

Summary of Clinical Trial Results

A study of ipatasertib given with immunotherapy and chemotherapy in people with triple-negative breast cancer that had spread to other parts of the body

See the end of the summary for the full title of the study.

About this summary

This is a summary of the results of a clinical trial (called a 'study' in this document) – written for:

- people who took part in the study and
- members of the public.

This summary is based on information known at the time of writing.

The study started in February 2018 and finished in March 2022. This summary contains information about one group of people in the study (Cohort 1) and was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from those seen in other studies with the same medicine.

- **This means that you should not make decisions based on this one summary – always speak to your doctor before making any decisions about your treatment.**

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Glossary

- TNBC = triple-negative breast cancer.

Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about TNBC that had spread to other parts of the body and the medicine being studied – ‘ipatasertib’ – taken together with chemotherapy and immunotherapy.

Key information about this study

Why was this study done?

- This study was done to look at a combination of medicines in people with a type of breast cancer called TNBC. This summary contains information about one group of people in the study (Cohort 1) who had TNBC that had spread to other parts of the body.
- The medicine being studied was called ‘**ipatasertib**’ – taken together with an immunotherapy called ‘**atezolizumab**’ and one of two commonly used chemotherapies called ‘**paclitaxel**’ and ‘**nab-paclitaxel**’.
- This cohort included 114 people in five countries.

What were the results?

- The main findings were:
 - 54% of people (61 out of 114) had their tumour shrink or disappear
 - The time between people’s tumours shrinking or disappearing and the cancer starting to grow or spread again was 7.4 months, on average.

How many people had serious side effects due to study medicines?

- Around 39% of people (44 out of 114 people) taking ipatasertib, atezolizumab and paclitaxel or nab-paclitaxel had serious side effects.

1. General information about this study

Why was this study done?

Doctors now use information about breast cancer cells to sort breast cancers into different types to help them decide which treatments will work best. Some cancer cells have a higher-than-normal number of receptors for the hormones oestrogen or progesterone ('hormone receptor-positive breast cancer') or a higher-than-normal amount of human epidermal growth factor receptor 2 (HER2; 'HER2-positive breast cancer'). In hormone receptor-positive breast cancer and HER2-positive breast cancer, cancer cells will grow and make copies of themselves more often. People in this study had a type of breast cancer called TNBC, which means that their cancer cells do not have a higher-than-normal number of receptors for the hormones oestrogen or progesterone, or a higher-than-normal number of HER2. Therefore, commonly used treatments for hormone receptor-positive breast cancer or HER2-positive breast cancer do not work in TNBC.

This means that other medicines are needed to be able to treat TNBC – by stopping the growth of the tumour or shrinking the tumour – and to help people live longer. If the tumour stops growing or shrinks, people may also be able to manage their cancer better.

Chemotherapy is a commonly used type of treatment for breast cancer that kills cancer cells and stops the cancer from growing.

Everyone has a protein called 'AKT' in their body. In some types of breast cancer, changes (called 'mutations') in AKT, or other proteins of this family, make it work differently, and help cancer cells grow. 'Ipatasertib' is a type of cancer medicine called a 'growth blocker' and it works by blocking AKT.

This study also used an immunotherapy called 'atezolizumab'. Atezolizumab works by attaching to the PD-L1 protein on cancer cells and blocking it. This stops the cancer cells from using the PD-L1 protein to avoid being destroyed by the immune system.

All the people who took part in this study had TNBC. Most people in the study were in Cohort 1 – these people all had TNBC that had spread to other parts of the body (called 'metastatic' TNBC) and had not had chemotherapy to treat their metastatic cancer.

What were the study medicines?

The medicine being studied is '**ipatasertib**':

- You say this as 'eye – pat – a – sert – ib'.
- Ipatasertib is a cancer medicine called a 'growth blocker'. It works by blocking a protein called 'AKT' that helps cancer cells grow.

The existing **immunotherapy** medicine used in this study was ‘atezolizumab’:

- You say this as ‘a – teh – zo – liz – oo – mab’.
- Atezolizumab works by stopping cancer cells from blocking cells in the immune system, meaning that the immune system is able to attack the cancer cells.

The **chemotherapy** medicines used in this study were:

- ‘Paclitaxel’ – you say this as ‘pac – lee – tax – el’.
- ‘Nab-paclitaxel’ – you say this as ‘nab – pac – lee – tax – el’.
- These medicines work by stopping cancer cells from dividing into new cells, so they block the growth of the tumour.

What did researchers want to find out?

- Researchers did this study to see how well ipatasertib in combination with atezolizumab and chemotherapy worked (see section 4, “What were the results of the study?”).
- They also wanted to find out how safe the medicines were – by checking how many people had side effects and seeing how serious they were, when taking each of the medicines during this study (see section 5, “What were the side effects?”).

The main questions that researchers wanted to answer were:

1. How many people had their tumour shrink or disappear?
2. How much time was there between people’s tumours shrinking or disappearing and the cancer starting to grow or spread again?

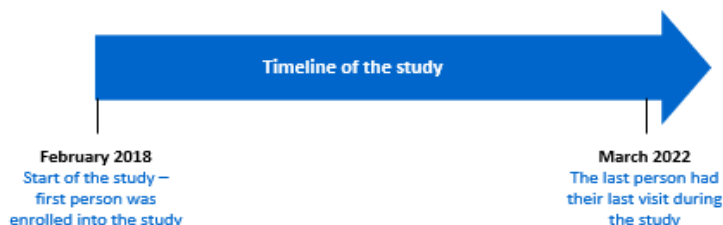
What kind of study was this?

This study was a ‘Phase 1’ study, which means that this was one of the first studies for ipatasertib. A small number of people with metastatic TNBC took ipatasertib, and the researchers did medical tests on the people who took part to find out more about ipatasertib.

This was an ‘open-label’ study. This means that both the people taking part in the study and the study doctors knew which study medicines people were taking.

When and where did the study take place?

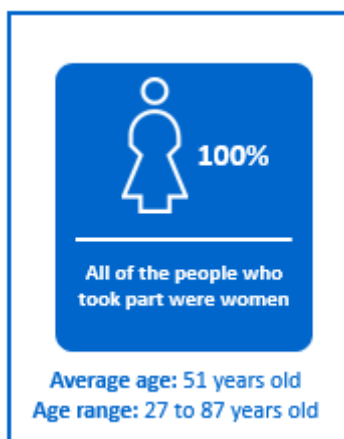
The study started in February 2018 and finished in March 2022. This summary was written after the study had ended.



The study took place at 17 study centres – across five countries in North America, Europe and Asia Pacific. The countries were: Australia, France, Spain, the United Kingdom and the United States.

2. Who took part in this study?

In Cohort 1, 114 people with metastatic TNBC took part. Here is more information about the people who took part in Cohort 1.



People could take part in this study if they had:

- Triple-negative breast cancer that had spread from where it started to nearby cells or to other parts of the body
- A life expectancy of at least 6 months

People could NOT take part in this study if they had:

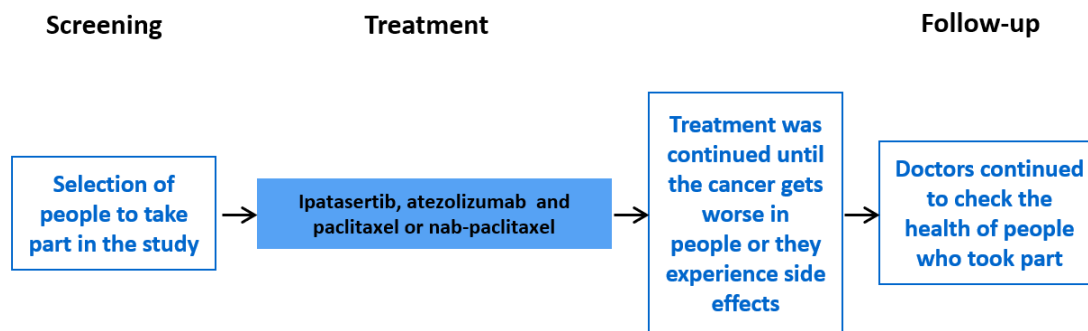
- Taken a medicine that works in a similar way to ipatasertib
- Other types of cancer in the last 5 years before the start of the study
- Certain health problems, including a history of liver disease, inflammatory bowel disease, or heart problems

3. What happened during the study?

Ipatasertib was given as a tablet on Days 1–21 of a 4-week cycle and atezolizumab and chemotherapy (paclitaxel or nab-paclitaxel) were given through a needle into a vein on certain days in the treatment cycle.

- People were given the study medicines until their cancer got worse or they experienced side effects.

When the study finished, the people who took part were asked to go back to their study centre for more visits – to check their overall health. Look below to see more information about what happened in the study.

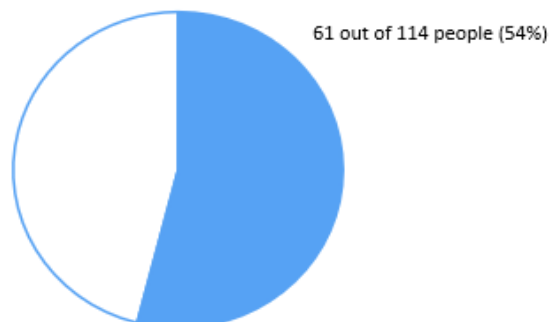


4. What were the results of the study?

Question 1: How many people had their tumour shrink or disappear?

Researchers looked at the number of people who had their tumour shrink or disappear in response to the study medicines they were taking.

How many people had their tumour shrink or disappear?



Question 2: How much time was there between people's tumours shrinking or disappearing and the cancer starting to grow or spread again?

In this study, the length of time between people's tumours shrinking or disappearing and the cancer starting to grow or spread again was 7.4 months, on average (in some people it took longer to get worse and in others it got worse sooner than 7.4 months).

This section only shows the key results from this study. You can find information about all other results on the websites at the end of this summary (see section 8).

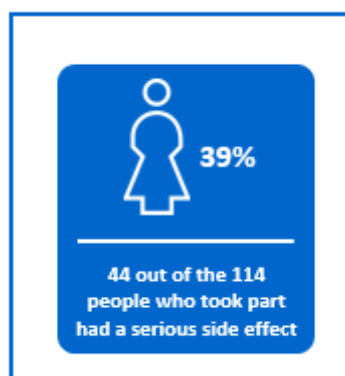
5. What were the side effects?

Side effects are medical problems (such as feeling dizzy) that happen during the study.

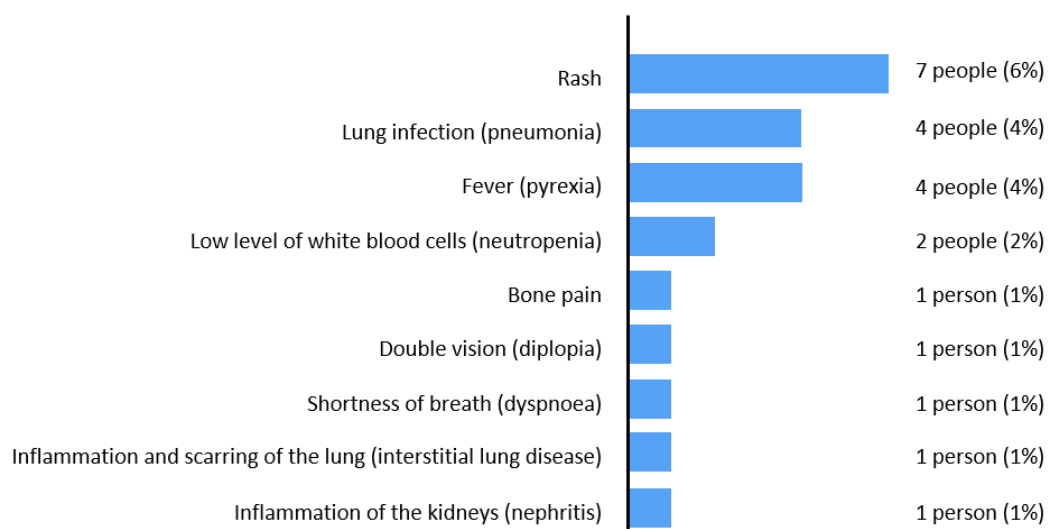
- Side effects may be mild to very serious and can be different from person to person.
- Not all of the people in this study had all of the side effects.
- It is important to be aware that the side effects reported here are from this single study and may be different from those seen in other studies, or those that appear on the medicine leaflets.
- Serious and common side effects are listed in the following sections.

Serious side effects

A side effect is considered 'serious' if it is life-threatening, needs hospital care, or causes lasting problems. The number of people who had serious side effects is shown below.



The most common serious side effects are shown in the following image. Some people had more than one side effect – this means that they are included in more than one row in the image.



Two out of 114 people (2%) in the study died due to side effects.

During the study, some people stopped taking their medicine because of side effects:

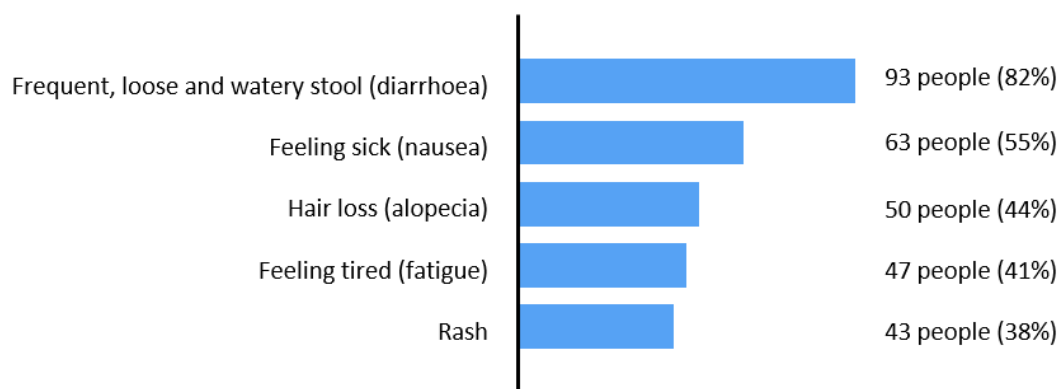
- 7 out of 114 people (6%) stopped taking ipatasertib
- 5 out of 114 people (4%) stopped taking atezolizumab
- 38 out of 114 people (33%) stopped taking paclitaxel or nab-paclitaxel.

Most common side effects

The proportion of people who had side effects is shown below.



The five most common side effects are shown in the following image. Some people had more than one side effect – this means that they are included in more than one row in the image.



Other side effects

You can find information about other side effects (not shown in the sections above) on the websites listed at the end of this summary – see section 8.

6. How has this study helped research?

The information in this summary is from the Cohort 1 study of 114 people with metastatic TNBC. These results helped researchers learn more about this type of breast cancer, how well ipatasertib plus chemotherapy and immunotherapy works and how safe it is, when used to treat metastatic TNBC.

Researchers wanted to learn how much time there was between people’s tumours shrinking or disappearing and the cancer starting to grow or spread again in people who were given ipatasertib plus paclitaxel and atezolizumab for TNBC that had spread to nearby cells or

other parts of the body. In this cohort, 54% of people (61 out of 114) had their tumour shrink or disappear and the time between people's tumours shrinking or disappearing and the cancer starting to grow or spread again was 7.4 months, on average.

The people in this study did not have any new side effects that had not been seen before in people who took ipatasertib, paclitaxel or atezolizumab in other studies.

7. Are there plans for other studies?

Other studies looking at the safety and effects of ipatasertib are happening, and are looking at the use of ipatasertib in different clinical settings, for example:

- When given together with other treatments
- In other types of breast cancer, including 'hormone receptor-positive, HER2-negative' breast cancer
- In other types of cancer

8. Where can I find more information?

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

- <https://clinicaltrials.gov/study/NCT03800836>
- <https://forpatients.roche.com/en/trials/cancer/bc/a-study-to-evaluate-the-safety-and-efficacy-of-ipataser-98538.html>

If you would like to find out more about the results of this study, the full title of the relevant scientific paper is: "First-Line Ipatasertib, Atezolizumab, and Taxane Triplet for Metastatic Triple-Negative Breast Cancer: Clinical and Biomarker Results". The authors of the scientific paper are: Peter Schmid, Nicholas Turner, Carlos H. Barrios, Steven Jay Isakoff, Sung-Bae Kim and others. The paper is published in the journal 'Clinical Cancer Research', volume number 30, on pages 767–778. <https://doi.org/10.1158/1078-0432.CCR-23-2084>

Who can I contact if I have questions about this study?

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form – <https://forpatients.roche.com/en/trials/cancer/bc/a-study-to-evaluate-the-safety-and-efficacy-of-ipataser-98538.html>
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

Who organised and paid for this study?

This study was organised and paid for by F. Hoffmann-La Roche Ltd who have their headquarters in Basel, Switzerland.

Full title of the study and other identifying information

The full title of this study is: “A Study to Evaluate the Safety and Efficacy of Ipatasertib in Combination With Atezolizumab and Paclitaxel or Nab-Paclitaxel in Participants With Locally Advanced or Metastatic Triple-Negative Breast Cancer”.

- The protocol number for this study is: CO40151.
- The ClinicalTrials.gov identifier for this study is: NCT03800836.
- The EudraCT number for this study is: 2017-001957-15.