

## Summary of Clinical Trial Results

### IPATunity130 (Cohort C): A study of ipatasertib given with chemotherapy and immunotherapy, in people with a type of breast cancer called 'locally advanced or metastatic triple-negative breast cancer' whose tumours do not have a particular gene change

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 IPATunity130 study looked at people with 2 different types of breast cancer. This summary has results from the part of the study which looked at people with a type of cancer called triple-negative breast cancer (TNBC).

This part of the study (called 'Cohort C') started in March 2019 and ended in January 2023. This summary includes the results that were collected and analysed in October 2021. At the time of writing this summary, the study was closed.

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 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.**

#### Thank you to the people who participated in this part of the study

The people who took part have helped researchers to answer important questions about triple-negative breast cancer (TNBC) that had spread to other parts of the body and the medicine being studied – 'ipatasertib' – taken together with chemotherapy and immunotherapy.

#### Contents of the summary

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#### Glossary

- TNBC = triple-negative breast cancer.

## Key information about this study (IPATunity130 Cohort C)

### Why was this study done?

- This study was done to look at how a combination of medicines worked in people with a type of breast cancer called TNBC.
- The medicine being studied was called '**ipatasertib**' – taken together with a commonly used chemotherapy called '**paclitaxel**' and an immunotherapy called '**atezolizumab**'.
- This study included 102 people in 11 countries.

### What were the results?

- The main findings were that:
  - For the people in this study, their cancer did not get worse for 7.1 months on average after starting the treatment.

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

- About 19% of people (19 out of 102 people) in this study had serious side effects.
- At the time of writing this summary, the study was closed.

## 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. People in this study had a type of breast cancer called TNBC, which means that their cancer cells do not have receptors for the hormone oestrogen, the hormone progesterone or the human epidermal growth factor receptor 2 (HER2) protein. Although other types of breast cancers can be treated with therapies that target these receptors, these therapies do not work in TNBC.

Chemotherapy is another type of treatment for breast cancer that kills cancer cells and stops the cancer from growing. However, chemotherapy may work for only a short time and then the cancer may get worse again. Also, in some people, the cancer still grows even with any type of treatment.

This means that new medicines are needed to be able to treat the cancer more effectively – 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 be able to manage their cancer better.

A medicine called 'ipatasertib' is a type of cancer medicine called a 'growth blocker'. It works by blocking a protein called 'AKT', which is part of a family of proteins that help cancer cells grow. Everyone has 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. These changes can help the cancer grow. One study, in TNBC, showed that these changes may help ipatasertib plus chemotherapy to work better.

This part of the 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 that had spread to other parts of the body. None of the people who took part in this part of the study had changes in AKT, or other members of this protein family, and none of the people had changes in the genes *PIK3CA* and *PTEN*. To confirm that people in this study did not have these changes, a piece of the tumour was tested.

In this part of the study, researchers wanted to see how well the combination of ipatasertib with chemotherapy (paclitaxel) and immunotherapy (atezolizumab) worked in people with this type of cancer. They wanted to see if this combination would slow down how long it took for the cancer to get worse (in other words, spread, spread further, or grew larger)– and help these people to live longer. For people in this study, treatment with chemotherapy (paclitaxel) was their first treatment since being diagnosed with this type of breast cancer.

## What were the study medicines?

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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 **chemotherapy** medicine used in this study was **'paclitaxel'**:

- You say this as 'pac – lee – tax – el'.
- Paclitaxel works by stopping cancer cells from dividing into new cells, so it blocks the growth of the tumour.

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.

## What did researchers want to find out?

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

**The main question that researchers wanted to answer was:**

In this part of the study, how much time was there between the start of treatment and the cancer getting worse?

## What kind of study was this?

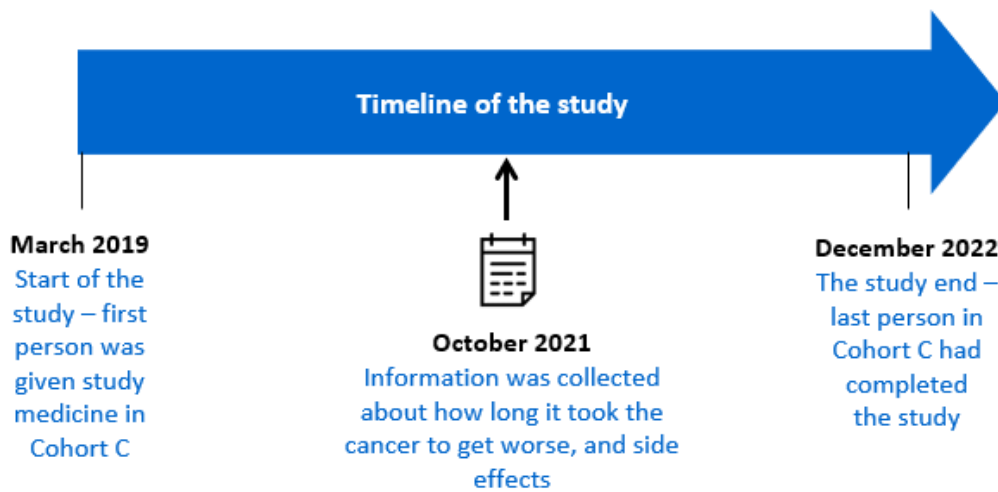
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This study was a **'Phase 3'** study. This means that ipatasertib had been tested in a smaller number of people with advanced breast cancer before this study. In this study, a larger number of people with TNBC that had spread to other parts of the body received ipatasertib plus paclitaxel and atezolizumab. This was to find out how much time there was between the start of treatment and the cancer getting worse when adding ipatasertib to paclitaxel and atezolizumab.

## When and where did the study take place?

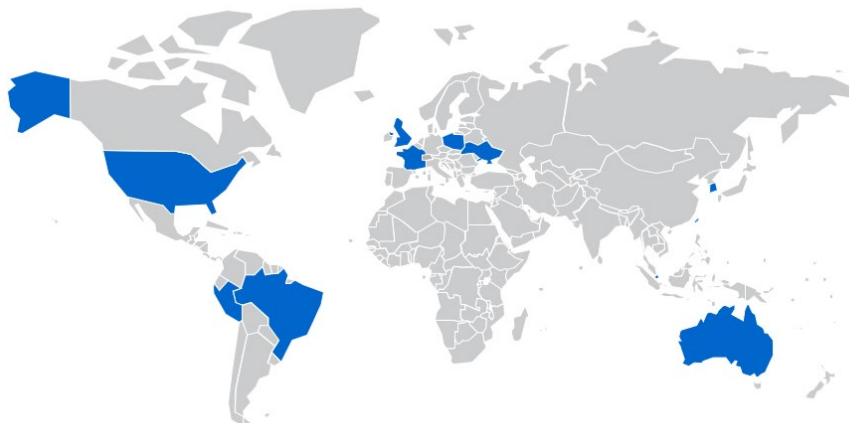
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The study started in March 2019 and ended in December 2022. This summary includes the results up until October 2021. At the time of writing this summary, the study had ended.



The symbol on the timeline (📅) shows when the information shown in this summary was analysed (October 2021 – 31 months after the study had started).

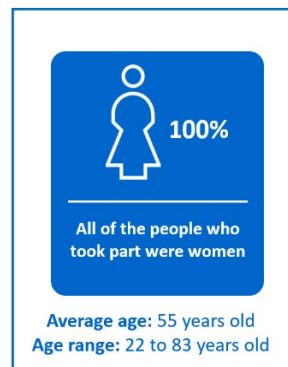
The study took place at 45 study centres – across 11 countries. This map shows the countries where this study took place.



- Australia
- Brazil
- France
- Republic of Korea
- Peru
- Poland
- Singapore
- Taiwan
- Ukraine
- United Kingdom
- United States

## 2. Who took part in this study?

In this study, 102 people with TNBC without certain gene changes in their tumour tissue took part. Here is more information about the people who took part in the study.



### People could take part in this study if they:

- Had triple-negative breast cancer
- Had breast cancer that had spread from where it started to nearby cells or to other parts of the body
- Had breast cancer without changes (mutations) in the genes called *PIK3CA*, *AKT* and *PTEN*
- Allowed doctors to take samples of their tumour(s)

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

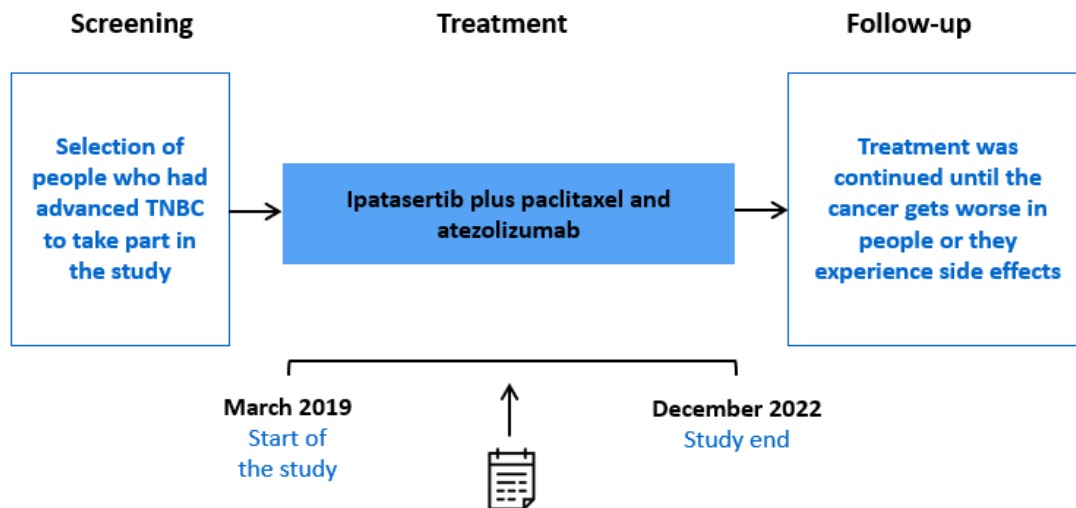
- Previously had chemotherapy for breast cancer that had spread to other parts of the body
- Taken a medicine that works in a similar way to ipatasertib
- Cancer that had spread to the brain or spinal cord
- Other types of cancer in the last 5 years before the start of the study
- Certain health problems, including a history of liver disease, inflammatory bowel disease, or heart problems

## 3. What happened during the study?

All people in this study took ipatasertib plus paclitaxel and atezolizumab. This table shows the number of people who took the study treatment and how often the medicines were taken.

<b>Number of people in this part of the study</b>	102
<b>Number of people who actually took the medicines</b>	102
<b>How the medicines were taken</b>	Ipatasertib: tablet taken by mouth Paclitaxel: given through a needle into a vein Atezolizumab: given through a needle into a vein
<b>When the medicines were taken in each 28-day treatment cycle</b>	Ipatasertib: daily (Days 1–21) Paclitaxel: Days 1, 8 and 15 Atezolizumab: Days 1 and 15

The study is closed. Look below to see more information about what happened in the study and the different study periods.



The symbol on the timeline (📅) shows when the information shown in this summary was analysed (October 2021–31 months after the study had started).

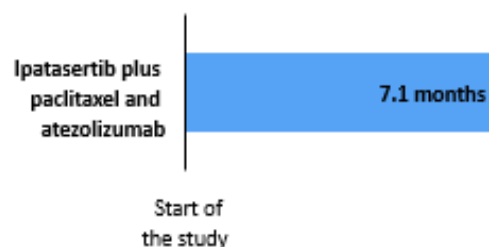
#### 4. What were the results of the study?

**Question 1:** In this study, how much time was there between the start of treatment and the cancer getting worse?

After starting the medicine, people in the study were monitored for about 16.7 months on average.

Researchers looked at how much time there was before the cancer became worse (in other words, spread, spread further, or grew larger).

In this study the cancer got worse after about 7.1 months, on average (in some people it took longer to get worse and in others it got worse sooner than 7.1 months).



This section shows only 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 may happen during the study.

- The side effects described in this summary are included because the study doctor believes they were related to the medicines in the study.
- Not all of the people in this study had all of the side effects.
- Side effects may be mild to severe.
- Side effects can be different from person to person.
- It is important to be aware that the side effects reported here are from this one study. Therefore, the side effects shown here may be different from those seen in other studies, or those that appear in the medicine leaflets.
- Serious and common side effects are listed in the following sections.

### Serious side effects

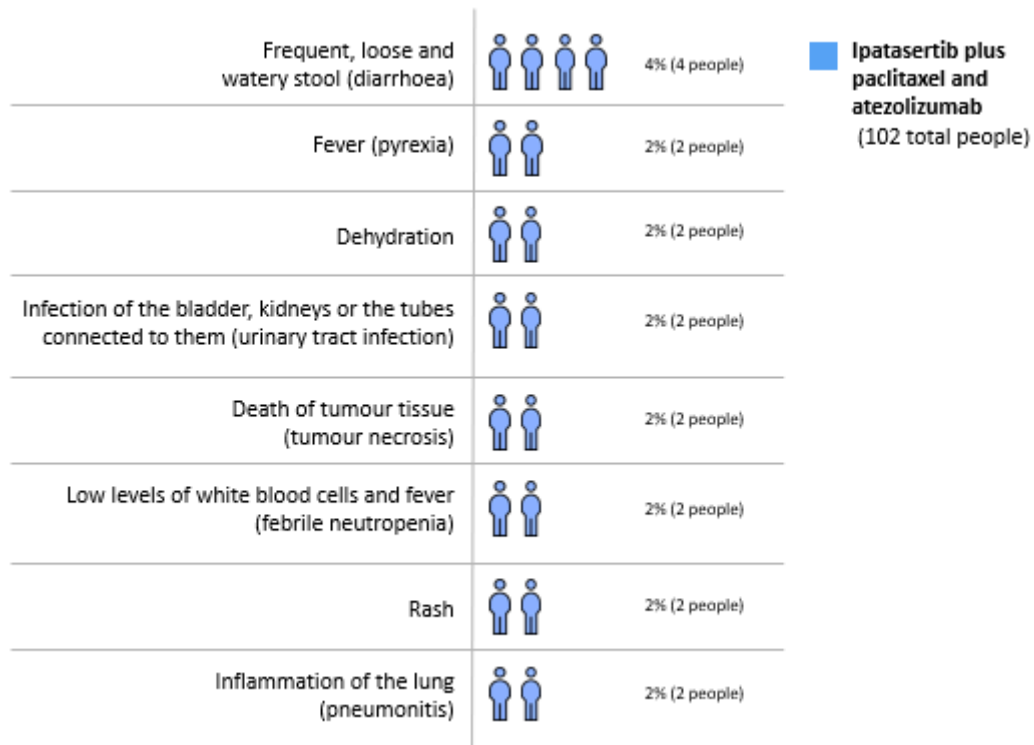
A side effect is considered 'serious' if it is life-threatening, needs hospital care or causes lasting problems.

During this study, 19 in every 100 people (19%) had at least one serious side effect that was due to the medicines being taken (ipatasertib, paclitaxel and atezolizumab). The number of people who had serious side effects in the study due to the medicines taken is shown below.





This picture shows the serious side effects due to the study medicines that happened in 2 or more people in the study – these are the most common serious side effects.

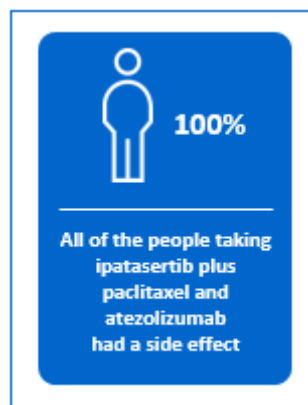


Some people in the study died due to side effects which the study doctor believed were due to one of the study medicines:

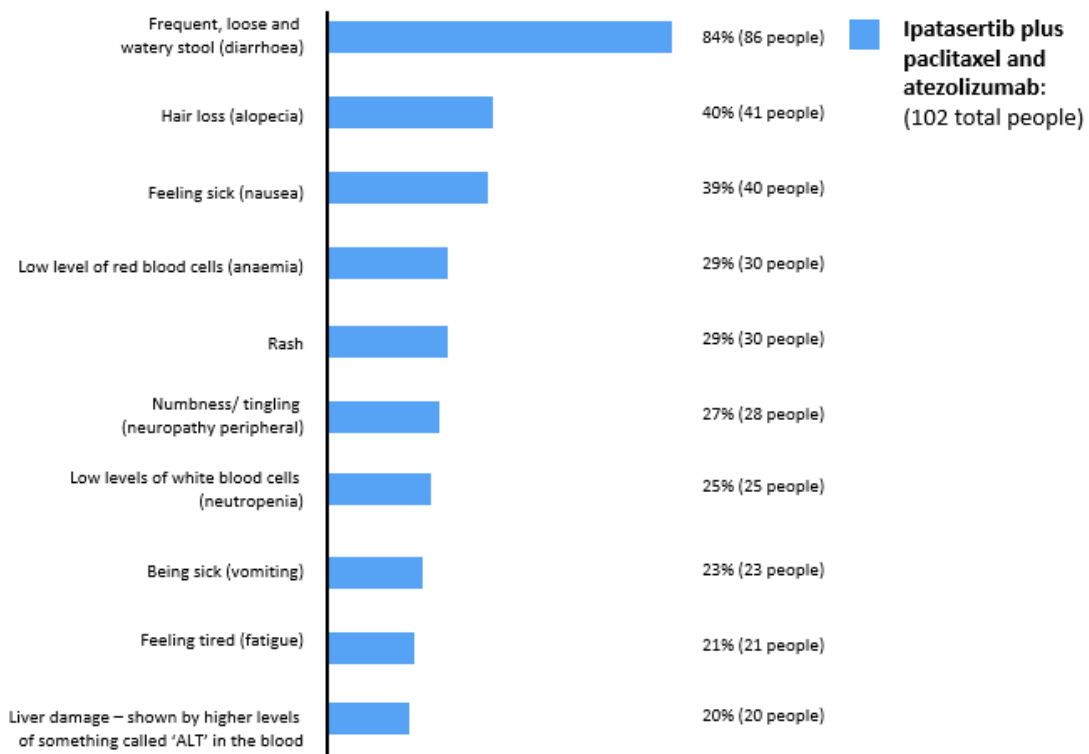
- 1 out of 102 people (1%) died.

### Most common side effects

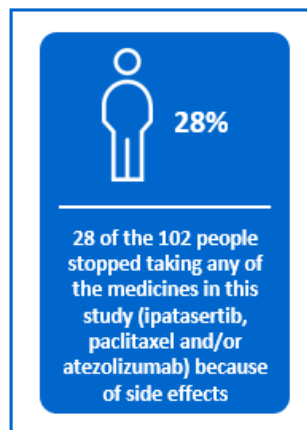
Everyone in this part of the study (100%) had at least one side effect (serious or not) that was due to the medicines being taken (ipatasertib, paclitaxel and atezolizumab). The number of people in each group who had side effects due to the medicines taken is shown below.



This graph shows the most common side effects due to the study medicines – these are the 10 most common side effects. Some people had more than one side effect.



During the study, some people decided to stop taking any medicine because of side effects due to the study medicines. This is shown below.



### 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 one study of 102 people with TNBC that had spread to other parts of the body. These results helped researchers learn more about how well ipatasertib plus paclitaxel and atezolizumab works to treat this type of breast cancer and how safe it is.

Ipatasertib works by blocking a protein called 'AKT', which works together with other proteins, such as PI3K and PTEN, to help cancer cells grow. Everyone has PI3K, AKT and PTEN in their body. In some types of breast cancer, changes (called 'mutations') in the *PI3KCA*, *AKT* and *PTEN* genes make the PI3K, AKT and PTEN proteins work differently. These changes can help the cancer grow. Researchers wanted to learn how much time there was between the start of treatment and the cancer getting worse in people who were given ipatasertib plus paclitaxel and atezolizumab for TNBC that had spread to nearby cells or other parts of the body.

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. These studies are looking at the use of ipatasertib in different situations, for example:

- Together with other treatments
- In other types of breast cancer, including 'hormone receptor-positive, HER2-negative'
- 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/NCT03337724>
- <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-001548-36>
- <https://forpatients.roche.com/en/trials/cancer/bc/a-study-of-ipatasertib-in-combination-with-paclitaxel-as-a-treat.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?

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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-of-ipatasertib-in-combination-with-paclitaxel-as-a-treat.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?

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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

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The full title of this study is: “Study of Ipatasertib in Combination With Paclitaxel as a Treatment for Participants With PIK3CA/AKT1/PTEN-Altered, Locally Advanced or Metastatic, Triple-Negative Breast Cancer or Hormone Receptor-Positive, HER2-Negative Breast Cancer (IPATunity130)”.

The study is known as ‘IPATunity130’.

- The protocol number for this study is: CO40016.
- The ClinicalTrials.gov identifier for this study is: NCT03337724.
- The EudraCT number for this study is: 2017-001548-36.