Plain Language Clinical Study
Summary

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medicine works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine Studied: Sasanlimab (formerly known as PF-06801591)

Protocol Number: B8011011 (Landscape 1011 Study)

Dates of Study: 10 November 2020 to 29 October 2024

Title of this Study: Study of Immunotherapy (Sasanlimab) in Combination With Targeted Therapies in People With Advanced Non-Small Cell Lung Cancer (NSCLC)

[A Phase 1b/2 Open-Label Umbrella Study of Sasanlimab Combined With Anti-Cancer Therapies Targeting Multiple Molecular Mechanisms in Participants With Non-Small Cell Lung Cancer (NSCLC)]

Date of this Report: 17 May 2025

Pfizer

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. Do you have any questions about the study or the results? If so, please contact the doctor or staff at your study site.

Why was this study done?

What is non-small cell lung cancer?

Non-small cell lung cancer (**NSCLC**) is the most common type of lung cancer. NSCLC is a group of lung cancers that are named based on the kind of cells found in the cancer. This study had 2 sub-studies, which included participants with NSCLC that had spread outside the lungs:

- **Sub-Study A** included participants with NSCLC who had changes in the BRAF gene. The BRAF gene controls the growth of cells. Changes in the BRAF gene can cause cells to grow uncontrollably and become cancer cells that then grow and spread in the body.
- **Sub-Study B** included either:
    - participants with NSCLC regardless of "programmed death ligand-1 (PD-L1)" status and of any cancer medicines received. **PD-L1** is a protein found on the surface of cancer cells that blocks the body's immune system from attacking the cancer cells.
    - participants with NSCLC who had positive PD-L1 status, who had not received treatment for NSCLC, or who had NSCLC that worsened after the first treatment.

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What is sasanlimab?

Sasanlimab (sa-SAN-lee-mab) is a medicine that is given via injection in the fat layer of the skin. This type of injection is called a subcutaneous (SC) injection.

This study tested sasanlimab as a possible treatment for patients with NSCLC when given together with other cancer medicines.

- In **Sub-Study A**, sasanlimab was given together with encorafenib (en-KOR-a-fen-ib) and binimetinib (BIN-ee-MEH-tin-ib).
- In **Sub-Study B**, sasanlimab was given together with axitinib (ak-SIH-tih-nib) and SEA-TGT.

Each of the study medicines in Sub-Study A and Sub-Study B is designed to work against cancer in a different way.

What was the purpose of this study?

Each sub-study was divided into 2 phases.

- The purpose of the **Phase 1** study was to learn whether participants could tolerate sasanlimab plus other cancer medicines and to select which doses of sasanlimab plus other cancer medicines should be used in Phase 2.
- The purpose of the **Phase 2** study was to learn if the selected doses of sasanlimab plus other cancer medicines could help treat NSCLC and to learn more about the safety of the selected doses of sasanlimab plus other cancer medicines.

Researchers wanted to know:

- **What were the doses of sasanlimab plus other medicines to be used in Phase 2?**
- **Did sasanlimab plus other medicines help treat NSCLC (Phase 2)?**
- **What medical problems did participants have during the study?**

The entire study stopped early and was not completed as planned. For both Sub-Study A and Sub-Study B, the planned number of participants was not reached.

What happened during the study?

How was the study done?

Sub-Study A

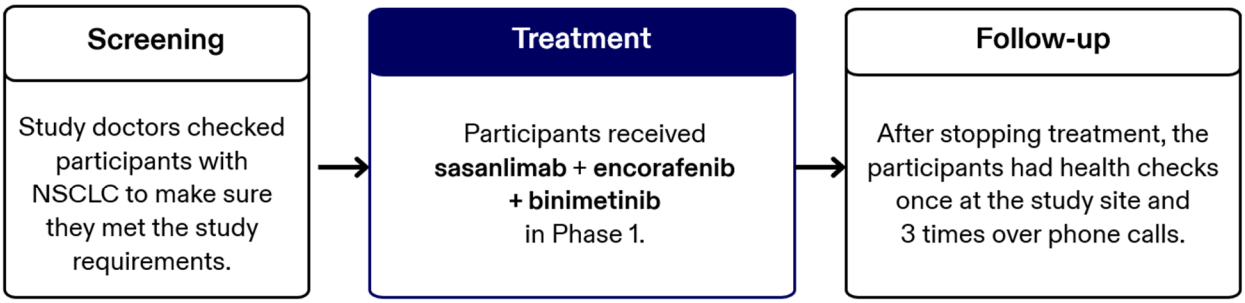
Phase 1 of Sub-Study A tested the 3-drug combination of sasanlimab, encorafenib, and binimetinib. Participants took **sasanlimab** 300 milligrams (mg) by SC injection every 4 weeks. They also took an assigned dose of **encorafenib** capsules once per day and **binimetinib** tablets twice per day.

- 4 participants received **sasanlimab** 300 mg, **encorafenib** 300 mg, plus **binimetinib** 45 mg
- 9 participants received **sasanlimab** 300 mg, **encorafenib** 450 mg, plus **binimetinib** 45 mg

Phase 2 of Sub-Study A was planned to enroll participants to receive sasanlimab, encorafenib, and binimetinib at the doses selected from Phase 1. However, Phase 2 of Sub-Study A was not started because the Sponsor stopped the study early due to a business decision. There were no safety concerns.

The figure below shows how Sub-Study A was done.

Figure 1 How Sub-Study A was done



Phase 2 of Sub-Study A was not started because the sponsor stopped the study early due to a business decision and not because of safety concerns.

Sub-Study B

Phase 1 of Sub-Study B first tested the 2-drug combination of sasanlimab plus axitinib. Participants took **sasanlimab** 225 mg by SC injection every 3 weeks. They also took an assigned dose of **axitinib** tablets twice per day.

- 3 participants received **sasanlimab** 225 mg plus **axitinib** 5 mg

Once researchers made sure that the doses of the 2-drug combination of sasanlimab plus axitinib were tolerated, the 3-drug combination of sasanlimab, axitinib, and SEA-TGT was tested. Participants received **SEA-TGT** as an injection into the vein (IV injection) every 3 weeks.

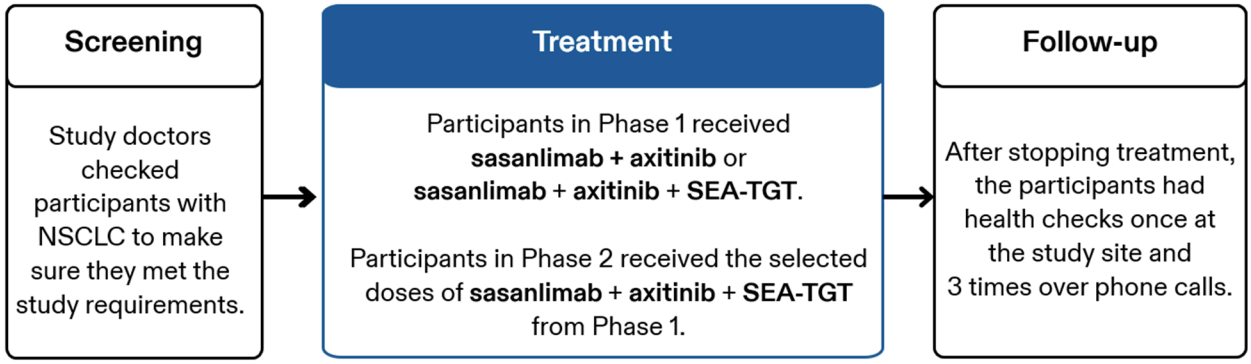
- 6 participants received **sasanlimab** 225 mg, **axitinib** 5 mg, plus **SEA-TGT** 1 milligram per kilogram of body weight (mg/kg)

Phase 2 of Sub-Study B started after the doses of sasanlimab, axitinib, and SEA-TGT were selected from Phase 1.

- 12 participants received **sasanlimab**, **axitinib**, and **SEA-TGT** at the doses selected in Phase 1

The figure below shows how Sub-Study B was done.

Figure 2 How Sub-Study B was done



Sub-Study A and Sub-Study B

The participants and researchers knew which treatment participants received during the study. This is known as an "open-label" study.

Throughout the study, study doctors checked on the participants' health and asked them how they were feeling.

Where did this study take place?

The Sponsor ran this study at 22 locations in Australia, Belgium, Taiwan, and the United States.

When did this study take place?

It began on 10 November 2020 and ended on 29 October 2024.

Who participated in this study?

The study included adult participants with NSCLC that had spread outside of the lungs.

Sub-Study A

- A total of 7 men and 6 women participated.
- All participants were between the ages of 44 and 77 years.

Of the 13 participants who started the study, they all received at least 1 dose of sasanlimab, encorafenib, plus binimetinib. At the end of the study, all 13 participants stopped taking sasanlimab, encorafenib, plus binimetinib, with the most common reasons being that they developed medical problems and the Sponsor stopped the study early. Of these 13 participants, 4 who were still benefiting from the study medicines continued taking study medicines through the Post-Trial Access programs.

Sub-Study B

- A total of 15 men and 6 women participated.
- All participants were between the ages of 48 and 78 years.

Of the 21 participants who started the study, they all received sasanlimab and axitinib, while 18 received SEA-TGT in addition. At the end of the study, all participants stopped taking the study medicines, with the most common reason being that their NSCLC got worse.

How long did the study last?

Study participants were in the study for different lengths of time, depending on how long they took their study treatment. The entire study ran for almost 4 years before the Sponsor stopped the study. This study stopped early and was not completed as planned. The decision was due to changes in development strategy and not due to any safety concerns.

When the study ended in October 2024, the Sponsor did the final analysis of the information collected. The Sponsor then created a report of the results. This is a summary of that report.

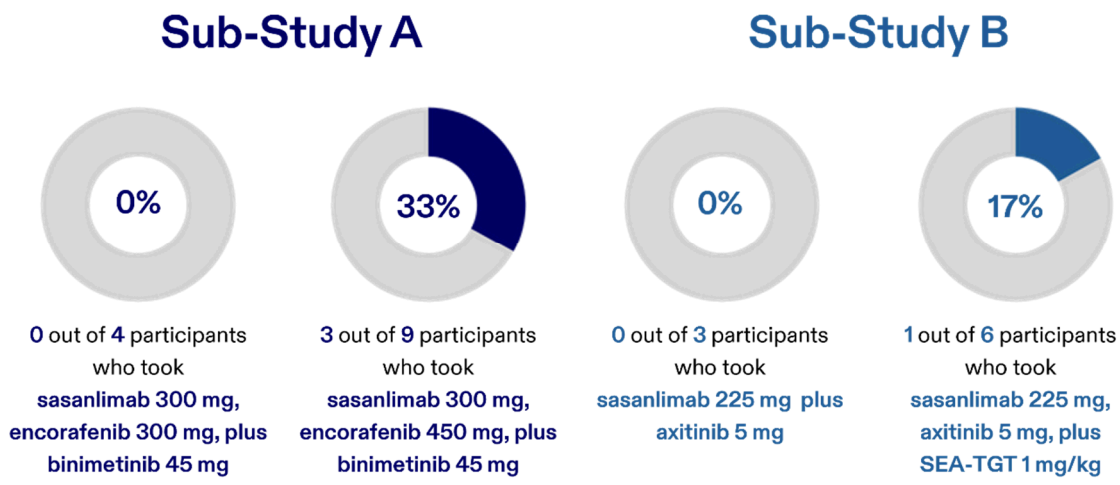
What were the results of the study?

What were the doses of sasanlimab plus other medicines to be used in Phase 2?

To answer this question, researchers looked at whether participants developed a dose-limiting toxicity. **Dose-limiting toxicities** (**DLTs**) are medical problems that prevent an increase in dose or limit the possibility of treating a participant at the planned dose.

The figure below shows the results of participants who received at least 1 dose of sasanlimab plus other cancer medicines and who were observed during the DLT-observation period. There were 13 participants in Sub-Study A and 9 participants in Sub-Study B who were observed for DLTs.

Figure 3 How many participants had DLTs?



The DLTs during **Sub-Study A** were sudden severe allergic reaction, breakdown of muscles that often leads to serious complications, and failure of the lungs that leads to low oxygen in the blood. The DLT during **Sub-Study B** was high blood pressure.

Based on the DLT results above, researchers were able to find out the highest doses of sasanlimab plus other cancer medicines that participants could tolerate during Phase 1.

The highest doses of sasanlimab, encorafenib, plus binimetinib that were given in **Phase 1 of Sub-Study A** were:

- sasanlimab 300 every 4 weeks
- encorafenib 450 mg once per day
- binimetinib 45 mg twice per day

No dose in Phase 1 was selected for use in Phase 2 because Phase 2 was not started.

The selected doses of sasanlimab, axitinib, plus SEA-TGT to be used in **Phase 2 of Sub-Study B** were:

- sasanlimab 225 mg every 3 weeks
- axitinib 5 mg twice per day
- SEA-TGT 1 mg/kg every 3 weeks

Did sasanlimab plus other medicines help treat NSCLC (Phase 2)?

To answer this question, researchers compared the size of each participant's NSCLC tumor before and after receiving sasanlimab plus other cancer medicines. Researchers then checked the number of participants whose tumors had shrunk in size or had gone away after receiving sasanlimab plus other cancer medicines. This is called an objective response.

Because the entire study stopped early and was not completed as planned:

- The objective response result for Sub-Study A was not possible to analyze as Phase 2 was not started.
- The results shown below for Sub-Study B were not meaningful, as there was not enough information to reach a conclusion.

In **Sub-Study B**, 3 out of 21 participants (14%) had tumors that shrank in size after receiving sasanlimab, axitinib, plus SEA-TGT.

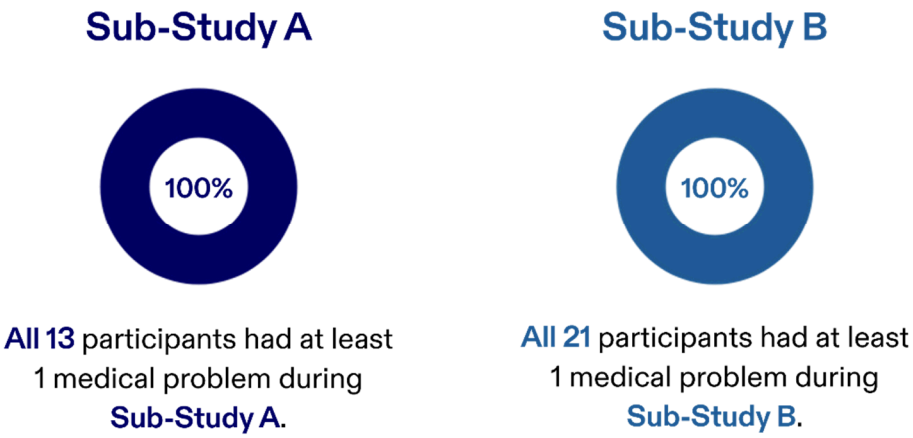
This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medicine might have on a participant.

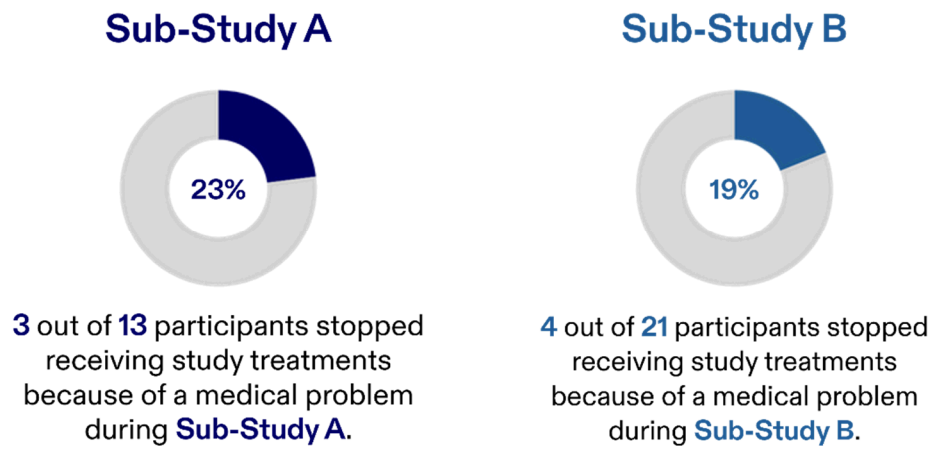
The figure below shows the number of participants who had at least 1 medical problem in each sub-study.

Figure 4 How many participants had medical problems?



The figure below shows the number of participants who stopped receiving study treatments because of medical problems in each sub-study.

Figure 5 How many participants stopped receiving study treatments because of medical problems?



The table below shows the most common medical problems in **Sub-Study A** – those reported by 30% of participants or more.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st column** lists the most commonly reported medical problems in **Sub-Study A**. All medical problems were reported by 30% of participants or more.
- The **2nd column** shows the total number and percentage of participants in **Sub-Study A** who took sasanlimab, encorafenib, plus binimetinib and reported each medical problem.

Table 1. Commonly reported medical problems in Sub-Study A	
Medical Problem	**Total (13 Participants)**
Elevated liver enzyme (ALT increased)	5 out of 13 participants (39%)
Joint pain	5 out of 13 participants (39%)
Feeling tired	5 out of 13 participants (39%)
Muscle pain	5 out of 13 participants (39%)
Nausea	5 out of 13 participants (39%)
Fever	5 out of 13 participants (39%)

The table below shows the most common medical problems in **Sub-Study B** – those reported by 30% of participants or more.

Below are instructions on how to read Table 2.

Instructions for Understanding Table 2.

- The **1st column** lists the most commonly reported medical problems in **Sub-Study B**. All medical problems were reported by 30% of participants or more.

- The **2nd column** shows the total number and percentage of participants in **Sub-Study B** who took sasanlimab, axitinib, plus SEA-TGT and reported each medical problem.

Table 2. Commonly reported medical problems in Sub-Study A

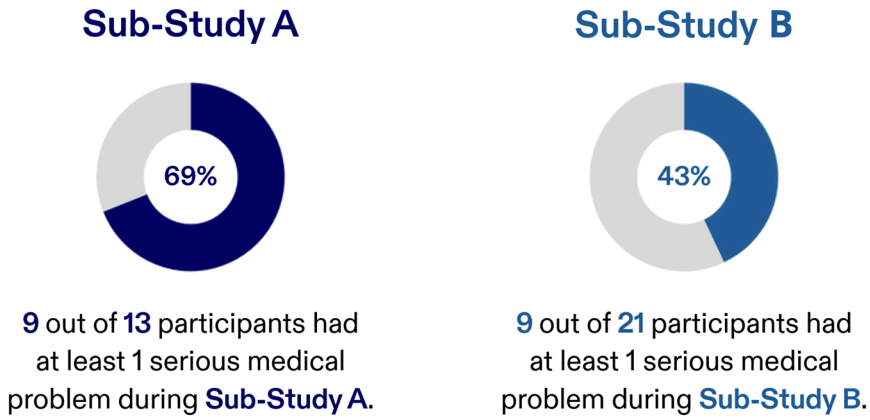
Medical Problem	Total (21 Participants)
Feeling tired	11 out of 21 participants (52%)
Diarrhea	9 out of 21 participants (43%)
Elevated liver enzyme (AST increased)	8 out of 21 participants (38%)
Skin rash	8 out of 21 participants (38%)

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

The figure below shows the number of participants who had at least 1 serious medical problem in each sub-study.

Figure 6 How many participants had serious medical problems?



During **Sub-Study A**, all serious medical problems happened in 1 participant each, except for fever, which happened in 2 participants. One (1) participant died because of a condition when muscle breaks down too quickly ("rhabdomyolysis"), which study doctors believe may have been related to at least 1 medicine in the study treatment combination.

During **Sub-Study B**, all serious medical problems happened in 1 participant each, except for lung infection ("pneumonia"), which happened in 2 participants. One (1) participant died because of an extreme reaction to an infection ("sepsis"), which study doctors do not believe to be related to study treatment.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **B8011011**

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT04585815**
https://euclinicaltrials.eu	Use the study identifier **2020-002829-28**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study,
thank you for volunteering.
We do research to try to find the
best ways to help patients, and you helped
us to do that!

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