NOVARTIS

# Clinical Trial Results Summary

# A clinical trial to learn about the safety and effects of capmatinib given with spartalizumab in participants with advanced non-small cell lung cancer

**Protocol number: CINC280D2201**

## Thank You!

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. Thank you for taking part in this trial for the drugs INC280 and PDR001, also known as capmatinib and spartalizumab, respectively. You helped researchers learn more about how the combination of capmatinib and spartalizumab works in people with advanced non-small cell lung cancer and how safe is it to use it.

This summary only shows the results of a single clinical trial. Other clinical trials may have different findings. Researchers and health authorities, such as the Food and Drug Administration (FDA) in the United States and the European Medicines Agency (EMA) in Europe, look at the results of many clinical trials to understand which drugs work and if they are safe. If you have any questions about these trial results, please talk to the doctor or staff at your trial site.

# Why was the research needed?

Researchers were looking for a better way to treat advanced non-small cell lung cancer (NSCLC). In NSCLC, a type of lung cancer, abnormal growth of large cells in the lungs occurs gradually. Symptoms of continuous cough, coughing with blood, shortness of breath, chest pain, weakness, and weight loss are not visible until it becomes advanced. In advanced NSCLC, this growth has further spread beyond the lungs to nearby tissues or other parts of the body.

Currently available treatments for advanced NSCLC mainly include anti-cancer drugs, high doses of radiation, or a combination of these. However, these treatment options are not completely successful. Therefore, new methods for treating advanced NSCLC are needed.

In this trial, researchers wanted to find out how the combination of capmatinib and spartalizumab effects advanced lung cancer and is safe in participants with advanced NSCLC.

This trial was to be conducted in 2 parts. In Part 1, researchers studied the safety and effects of the trial drugs in a small number of participants.

The main question the researchers wanted to answer in Part 1 of this trial was:

**What adverse events did the participants have during the trial?**

*Adverse events are medical problems that happen in clinical trials. They are defined on Page 4 in this summary.*

In Part 2, researchers wanted to assess the effects of the trial treatments on advanced NSCLC. However, the results for Part 1 suggested that this treatment was safe but not beneficial in treating advanced NSCLC. None of the participants had a response to the trial treatment. Therefore, researchers decided to stop the trial after completing Part 1.

## Trial drugs

The drugs given in this trial were:

**Capmatinib**, also known as INC280

**Spartalizumab,** also known as PDR001

Capmatinib is an approved drug used for treatment in patients with advanced lung cancer. Throughout the trial, the participants were allowed to continue taking the medicines that were considered necessary for their health condition.

# Who was in this trial?

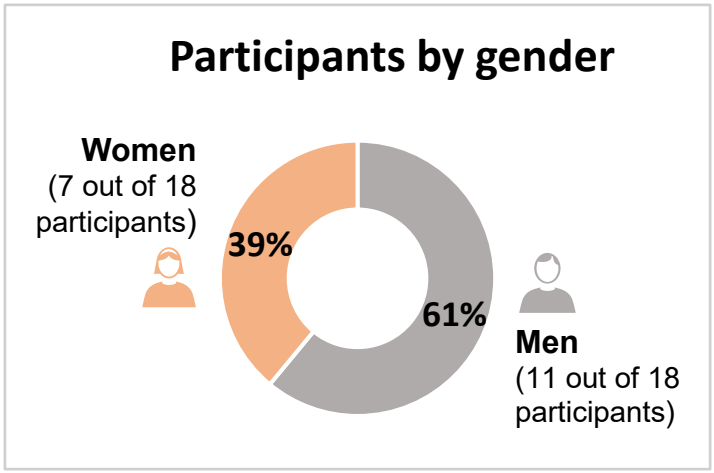
The participants could take part in this trial if they:

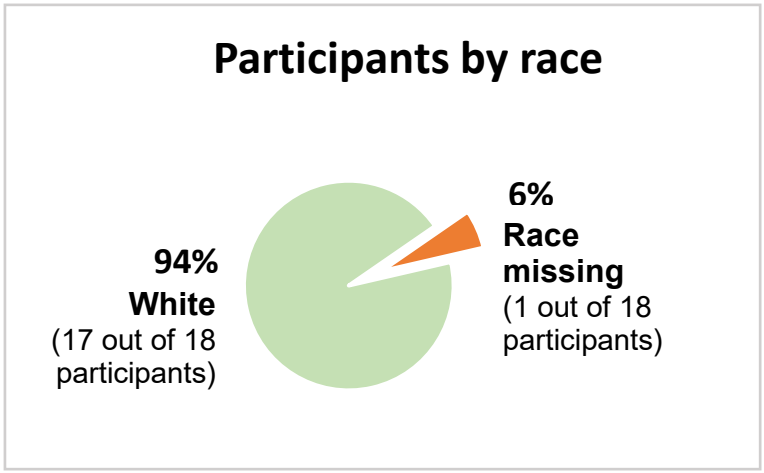
- were at least 18 years of age,
- had NSCLC that kept growing even with treatment,
- had already tried specific cancer treatments,
- had at least one measurable area of abnormal tissue,
- had recovered from side effects of previous anti-cancer treatment, and
- had adequate blood, liver, and kidney function.

18 participants from 6 countries participated in this trial.

| Country | Number of Participants |
|---|---|
| Belgium | 3 |
| France | 4 |
| Germany | 3 |
| Israel | 1 |
| Spain | 5 |
| United States | 2 |

The average age of participants was 61 years. Participants' age ranged from 37 to 81 years.

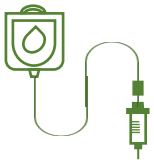


# How was Part 1 of this trial done?

Participants received the following treatment in cycles of 28 days each:

Capmatinib tablets: Participants received 400 mg capmatinib by mouth, once in the morning and once in the evening (twice a day).



Spartalizumab: Participants received 400 mg spartalizumab at the study site after taking the morning dose of capmatinib. Spartalizumab was given as an infusion into the vein once in each 28-day cycle.

Participants continued the trial treatment until:

- their disease worsened,
- they did not want to be in the trial any longer,
- they got pregnant,
- they became unreachable, or
- they died.

Both the researchers and the participants knew what treatment was given to participants.

Participants' health was monitored throughout the trial. They were followed up for about 6 months for effects and safety, and to know for how long they lived.

# What were the key results of this trial?

Medical problems that happen in clinical trials are called "adverse events".

A lot of research is needed to know whether a drug causes an adverse event. During a trial, all adverse events are recorded, whether or not they are thought to be caused by the trial drug. When new drugs are being studied, researchers keep track of all adverse events participants have.

This section is a summary of the adverse events that happened during this trial. The websites listed at the end of this summary may have more information about all the adverse events that happened in this trial.

*An adverse event is an unwanted sign, symptom, or disease that participants have during a trial.*

*An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or the participant needs hospital care. These problems may or may not be caused by the trial drug.*

## What adverse events did the participants have during the trial?

| Number of Participants (%) With Adverse Events | |
|---|---|
| | **Capmatinib + Spartalizumab (out of 18 participants)** |
| At least 1 adverse event | 18 (100%) |
| At least 1 serious adverse event | 10 (56%) |
| Stopped trial treatments due to adverse events | 5 (28%) |
| Deaths* | 5 (28%) |

*4 deaths were due to advanced NSCLC and 1 death was due to respiratory failure.

## What were the most common non-serious adverse events?

The most common non-serious adverse events that happened in at least 15% (15 out of 100) of participants during this trial are presented in the next table.

### Number (%) of participants with most common non-serious adverse events

| | **Capmatinib + Spartalizumab (Out of 18 participants)** |
|---|---|
| **Feeling sick to your stomach** (Nausea) | 7 (39%) |
| **Increase in blood creatinine levels*** (Blood creatinine increased) | 5 (28%) |
| **Diarrhea** (Diarrhoea) | 5 (28%) |
| **Shortness of breath** (Dyspnoea) | 5 (28%) |
| **Vomiting** (Vomiting) | 5 (28%) |
| **Weakness** (Asthenia) | 4 (22%) |
| **Feeling tired** (Fatigue) | 4 (22%) |
| **Swelling in lower legs or hands** (Oedema peripheral) | 4 (22%) |
| **Fever** (Pyrexia) | 4 (22%) |
| **Weight loss** (Weight decreased) | 3 (17%) |

*Increase in blood creatinine levels suggests reduced kidney function.

## What were the serious adverse events?

The most common serious adverse event (SAE) that happened in 3 out of 18 participants (17%) during this trial was 'feeling tired (fatigue)'. All other SAEs occurred in 1 participant. All SAEs are shown below.

### Number (%) of participants with serious adverse events

| | Capmatinib + Spartalizumab (Out of 18 participants) |
|---|---|
| **Feeling tired** (Fatigue) | 3 (17%) |
| **Stomach infection** (Abdominal infection) | 1 (6%) |
| **Life-threatening allergic reaction** (Anaphylactic reaction) | 1 (6%) |
| **Airway obstruction** (Bronchial obstruction) | 1 (6%) |
| **Heart failure** (Cardiac failure congestive) | 1 (6%) |
| **Decrease in appetite** (Decreased appetite) | 1 (6%) |
| **Blood clot in a vein** (Deep vein thrombosis) | 1 (6%) |
| **Allergic reaction to the treatment** (Drug hypersensitivity) | 1 (6%) |
| **Shortness of breath** (Dyspnoea) | 1 (6%) |
| **Deterioration in health** (General physical health deterioration) | 1 (6%) |
| **Coughing up blood** (Haemoptysis) | 1 (6%) |
| **Lung infection** (Pneumonia) | 1 (6%) |
| **Fever** (Pyrexia) | 1 (6%) |
| **Insufficient oxygen in the blood** (Respiratory failure) | 1 (6%) |
| **Chest infection** (Respiratory tract infection) | 1 (6%) |
| **Abnormal heart rhythm** (Ventricular arrhythmia) | 1 (6%) |

## How many participants stopped trial drug due to adverse events?

During the trial, 5 out of 18 (28%) of participants stopped trial treatments early due to the following adverse events: increase in liver test value of alanine aminotransferase in the blood (alanine aminotransferase increased), cancer pain, allergic reaction to the treatment, tiredness (lethargy), increase in pancreatic test value of lipase in the blood (lipase increased), insufficient oxygen in the blood, and feeling drowsy (somnolence).

# How was this trial useful?

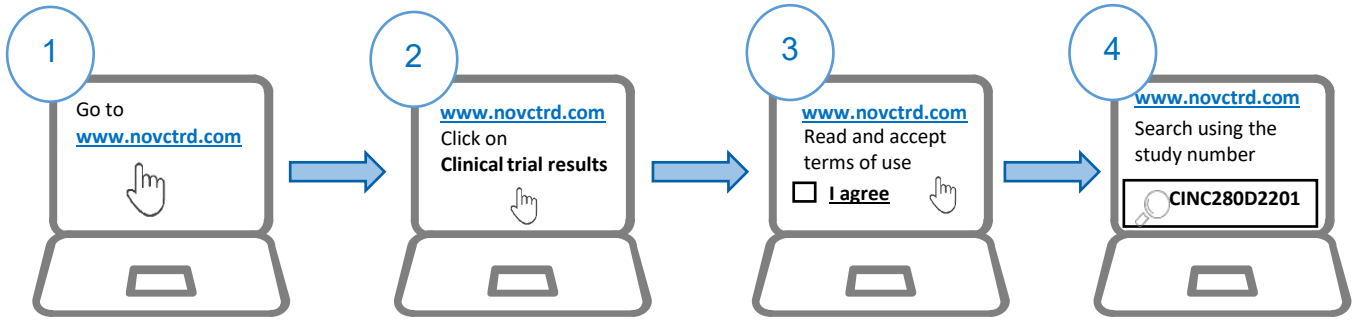
Researchers found that the combination capmatinib with spartalizumab is safe but not beneficial in treating participants with advanced NSCLC. Results from this trial may be used in informing other clinical trials for people with advanced NSCLC.

If you have any questions about these trial results, please talk to the doctor or staff at your trial site.

# Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website (www.novctrd.com).

Please follow the below steps:



You can find more information about this trial on the following websites:

- www.clinicaltrials.gov Use the NCT identifier NCT03647488 in the search field.
- https://www.clinicaltrialsregister.eu/ctr-search/search Use the EudraCT identifier 2018 001420-19 in the search field.

**Full clinical trial title:** A phase II, multicenter, randomized, two-arm study of capmatinib (INC280, an oral MET inhibitor) and spartalizumab (PDR001, a PD-1 inhibitor) combination therapy versus docetaxel in pretreated adult patients with EGFR wild-type, ALK rearrangement negative locally advanced/metastatic non-small cell lung cancer

**Trial dates:** The trial started in December 2018 and ended in September 2020.

## Thank you

Thank you for taking part in this trial. As a clinical trial participant, you belong to a large community of people around the world. You helped researchers answer important health questions and test new medical treatments.

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Novartis is a global healthcare company based in Switzerland that provides solutions to address the evolving needs of patients worldwide.

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