Plain Language Summary of Clinical Study Results

Short Study Title:	A Study of BMS-986442 With Nivolumab With or Without Chemotherapy in Solid Tumors and Non-small Cell Lung Cancer.
Study Medicine:	BMS-986442
Date of Summary:	13 December 2024

Thank You!

Bristol-Myers Squibb the sponsor, would like to thank you for participating in this clinical study for a medicine called BMS-986442.

With your help, we learned more about BMS-986442, its safety, and its effect on solid tumors or lung cancer when used together with nivolumab.

Overview

In this study, researchers wanted to answer the following questions:

1. **What is the maximum tolerated dose (MTD) of BMS-986442 when taken together with nivolumab in participants with solid tumors or non-small cell lung cancer?**
   - The study ended before an MTD could be chosen.
2. **What other side effects did participants have during the study?**
   - Most of the study's side effects were related to how BMS-986442 was given. These included itching, rash (an area of irritated or swollen skin that can be red, bumpy, scaly, or itchy), and chills (feelings of coldness accompanied by shivering, often with a fever or infection.)

The study had planned to test BMS-986442 in combination with nivolumab and chemotherapy. However, this part of the study did not start because the study ended early. This was due to a business decision and was not due to any safety concerns.

The maximum tolerated dose (MTD) of a medicine is the highest dose that can be given to a patient without causing severe side effects. During clinical trials, doctors gradually increase the dose of the medicine to find the MTD. They carefully monitor patients to see how their bodies react and to make sure the side effects are manageable. The goal is to find a dose that is strong enough to be effective but still safe for patients to take.

BMS-986442 is a special type of medicine designed to help the immune system fight cancer by blocking certain proteins and boosting the activity of the immune cells.

Nivolumab is a medicine that helps your immune system fight cancer. It works by blocking a protein that stops your immune system from attacking cancer cells.

Chemotherapy is a type of cancer treatment that uses powerful medicines to kill cancer cells or stop them from growing and spreading. It can be given in various forms, such as pills or through an IV, and targets rapidly dividing cells in the body.

Symptoms or abnormal findings that study doctors think may or may not be related to treatment are called side effects.

Why was the study done?

This study was done to find better treatments for patients with **solid tumors (ST)** or **non-small cell lung cancer (NSCLC)** that have spread to other parts of the body.

Solid tumors (ST) are abnormal masses of tissue that form when cells grow and divide more than they should or do not die when they should. They can occur in different parts of the body, such as the organs, muscles, or bones.

Non-small cell lung cancer (NSCLC) is a type of solid tumor that starts in the tissues of the lungs. NSCLC grows and spreads more slowly than other types of lung cancer.

Researchers were looking for new ways to help the immune system fight cancer by targeting certain proteins that help cancer cells hide. They believe that combining new treatments like BMS-986442 with existing ones like nivolumab and chemotherapy could make cancer treatment more effective.

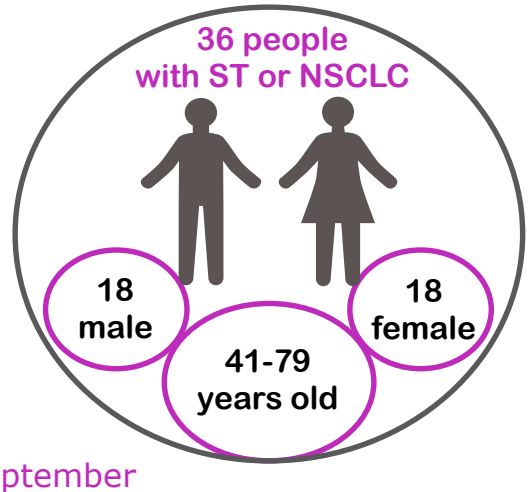
The main goals of the study were to:

a. **understand how safe BMS-986442 is when used with nivolumab or nivolumab and chemotherapy, and**

b. **to find the best doses to use for future studies.**

The study was planned to test BMS-986442 in combination with both nivolumab and chemotherapy. However, the combination with chemotherapy was not tested because the study ended early. This was due to a business decision and not because of any safety concerns.

Who took part in the study?



The study included 36 people with solid tumors or NSCLC that had spread to other parts of the body.

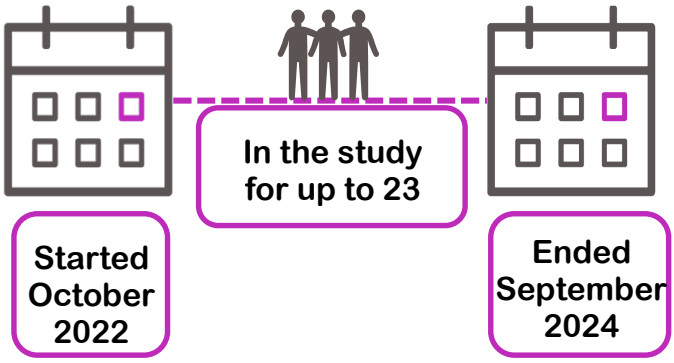
- In total, 18 male and 18 female participants took part.
- They were between 41 and 79 years old.

What happened during the study?

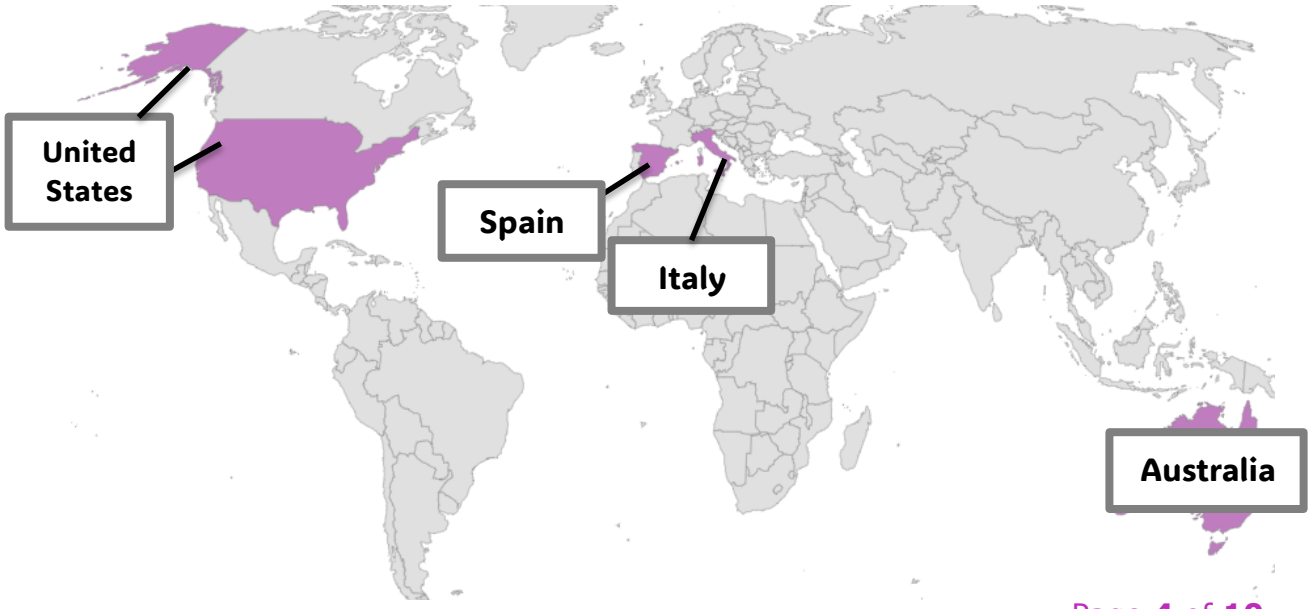
The study started in October 2022 and ended in September 2024.

The participants were in the study for 23 months or until:

- their cancer got worse or
- they died or
- they left the study early because of:
  - side effects,
  - their choice or
  - the study doctor's decision

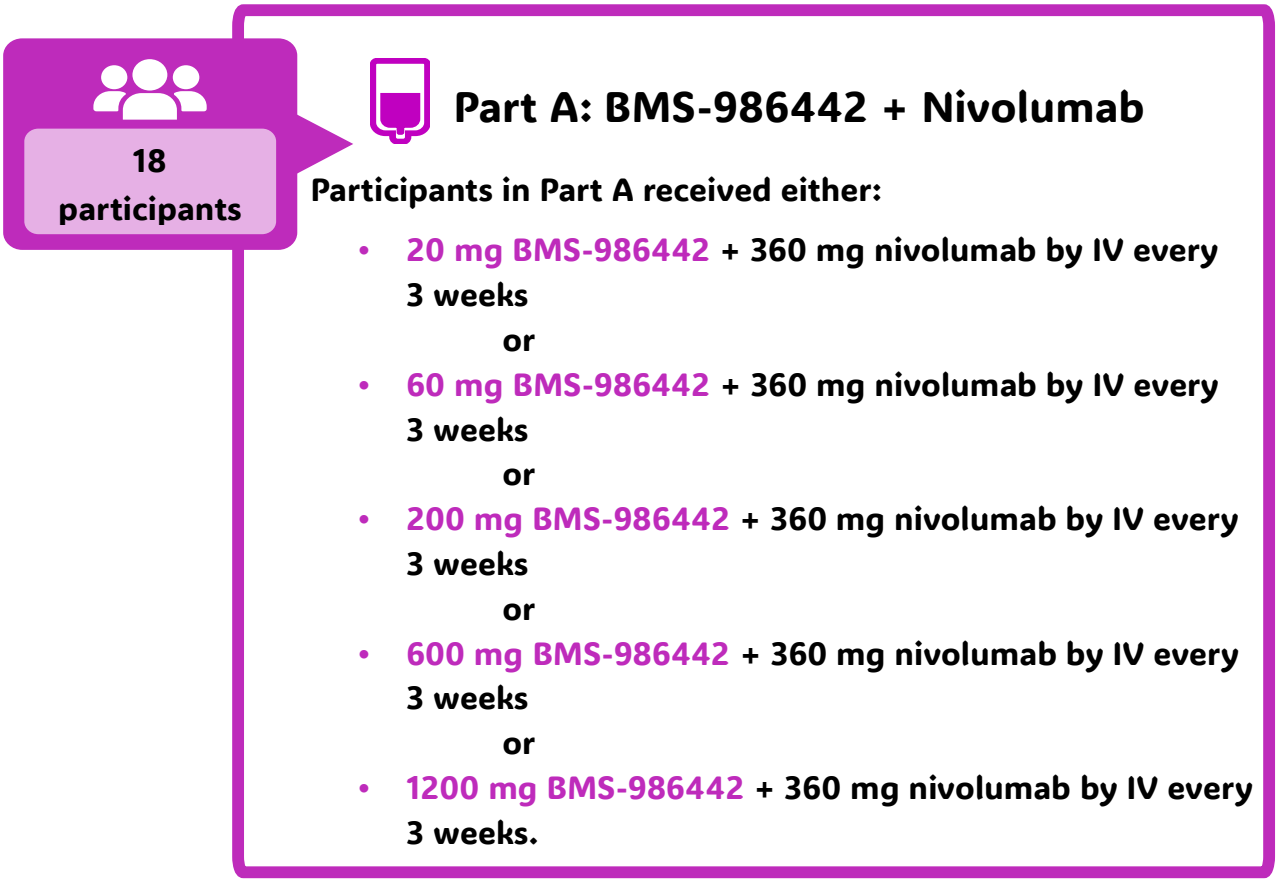


The map below shows where study participants were from.



What treatments were studied?

Study participants received treatment in either Part A or Part B of the study as follows.



The study was planned to test BMS-986442 in combination with nivolumab and chemotherapy in Parts C, D, and E. However, these parts of the study were not started because the study ended early.

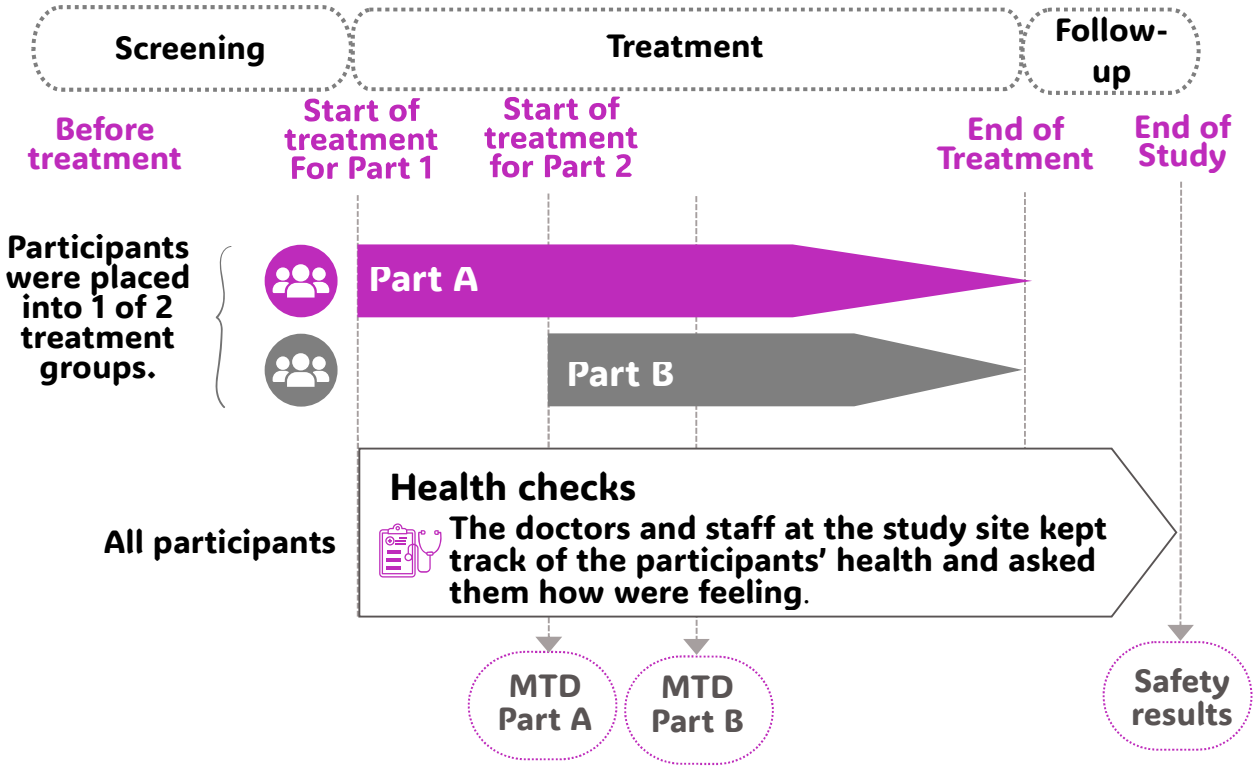
How was the study done?

This section describes what kind of study it was and what happened in the study.

Open-Label

This was an open-label study. This means that the participants, the study doctors, and the other study staff knew which treatments the participants got during the study.

The figure below shows what happened in the study.



MTD – Maximum Tolerated Dose

What were the main results of the study?

This section includes the results of 30 participants who received study treatment and were monitored for **dose-limiting toxicities**.

1. **What is the maximum tolerated dose (MTD) of BMS-986442 when taken together with nivolumab in participants with solid tumors or non-small cell lung cancer?**

To answer this question, study doctors carefully monitored patients to see how their bodies reacted to the study medicine. They also checked whether participants had any severe or harmful side effects, called **dose limiting toxicities (DLTs).**

The maximum tolerated dose (MTD) is the highest dose of a medicine that can be given to a patient without causing severe side effects. If a patient experiences a side effect that is too severe or harmful at a certain dose, that side effect is called a dose limiting toxicity (DLT). This helps doctors determine the safest and most effective dose of the medication for future patients. The goal is to find a dose that is strong enough to be effective but still safe for patients to take.

Dose-Limiting Toxicities (DLTs)

Part A

0% of participants had dose-limiting toxicities (DLTs) in Part A.
That is 0 out of 16 participants.

Part B

7% of participants had dose-limiting toxicities (DLTs) in Part B.
That is 1 out of 14 participants.

The study ended before an MTD could be chosen.

2. What side effects did participants have during the study?

The safety of every participant is important throughout the development and testing of study medicines. The study doctors keep a record of all symptoms the participants have during the study.

Symptoms or abnormal findings that study doctors think may or may not be related to treatment are called side effects.

A side effect that is life-threatening, needs hospital care, or is considered by the study doctor as medically important is called a serious side effect.

The table below shows the number of participants who had side effects that may have been related to the study treatment.

Side effects related to study treatment	Part A 18 participants	Part B 18 participants
	Number of participants (%)	
How many participants had any side effects?	12 (67%)	11 (61%)
How many participants had serious side effects?	2 (11%)	3(17%)
How many participants stopped taking the study medicine because of side effects?	2 (11%)	1 (6%)
How many participants died from side effects?	0 (0%)	0 (0%)

What were the side effects?

The 5 most common side effects reported across Part A and Part B during this study were:

- Pruritis, also called itching.
- Rash, an area of irritated or swollen skin that can be red, bumpy, scaly, or itchy.
- Maculo-papular rash, a skin condition that appears as red spots and small, raised bumps, often causing itching or discomfort.
- Chills, feelings of coldness accompanied by shivering, often occurring with a fever or infection.
- Infusion-related reaction. An infusion-related reaction is when your body has a response, like fever, chills, or rash, to the medicine being given through your vein.

What were the serious side effects?

The most common serious side effect reported across Part A and Part B during this study was:

- Infusion-related reaction. An infusion-related reaction is when your body has a response, like fever, chills, or rash, to the medicine being given through your vein.

How has this study helped participants and researchers?

You have helped us learn more about the safety of BMS-986442 and how it works in participants with solid tumors and non-small cell lung cancer.

Researchers must look at the results of many studies to decide which treatments work and are safe.

This summary includes only the main results from this one study. Other studies may show new information or different results.

Further studies of BMS-986442 are ongoing. If you have questions about the study results or BMS-986442, please speak with a doctor or staff member at the study site.

Always talk to a doctor before making any treatment decisions.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

https://www.clinicaltrials.gov/study/NCT05543629?term=CA115-001&rank=1

https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2022-503108-26-00

Full Study Title: A Phase 1b/2 Study of BMS-986442 in Combination with Nivolumab or Nivolumab and Chemotherapies in Participants with Advanced Solid Tumors and Non-small Cell Lung Cancer.

Study Identification: CA115-001

Bristol-Myers Squibb is the sponsor of this study.

For general contact information, go to the link below:

www.globalbmsmedinfo.com