Clinical Results Summary

A study to learn about the safety and effects of INCB050465 and itacitinib (INCB039110) in participants with previously treated B-cell malignancies

Also known as: CITADEL-101

Thank you!

We thank participants for taking part in this research study ("study") for INCB050465 and itacitinib. Their time and commitment have helped us try to bring new medicines to patients.

CONTENTS

Important: This summary only shows the results of this single study. Other studies using the same drug may have different results. Researchers and health authorities look at the results of many studies to understand how treatments work and if there are any safety concerns. It takes many studies around the world to advance medical science and healthcare. Please do not use the results of this one study to make any healthcare decisions for yourself, or for your family and friends. Talk to your doctor or study doctor before changing any treatment you are taking or if you have any questions about the results of this study.

1. Why was this study done?

Researchers were looking at what medical events participants had, to determine if there were any safety concerns with taking INCB50465 when it was taken alone, or when it was taken with itacitinib or with rituximab, ifosfamide, carboplatin, and etoposide (a chemotherapy called R-ICE). The study drugs were tested in participants who had B-cell malignancies. B-cell malignancies are a type of cancer that forms in a type of white blood cell called B-lymphocytes, which help the body to fight infections. The most common symptoms that people with B-cell malignancies may have are sweating during the night, fever, weight loss, decreased appetite, difficulty breathing, and feeling tired. There can be other symptoms of B-cell malignancies that are not listed here.

Phase 1 studies are done to find out how a new study drug works in a small number of participants with a disease or condition. This helps researchers figure out what dose to use in future studies, and to understand what happens to the study drug in the body and how safe it is.

In Phase 2 studies, the study drug is given to a small number of participants with a disease or condition to gather information about how well the study drug works and how safe it is.

This was a Phase 1/2 study.

The main question the researchers wanted to answer in this study was:

How many participants had medical events during this study?

Researchers did not look at whether INCB050465 and itacitinib helped to improve symptoms of B-cell malignancies in study participants.

There were some additional questions that researchers wanted to answer, but these are not discussed in this summary. This information can be found using the internet links provided at the end of this document.

2. Which drugs were studied?

Participants received INCB050465 alone, in combination with itacitinib, and with R-ICE. INCB050465 is an investigational drug, which means that health authorities have not yet approved it to treat B-cell malignancies or any other disease.

The participants were grouped based on the type of cancer they had and which one of the three treatments they received: INCB050465 alone, INCB050465 plus itacitinib, or INCB050465 plus R-ICE.

	**INCB050465**: Incyte Corporation (the "sponsor") was studying INCB050465, given in tablets, for the treatment of B-cell malignancies.
	**Itacitinib**: Incyte Corporation (the "sponsor") was studying itacitinib, given in tablets, for the treatment of B-cell malignancies.

In this study, both the researchers and the participants knew which drug was given to which participants.

3. Who could take part in this study?

People could take part in this study if they:

- were 18 years or above in age;
- were expected to live for at least 12 weeks;
- had received at least 1 treatment for their cancer; and
- were not eligible for a stem cell transplant.

People could not take part in this study if they:

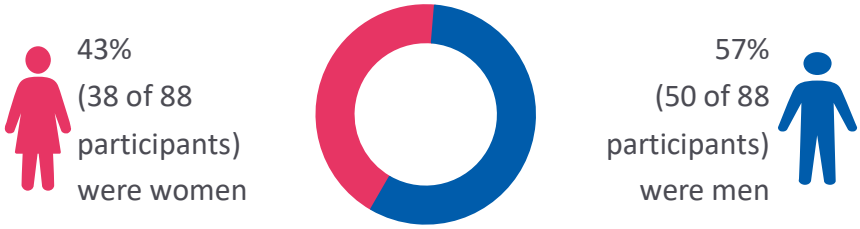
- had a history of brain cancer;
- had abnormal kidney or liver function;
- were unable to work but able to walk and manage self-care and be out of bed for more than 50% of waking hours,
  OR
  were able to manage limited self-care and be out of bed for less than 50% of waking hours,
  OR
  were unable to manage any self-care and were totally bound to bed.

There were other conditions participants had to fulfill to join this study. Visit the website listed at the end of this summary for more information.

4. Who participated in this study?

This study included 88 participants from the United States.

This study included men and women with B-cell malignancies between the ages of 24 and 89 years.



5. When was this study done?

The study started in September 2016 and ended in April 2021. When the study ended, the researchers created a report of the study results that were available. This summary is based on that report.

6. What were the overall results of this study?

Key results from this study are shown for each study group of participants collectively. This summary does not show the results from each individual participant. An individual participant's results could be different from the total group of participants.

The main question that researchers wanted to answer was related to safety and the number of medical events participants had after taking the study medication.

How many participants had medical events during this study?

A medical event is an unwanted symptom or problem that a participant had during the study. Researchers look at and assess all medical events that participants have during a study,

whether or not they think the event might be related to the study drug. The number of participants who experienced these medical events, whether or not they are thought to be related to study treatment, are summarized below.

During this study, 94% of participants (68 out of 72) who took INCB050465 alone had medical events.

During this study, 82% of participants (9 out of 11) who took INCB050465 with itacitinib had medical events.

All participants (5 out of 5) who took INCB050465 with R-ICE had medical events.

Medical events that the study doctor thought might be related to study treatment, also known as side effects, are summarized in Section 7.

7. What side effects did participants have during this study?

A lot of research is needed to know whether a drug causes a side effect. Side effects are unwanted medical events that the study doctor thought might be related to the study drug.

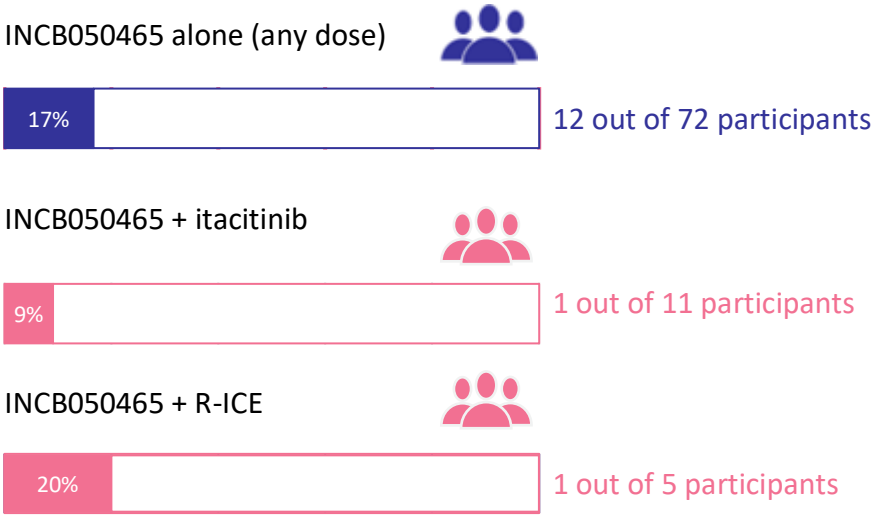
This section is a summary of the most common serious and non-serious side effects that participants experienced during the study.

The website listed at the end of this summary has more information about the medical events that may or may not be caused by the study drugs that happened in this study.

How many participants had serious side effects?

Serious side effects are those that may cause death, disability that lasts for a long time, life-threatening conditions, or hospitalization.

Participants who had serious side effects:



The most common serious side effects, which happened in at least 5% of participants in any group who took INCB050465 alone, are presented below.

The most common serious side effects experienced by participants who took INCB050465 alone:

	INCB050465 5 mg (1 participant)	INCB050465 10 mg (3 participants)	INCB050465 15 mg (3 participants)	INCB050465 20 mg (34 participants)	INCB050465 30 mg (27 participants)	INCB050465 45 mg (4 participants)
Diarrhea *(Diarrhea)*	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**3%** (1 participant)	**7%** (2 participants)	**0%** (0 participants)
Inflammation in the large intestine *(Colitis)*	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**9%** (3 participants)	**0%** (0 participants)	**0%** (0 participants)
Lung infection *(Pneumonia)*	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**25%** (1 participant)
Redness of the skin *(Dermatitis exfoliative)*	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**4%** (1 participant)	**0%** (0 participants)

In the participants given INCB050465 with itacitinib, 1 participant who took 30 mg INCB050465 and 300 mg itacitinib experienced a serious side effect of loss of fluid from the body (dehydration).

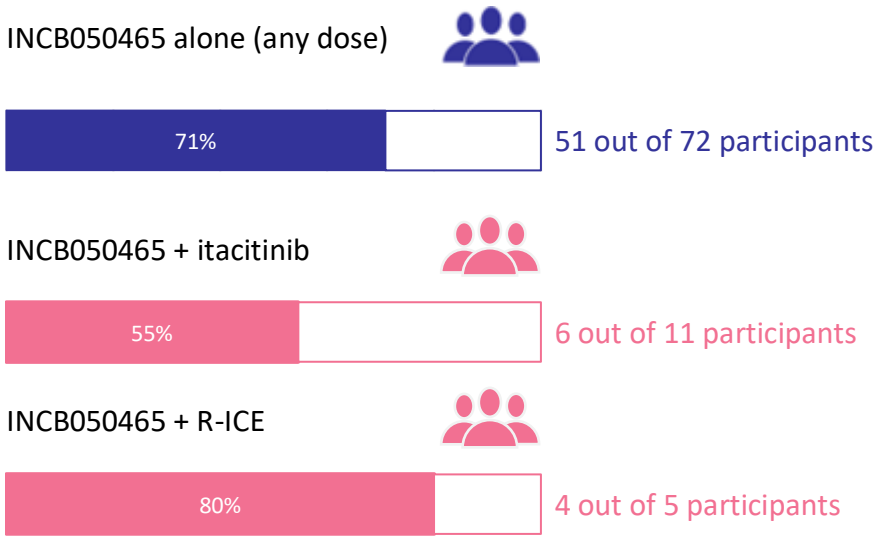
In the participants given INCB050465 with R-ICE, 1 participant who took 15 mg INCB050465 and R-ICE experienced serious side effects of decreased levels of white blood cells called neutrophils, fever due to decreased neutrophil count, irregular heartbeat, rapid pumping of the heart's upper chambers, and difficulty breathing.

None of the participants died during the study.

What were the most common non-serious side effects?

Side effects other than the serious side effects are reported in this section.

Participants who had non-serious side effects:



The most common non-serious side effects, reported by at least 30% of participants in any group who took INCB050465 alone, are presented below.

The most common non-serious side effects experienced by participants who took INCB050465 alone:

	INCB050465 5 mg (1 participant)	INCB050465 10 mg (3 participants)	INCB050465 15 mg (3 participants)	INCB050465 20 mg (34 participants)	INCB050465 30 mg (27 participants)	INCB050465 45 mg (4 participants)
Allergic reaction to the treatment *(Drug hypersensitivity)*	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)
Bumpy red patches with white scales *(Psoriasis)*	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)
Cough *(Cough)*	**0%** (0 participants)	**0%** (0 participants)	**33%** (1 participant)	**3%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)
Diarrhea *(Diarrhea)*	**0%** (0 participants)	**33%** (1 participant)	**33%** (1 participant)	**27%** (9 participants)	**22%** (6 participants)	**25%** (1 participant)

	INCB050465 5 mg (1 participant)	INCB050465 10 mg (3 participants)	INCB050465 15 mg (3 participants)	INCB050465 20 mg (34 participants)	INCB050465 30 mg (27 participants)	INCB050465 45 mg (4 participants)
Difficulty breathing *(Dyspnoea)*	**0%** (0 participants)	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**4%** (1 participant)	**0%** (0 participants)
Feeling tired *(Fatigue)*	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**21%** (7 participants)	**11%** (3 participants)	**0%** (0 participants)
Hair loss *(Alopecia)*	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)
High level of a type of fat called triglycerides in the blood *(Hyper-triglyceridaemia)*	**0%** (0 participants)	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)
Increase in level of cholesterol in the blood *(Blood cholesterol increased)*	**0%** (0 participants)	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)
Muscle weakness *(Muscular weakness)*	**100%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)	**7%** (2 participants)	**0%** (0 participants)
Nausea *(Nausea)*	**100%** (1 participant)	**0%** (0 participants)	**33%** (1 participant)	**15%** (5 participants)	**15%** (4 participants)	**0%** (0 participants)
Stomach pain *(Abdominal discomfort)*	**0%** (0 participants)	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**0%** (0 participants)
Redness of the skin *(Dermatitis exfoliative)*	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**0%** (0 participants)	**4%** (1 participant)	**0%** (0 participants)
Vomiting *(Vomiting)*	**0%** (0 participants)	**0%** (0 participants)	**33%** (1 participant)	**0%** (0 participants)	**7%** (2 participants)	**0%** (0 participants)

In the participants given INCB050465 with itacitinib, 2 participants who took 30 mg INCB050465 and 300 mg itacitinib together reported a side effect of decreased appetite. In the 20 mg INCB050465 and 300 mg itacitinib group, 2 participants reported a side effect of cough.

In the participants given INCB050465 with R-ICE, 2 participants who took 15 mg INCB050465 and R-ICE experienced a side effect of decreased white blood cells called neutrophils, and 1 participant had sweating during the night (night sweats). In the 20 mg INCB050465 and R-ICE group, 1 participant reported a side effect of sweating during the night.

How many participants stopped the study drug because of side effects?

19% (14 out of 72) of participants given INCB050465 alone stopped the study drug early because of side effects related to the study drug. The most common side effects that led to participants stopping the study drug were diarrhea, inflammation in the large intestine, and skin rash.

9% (1 out of 11) of participants given INCB050465 with itacitinib stopped treatment early due to an increased level of calcium in the blood (hypercalcemia).

20% (1 out of 5) of participants given INCB050465 with R-ICE stopped the study drug early because of side effects. The most common side effects that led to participants stopping treatment with INCB050465 with R-ICE were decreased white blood cells called neutrophils, fever due to decreased neutrophil count, irregular heartbeat, rapid pumping of the heart's upper chambers, difficulty breathing, and excess fluid in the lungs (pulmonary edema).

8. How has this study helped patients and researchers?

This study helped researchers learn about the safety of INCB050465 and itacitinib in participants with B-cell malignancies.

The study was completed as planned.

You can find more information about this study by going to the website listed at the end of this summary.

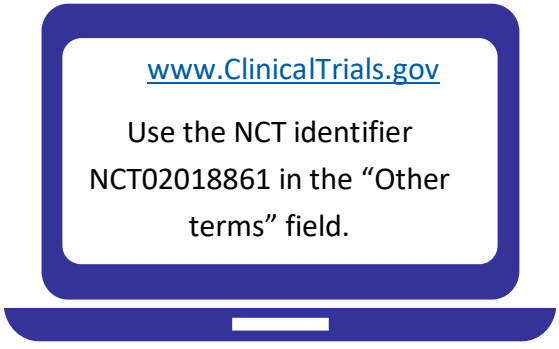
Results from this study may also be used to help design other studies with INCB050465.

9. Are there plans for further studies?

Additional clinical studies with INCB050465 are ongoing.

10. Where can I find more information about this study?

You can find more information about this study on the following website:



Please remember that the results on this website may be presented in a different way. If you were a study participant and have questions about the results of this study, please speak with the doctor or staff at your study site.

Full study title: A phase 1/2, open-label, dose-escalation, safety and tolerability study of INCB050465 and INCB039110 in subjects with previously treated B-cell malignancies
Protocol number: INCB50465-101
Sponsor: Incyte Corporation

Sponsor's phone numbers:
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