 8-12 breast cancer patients to evaluate the safety and preliminary efficacy of SYS6010 monotherapy.

Combination Cohort: Includes dose-escalation and expansion phases. Dose-escalation phase: A "3+3" design will be used to explore the safety of SYS6010 combined with SYH2051, with SYH2051 doses ranging from 60-80 mg.

Expansion phase: Upon completion of dose-escalation and confirmation of safety, breast cancer patients may be enrolled in the expansion phase.

Group B (SYS6010 3.6 mg/kg, Q2W):

Monotherapy Cohort: Planned enrollment of 8-12 breast cancer patients. Combination Cohort: Similar to Group A, with SYH2051 doses ranging from 40-60 mg.

Group C (SYS6010 3.6 mg/kg, Q2W): Enroll 40 EGFR-expressing HR+/HER2- breast cancer patients to further evaluate the safety and efficacy in this specific population.

#### Phase II Design:

Based on molecular subtypes of breast cancer, cohort studies will be conducted.

Each cohort will enroll 125 patients, randomized in a 2:2:1 ratio into three groups:

SYS6010 + SYH2051 SYS6010 monotherapy Chemotherapy control.

### Official Title

A Phase 1b/2 Clinical Study to Evaluate the Safety and Efficacy of SYS6010 as a Monotherapy or in Combination With SYH2051 Compared to Investigator's Choice Chemotherapy in Patients With EGFR-Expressing Advanced Unresectable or Metastatic Solid Tumors, Including But Not Limited to Breast Cancer

### Conditions ⓘ

Advanced Solid Tumors

Breast Cancer

### Intervention / Treatment ⓘ

- Drug: SYS6010 injection
- Drug: monotherapy chemotherapy
- Drug: SYH2051 tablets

### Study Start (Estimated) ⓘ

2025-03-20

### Primary Completion (Estimated) ⓘ

2027-06-15

### Study Completion (Estimated) ⓘ

2028-01-15

### Enrollment (Estimated) ⓘ

410

### Study Type ⓘ

Interventional



### Phase ⓘ



Phase 1

Phase 2

- SYS6010-008

## Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](#)  related topics: [Breast cancer](#) 

[MedlinePlus](#)  related topics: [Breast Cancer](#) 

[FDA Drug and Device Resources](#)

## 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](#).

### Study Contact

**Name:** Clinical Trials Information Group officer

**Phone Number:** 86-0311-69085587

**Email:** [ctr-contact@cspc.cn](mailto:ctr-contact@cspc.cn)

**No location data**

## 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](#).

### Eligibility Criteria

#### Description

#### Inclusion Criteria:

- 1. Age  $\geq$  18 years. 2. Phase 1b/Phase 2: Breast cancer (no tumor type restriction during the combination dose escalation phase).
- 3. Provide tumor tissue samples for immunohistochemical EGFR expression testing, with EGFR expression positive as confirmed by the central laboratory.
- 4. At least one measurable extracranial lesion according to RECIST v1.1 criteria (no requirement during the combination dose escalation phase of Phase 1b).
- 5. ECOG performance status score of 0-1. 6. Expected survival  $\geq$  3 months. 7. Major organ function meets the relevant laboratory test standards for hematology, renal function, liver function, and coagulation within 7 days prior to treatment.
- 8. Subject agrees to use effective contraception from the time of signing the informed consent form until 6 months after the last dose.
- 9. Willing to participate in the study, understand the study procedures, and sign a written informed consent form.

#### Exclusion Criteria:

- 1. Active central nervous system (CNS) metastases or carcinomatous meningitis. Patients with treated and stable brain metastases are eligible for inclusion.
- 2. Previously diagnosed HER2-positive breast cancer (IHC 3+ or ISH positive) (Applicable to Phase 1b Group C and Phase 2).

#### Ages Eligible for Study

18 Years and older (Adult, Older Adult)

#### Sexes Eligible for Study

All

#### Accepts Healthy Volunteers

No

3. Previously treated with antibody-drug conjugates (ADC) containing topoisomerase I inhibitors (Applicable to Phase 1b Group C and Phase 2).
4. Allergy to any component of SYS6010 or SYH2051, or to humanized monoclonal antibodies.
5. Allergy to any component of SYS6010 or SYH2051, or to humanized monoclonal antibodies (This is a repeat of criteria #4).
6. Adverse events from prior antitumor therapy not recovered to  $\leq$  Grade 1 (unless the investigator deems there is no safety risk).
7. Failure to meet the required washout period for prior medications or treatments as specified in the protocol.
8. History of severe cardiovascular or cerebrovascular diseases. 9. History of interstitial lung disease (ILD) / non-infectious pneumonia, or current ILD/non-infectious pneumonia, or imaging findings at screening that cannot rule out these conditions.
10. Thyroid dysfunction requiring medication, unless the condition is controlled by medication and no dose adjustments are needed.
11. Severe infection within 4 weeks prior to the first use of the investigational drug.
12. History of discontinuing EGFR-targeted therapy for  $\geq$  1 month due to skin toxicity, or current skin conditions requiring medication.
13. Gastrointestinal diseases or functional impairments that may significantly affect the absorption of the investigational drug (e.g., ulcerative disease, severe nausea/vomiting, diarrhea, malabsorption, etc.).
14. Uncontrolled pleural or peritoneal effusion. 15. Active HBV or HCV infection, syphilis, HIV infection, or AIDS. 16. Other conditions deemed by the investigator as unsuitable for participation in this clinical trial.

## Study Plan

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

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### How is the study designed?

#### Design Details

**Primary Purpose** ⓘ : Treatment

**Allocation** ⓘ : Randomized

**Interventional Model** ⓘ : Parallel Assignment

**Interventional Model Description:** Phase 1b: Dose escalation and expansion Phase 2: Randomized controlled trial

**Masking** ⓘ : None (Open Label)

#### Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: SYS6010 injection SYS6010 injection 3.2 mg/kg or 3.6 mg/kg, intravenous drip, Q2W	Drug: SYS6010 injection <ul style="list-style-type: none"> <li>SYS6010 is an antibody conjugate drug (ADC), composed of one anti-EGFR monoclonal antibody coupled to one JS1 via an enzyme specific linker</li> </ul>
Experimental: SYS6010 injection + SYH2051 tablets SYS6010 injection 3.2 mg/kg intravenous drip + SYH2051 60 or 80 mg, oral, Q2W Or SYS6010 injection 3.6 mg/kg intravenous drip + SYH2051 40 or 60 mg, oral, Q2W	Drug: SYS6010 injection <ul style="list-style-type: none"> <li>SYS6010 is an antibody conjugate drug (ADC), composed of one anti-EGFR monoclonal antibody coupled to one JS1 via an enzyme specific linker</li> </ul> Drug: SYH2051 tablets <ul style="list-style-type: none"> <li>SYH2051 is a Selective ATM protein kinase inhibitor</li> </ul>

Active Comparator: Monotherapy  
Chemotherapy Group

Investigator's choice of monotherapy  
chemotherapy (Eribulin, Capecitabine,  
Gemcitabine, Vinorelbine, or Taxanes. )

Drug: monotherapy chemotherapy

- Investigator's choice of monotherapy chemotherapy (Eribulin, Capecitabine, Gemcitabine, Vinorelbine, or Taxanes.)

## What is the study measuring?

### Primary Outcome Measures <sup>1</sup>

Outcome Measure	Measure Description	Time Frame
Dose-limiting toxicity(DLT) occurrence and incidence	The occurrence and incidence of dose-limiting toxicities (DLTs) will be assessed based on predefined criteria during the first 28 days after the initial dose. DLTs are defined as adverse events related to the study drug that meet the protocol-specified criteria for dose limitation.	Up to approximately 3 months after the first participant is enrolled
Adverse events (AE) occurrence and incidence	The occurrence and incidence of adverse events (AEs) will be evaluated according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) version 5.0. AEs will be monitored from the first dose until the safety follow-up period.	Up to approximately 36 months after the first participant is enrolled
Objective response rate (ORR) per RECIST v1.1	The objective response rate (ORR) will be assessed based on RECIST v1.1 criteria. ORR is defined as the proportion of patients achieving a complete response (CR) or partial response (PR) as the best overall response.	Up to approximately 36 months after the first participant is enrolled

### Secondary Outcome Measures <sup>1</sup>

Outcome Measure	Measure Description	Time Frame
Disease control rate (DCR) per RECIST 1.1		Up to approximately 36 months after the first participant is enrolled
Duration of response (DoR) per RECIST 1.1		Up to approximately 36 months after the first participant is enrolled
Progression free survival (PFS) per RECIST 1.1		Up to approximately 36 months after the first participant is enrolled
Overall survival(OS)		Up to approximately 36 months after the first participant is enrolled

PK parameters of toxin-bound antibody		Up to approximately 36 months after the first participant is enrolled
Description :total antibody and free toxin (JS-1) after single and continuous administration of SYS6010		Up to approximately 36 months after the first participant is enrolled
PK parameters after single and multiple administrations of SYH2051		Up to approximately 36 months after the first participant is enrolled

### Collaborators and Investigators

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

Sponsor ⓘ

CSPC Megalith Biopharmaceutical Co.,Ltd.

### 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 ⓘ

2025-01-01

First Submitted that Met QC Criteria ⓘ

2025-01-09

First Posted ⓘ

2025-01-15

#### Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2025-03-17

Last Update Posted ⓘ

2025-03-19

Last Verified ⓘ

2025-01

### More Information

[Record History](#)

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#### Terms related to this study

Additional Relevant MeSH Terms

Neoplasms by Site  
 Neoplasms  
 Breast Diseases  
 Skin Diseases  
 Breast Neoplasms

## Drug and device information, study documents, and helpful links

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Studies a U.S. FDA-Regulated Drug Product

Studies a U.S. FDA-Regulated Device Product

No

No

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