

A Phase Ia/Ib study of STA551 as a single agent and in combination with atezolizumab in patients with solid tumors

Submission date 10/04/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/06/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 26/08/2026	Condition category Cancer	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Cancer is a leading cause of death worldwide, and current treatments are not sufficient to control cancer or improve quality of life. In recent years, immunotherapy has become an important treatment option for some cancers. However, not all patients benefit from currently available immunebased therapies.

STA551 is an experimental drug designed to stimulate the immune system by targeting a protein called CD137, which helps activate immune cells and supports their growth and survival. STA551 has been developed to act preferentially in tumour tissue, which may reduce side effects in nontumour tissues.

The main aims of the study are to assess safety and tolerability, understand how the drug behaves in the body, determine the most appropriate dose for future studies, and explore preliminary antitumour activity when STA551 is used as a single agent or in combination with atezolizumab (an approved immunotherapy drug).

Who can participate?

Adults aged 18 years or older, both men and women, may be able to take part in this study if they have a locally advanced or metastatic solid tumour for which standard treatments are no longer effective, are not tolerated, or are considered unsuitable.

Participants must have adequate organ function and a good overall performance status.

What does the study involve?

- Participants will be assigned to one of three groups:
 - STA551 as a single agent
 - STA551 in combination with atezolizumab
 - STA551 in combination with atezolizumab and an imaging agent (Zr89 crefmirlimab berdoxam)
- STA551 and atezolizumab are administered every 21 days.

Throughout the study, participants will attend regular hospital visits for safety checks and assessments. These include physical examinations, blood tests, vital sign measurements, heart monitoring (ECGs), and imaging scans such as CT or MRI to assess the cancer.

In the group receiving the imaging agent, additional PET imaging tests will be performed.

What are the possible benefits and risks of participating?

STA551 is an experimental drug, and there are currently no known health benefits. Because it has been tested in a limited number of people, there may be side effects that are not yet known. Risks associated with STA551 include liver toxicity, hypersensitivity reactions (overactivation of the immune system), infusion-related reactions, immunerelated adverse events (for example, skin damage such as severe rash and itching), and risks to embryo–fetal development.

The following very common side effects are known to be associated with atezolizumab (occurring in more than 10% of patients):

fatigue, joint pain (arthralgia), lack of energy (asthenia), decreased appetite, diarrhoea, shortness of breath (dyspnoea), urinary tract infection, cough, headache, itching of the skin (pruritus), nausea, fever, rash, vomiting, muscle and bone pain (myalgia, musculoskeletal pain, bone pain), and back pain.

- Allergic reactions have occurred with atezolizumab.
- Allergic reactions may also occur with Zr89 crefmirlimab berdoxam.

Where is the study run from?

Chugai Pharmaceutical Co., Ltd. (Japan)

When is the study starting and how long is it expected to run for?

March 2020 to August 2027

Who is funding the study?

Chugai Pharmaceutical Co., Ltd. (Japan)

Who is the main contact?

udai.banerji@icr.ac.uk

Contact information

Type(s)

Principal investigator, Scientific, Public

Contact name

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Additional identifiers

EU Clinical Trials Register (EudraCT)

2023-508764-30-00

Integrated Research Application System (IRAS)

Study information

Scientific Title

A Phase Ia/Ib open-label, dose-escalation study of the safety and pharmacokinetics of STA551 as a single agent and in combination with atezolizumab in patients with locally advanced or metastatic solid tumors

Study objectives

Primary objectives:

Phase Ia and Phase Ib Dose Escalation Cohorts:

1. To determine the maximum tolerated dose (MTD) and the recommended Phase II dose (RP2D) of STA551 when administered as a single agent (Phase Ia) and in combination with atezolizumab (Phase Ib) in patients with locally advanced or metastatic solid tumors
2. To evaluate the safety and tolerability of STA551 when administered as a single agent (Phase Ia) and in combination with atezolizumab (Phase Ib)
3. To characterize the PK profile of STA551 administered as a single agent (Phase Ia) and in combination with atezolizumab (Phase Ib)

Phase Ib Expansion Cohorts Stage Part 1:

1. To make a preliminary assessment of the anti-tumor activity based on overall objective response rate (ORR) of selected dose(s) of STA551, when administered in combination with atezolizumab
 2. To evaluate the safety and tolerability of STA551 when administered in combination with atezolizumab
 3. To characterize the PK profile of STA551 when administered in combination with atezolizumab
- Phase Ib Expansion Cohorts Stage Part 2 (Selected Sites in United Kingdom and Spain):
4. To perform an exploratory evaluation of PD response by uptake of Zr-89 crefmirlimab berdoxam (CD8 PET tracer) when STA551 is administered at the selected dose as a single agent followed by combination with atezolizumab
 5. To evaluate the safety and tolerability of STA551 when administered as a single agent followed by combination with atezolizumab

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 06/05/2020, NRES Committee London – Surrey Borders (Skipton House, 80 London Rd, London, SE1 6LH, United Kingdom; +44 207 972 2568; surreyborders.rec@hra.nhs.uk), ref: 20/LO/0334

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Treatment

Study type(s)**Health condition(s) or problem(s) studied**

Locally advanced or metastatic solid tumors

Interventions

This clinical trial includes three groups (Stages) as follows;

- Phase Ia Dose Escalation Stage: STA551 as single agent
- Phase Ib Dose Escalation Stage: STA551 + Atezolizumab
- Phase Ib Expansion Stages: STA551 + Atezolizumab

STA551, atezolizumab are given different doses by infusion (by a tube into a vein in the arm).

Part 1**Intervention period**

Study treatment with STA551 (as monotherapy in Phase Ia, and in combination with atezolizumab in Phase Ib Dose-Escalation Cohorts Stage and Phase Ib Expansion Cohorts Stage Part 1) is administered intravenously on Day 1 of each 21-day cycle.

In the absence of unacceptable toxicity or clinically compelling evidence of disease progression, treatment with either STA551 (Phase Ia) or STA551 in combination with atezolizumab (Phase Ib) may be continued based on a favorable assessment of benefit and risk by the investigator.

Follow-up period

After initiation of study treatment, report all adverse events until 90 days after the last dose of study treatment or initiation of another systemic anti-cancer therapy, whichever occurs first. Patients will be contacted at approximately 60 - 90 days after the last dose of study treatment to determine whether any new adverse events have occurred or if the patient has initiated another systemic anti-cancer therapy. After this period, the investigator is not required to actively monitor patients for adverse events, but should report any serious adverse events that are believed to be related to prior study treatment. The investigator should follow each adverse event until the event has resolved to baseline grade or better, the event is assessed as stable by the investigator, the patient is lost to follow-up, or the patient withdraws consent. Every effort should be made to follow all serious adverse events considered to be related to study treatment or trial-related procedures until a final outcome can be reported.

Phase Ib expansion cohorts Stage Part 2**Intervention period**

STA551 is administered intravenously every 21 days.

STA551 is administered as monotherapy for the first two cycles, followed by combination

treatment with STA551 and atezolizumab from Cycle 3 onward.

The CD8 PET tracer (Zr 89 crefmirlimab berdoxam) is administered three times in total, with PET /CT imaging performed approximately 24 hours ($\pm$ 3 hours) after each tracer administration. In the absence of unacceptable toxicity or clinically compelling evidence of disease progression, treatment with either STA551 (Phase Ia) or STA551 in combination with atezolizumab (Phase Ib) may be continued based on a favorable assessment of benefit and risk by the investigator.

Follow-up period

After initiation of study treatment, report all adverse events until 90 days after the last dose of study treatment or initiation of another systemic anti-cancer therapy, whichever occurs first. Patients will be contacted at approximately 60 - 90 days after the last dose of study treatment to determine whether any new adverse events have occurred or if the patient has initiated another systemic anti- cancer therapy. After this period, the investigator is not required to actively monitor patients for adverse events, but should report any serious adverse events that are believed to be related to prior study treatment. The investigator should follow each adverse event until the event has resolved to baseline grade or better, the event is assessed as stable by the investigator, the patient is lost to follow-up, or the patient withdraws consent. Every effort should be made to follow all serious adverse events considered to be related to study treatment or trial-related procedures until a final outcome can be reported.

Intervention Type

Drug

Phase

Phase I

Drug/device/biological/vaccine name(s)

STA551, atezolizumab, Zirconium (Zr)-89 crefmirlimab berdoxam (CD8 PET tracer)

Primary outcome(s)

1. The maximum tolerated dose (MTD) and the recommended Phase II dose (RP2D) of STA551 when administered as a single agent (Phase Ia) and in combination with atezolizumab (Phase Ib) in patients with locally advanced or metastatic solid tumors measured using Incidence of dose-limiting toxicities (DLTs) at During the DLT evaluation period
2. Safety and tolerability of STA551 when administered as a single agent and in combination with atezolizumab measured using Incidence, nature, and severity of adverse events graded according to NCI CTCAE v5.0 at Throughout the study
3. Pharmacokinetics of STA551 administered as a single agent and in combination with atezolizumab measured using Serum concentration of STA551 and derived PK parameters (AUC, Cmax, Cmin, CL, Vd, accumulation ratio, t1/2, dose proportionality) at During treatment cycles (depending on the schedule of each cohort)
4. Preliminary anti-tumor activity of STA551, when administered in combination with atezolizumab measured using Objective response (OR), defined as a confirmed CR, partial response (PR) or stable disease (SD) per the Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1), as determined by the investigator at The end of Cycle 2, 4, 6, and 8, and then every 4 cycles thereafter (one cycle consists of 21 days), or as clinically indicated

5. Exploratory pharmacodynamic response when STA551 is administered at the selected dose as a single agent followed by combination with atezolizumab measured using Increase of Zr-89 crefmirlimab berdoxam (CD8 PET tracer) uptake as measured by change from baseline in background corrected Standardized Uptake Value (SUV)-based quantitative measures (e.g. SUVmax, SUVpeak, SUVmean) at Cycle 0 Day 2, Cycle 2 Day 9, and Cycle 4 Day 9

Key secondary outcome(s)

Completion date

31/08/2027

Eligibility

Key inclusion criteria

1. Signed Informed Consent Form (ICF)
2. Age ≥ 18 years
3. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
4. Adequate hematologic and end organ function
5. Histologically or cytologically documented solid tumors
6. Dose escalation cohorts: standard of care has proven to be ineffective or intolerable or is considered inappropriate. Patients with evaluable disease per RECIST v1.1
7. Expansion cohorts: Patients with a measurable disease as per RECIST v1.1

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

120 Years

Sex

All

Total final enrolment

119

Key exclusion criteria

1. Clinically significant New York Heart Association cardiac disease (Class II or greater), myocardial infarction within the previous 3 months, unstable arrhythmias, and/or unstable angina
2. Prior treatment with anti-CD137 agents
3. History or complication of autoimmune disease
4. Any history or grade 3 immune-related adverse event (irAE) that resulted in permanent discontinuation of prior immunotherapeutic agent, or Grade 2 irAE attributed prior anti-PD-L1 /PD-1 or anti CTLA-4 therapy

Date of first enrolment

11/03/2020

Date of final enrolment

12/08/2025

Locations

Countries of recruitment

United Kingdom

England

Japan

Poland

Romania

Spain

Taiwan

Study participating centre**Royal Marsden Hospital**

Downs Road

Sutton

England

SM2 5PT

Study participating centre**The Christie**

550 Wilmslow Road

Withington

Manchester

England

M20 4BX

Sponsor information

Organisation

Chugai Pharmaceutical Co., Ltd. (Japan)

ROR

<https://ror.org/01v743b94>

Funder(s)

Funder type

Funder Name

Chugai Pharmaceutical Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available