

Summary of Clinical Trial Results

MORPHEUS: results from 2 studies of people with hormone receptor-positive breast cancer (HR+ BC) and triple-negative breast cancer (TNBC) who were treated with different combinations of medicines, including atezolizumab, ipatasertib, and fulvestrant.

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

About This Summary

This is a summary of some of the results from 2 large clinical trials (called 'studies' in this document) called the MORPHEUS-Hormone Receptor (HR)-Positive Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Breast Cancer (**MORPHEUS-HR+ BC**) Study and the MORPHEUS-Triple Negative Breast Cancer (**MORPHEUS-TNBC**) Study. The results included in this summary are from 6 smaller groups (called 'subgroups' in this document) of people who were part of the larger **MORPHEUS-HR+ BC and MORPHEUS-TNBC Studies**.

This summary has been written for people who are taking part in these studies and members of the public.

This summary is based on information known at the time that this summary was written in March 2022. The **MORPHEUS-HR+ BC** and **MORPHEUS-TNBC Studies** are ongoing.

Key Questions

1. What has happened since these subgroup studies ended?
2. Why was this research needed?
3. General information about these subgroups with the 2 studies
4. Who took part in these subgroups?
5. What medicines were given to people in these subgroups?
6. What were the results for these subgroups?
7. What side effects did people in these subgroups experience?
8. What do these results mean for people and researchers?
9. Are there plans to add other people to these subgroups or to do other studies with these medicines?
10. Where can I find more information?

Thank you to our study participants!

Clinical study participants belong to a large community of people around the world who make it possible for researchers to answer important health questions and discover new medicines. Thank you!

About the studies

This summary includes the results from 2 MORPHEUS studies so far.

As the company that organized and funded these studies, Roche would like to provide everyone with the results. It is important to remember that 1 study can't tell us everything about the possible side effects of a drug and how well it may work. It takes a lot of people in many studies to learn as much as we can about atezolizumab when used in combination with other medicines. The results of these studies may be different from the results of other studies of these medicines.

This means that you should not make medical decisions based on this 1 summary. Always talk with your doctor before making any decisions about your treatment.

MORPHEUS-HR+ BC Study

The first study (**MORPHEUS-HR+ BC Study**) included people with HR+ breast cancer who were split into 4 subgroups. The subgroups were treated with different combination of medicines:

MORPHEUS HR+ BC			
Ipatasertib Group Ipatasertib + atezolizumab	Fulvestrant Group Fulvestrant + atezolizumab	Ipatasertib Plus Fulvestrant Group Ipatasertib + fulvestrant + atezolizumab	Control Group Fulvestrant
Started: Dec 2017 Ended: Oct 2021	Started: Dec 2017 Ongoing	Started: Dec 17 Ongoing	Started: Dec 2017 Ongoing

This study is still happening — study doctors are still collecting information. The information included in this summary was collected between December 2017 and September 2021. The 62 people in this study helped researchers find out how safe atezolizumab is and how well it works for people with HR+ breast cancer when used in combination with **ipatasertib**, **fulvestrant**, or **ipatasertib plus fulvestrant** compared with **fulvestrant** alone (control group).

MORPHEUS-TNBC Study

The second study (**MORPHEUS-TNBC Study**) included people with TNBC who were split into 2 subgroups that were treated with different medicines:

MORPHEUS TNBC	
Ipatasertib Group Ipatasertib + atezolizumab	Control Group Capecitabine
Started: Mar 2018 Ended: Mar 2021	Started: Mar 2018 Ended: Mar 2021

The 53 people in this study helped researchers find out how safe atezolizumab is and how well it works when used in combination with **ipatasertib** compared with **capecitabine** (control group) in people with TNBC.

1. What has happened since these subgroup studies ended

MORPHEUS-HR+ BC Study

The larger **MORPHEUS-HR+ BC Study** is still happening and people in the subgroups reported in this summary are still being monitored.

MORPHEUS-TNBC Study

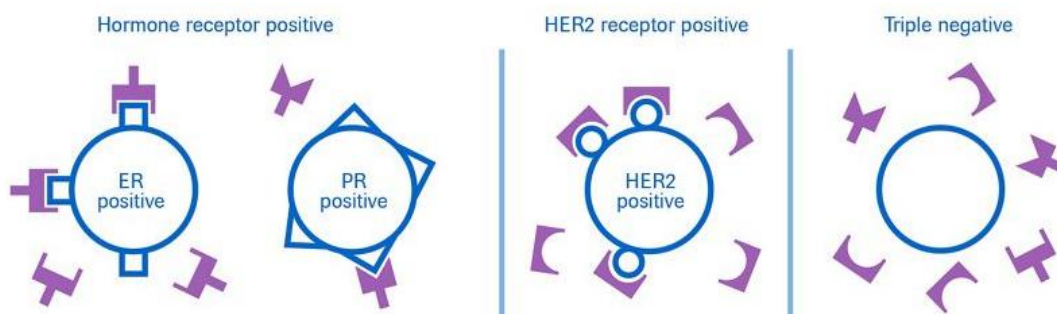
The larger **MORPHEUS-TNBC Study** is ongoing. The 2 subgroups included here were studied for 36 months (3 years) and for these 2 subgroups the study has ended.

2. Why was this research needed?

There are different types of breast cancer based on which types of proteins called receptors can be found on the tumour. Knowing the type of cancer can help doctors determine which treatments are most likely to work. People with breast cancer take a combination of different medicines to treat their cancer. Current treatments for many types of breast cancer include chemotherapy, which kills cancer cells and stops the cancer from growing. People who took part in the **MORPHEUS-HR+ BC Study** had HR+ breast cancer. This means that their cancer cells have receptors for hormones called oestrogen and progesterone. Several current treatments work by targeting the hormone receptors. However, new treatment combinations are needed for people with HR+ breast cancer that does not respond or stops responding to therapy.

People who took part in the second study (**MORPHEUS-TNBC Study**) had TNBC. This means their cancer cells do not have receptors for (1) the hormone oestrogen, (2) the hormone progesterone, or (3) a protein called HER2. Therapies that target these receptors can be used to treat other types of breast cancer, but they do not work in people with TNBC. When this study started, there were limited treatment options for people with TNBC, so there is a need to find new treatments.

Types of breast cancer



Breast cancer cells (large blue circles) can have different receptors (small blue squares, blue triangles or small blue circles) on the surface that receive signals (purple) to tell the cells to grow. If the breast cancer is 'triple negative', it doesn't have any of the common receptors, which makes

the cancer harder to treat. ER = oestrogen receptor; HER2 = human epidermal growth factor receptor 2; PR = progesterone receptor.

Current medicines may only work for a short time. In some people, the cancer still grows even with treatment. One newer type of medicine that has helped people with cancer live longer is cancer 'immunotherapy,' which helps peoples' own immune systems find and kill cancer. Normally, cancer stops the immune system from attacking it, which means the tumour can keep growing. Cancer immunotherapies, like atezolizumab, help the immune system attack the cancer. Researchers think that cancer immunotherapies might work better to shrink tumours if they are used in combination with other medicines.

What did the researchers want to find out?

Researchers wanted to find out if treatment with atezolizumab in combination with other medicines could help people with HR+ breast cancer or TNBC live longer or lengthen the amount of time before their cancer got worse, compared with:

- **Fulvestrant** (a current treatment for people with HR+ breast cancer)
- **Capecitabine** (a current treatment for people with TNBC)

The other medicine given in combination with atezolizumab is called ipatasertib (**see section 3**).

Researchers also wanted to find out how safe these combinations of medicines are. They did this by seeing how many people had side effects and seeing how severe these side effects were.

The results for these subgroups of people within the 2 studies helped answer important questions:

- How many people had smaller or no tumours after taking their medicine compared with the Control Group?
- How long did it take for people's cancer to get worse compared with the Control Group?
- How long did people live after taking their medicine compared with the Control Group?
- How many people had side effects, and how severe were these side effects?

3. General information about these subgroups within the 2 studies

What medicines were used to treat people in these subgroups?

MORPHEUS-HR+ BC Study

This study is made up of many subgroups. Only 4 of these subgroups are discussed here. Each subgroup received different medicines:

- **Ipatasertib Group:** People were treated with **atezolizumab plus ipatasertib**
- **Fulvestrant Group:** People were treated with **atezolizumab plus fulvestrant**
- **Ipatasertib Plus Fulvestrant Group:** People were treated with **atezolizumab plus ipatasertib plus fulvestrant**
- **Control Group:** People were treated with **fulvestrant alone**

The **MORPHEUS-HR+ BC Study** also includes people at different stages of their treatments. For example, people getting their first treatment are receiving 'first-line' treatment. Treatments are called 'second-line' when they are given after people received 1 treatment and the cancer got worse. Treatments are called 'third-line' when they are given after people received 2

different types of treatments and their cancer still got worse. In the **MORPHEUS-HR+ BC Study**, people received second-line or third-line treatment.

MORPHEUS-TNBC Study

This study is made up of many subgroups. Only 2 of these subgroups are discussed here. Each subgroup received different medicines:

- **Ipatasertib Group:** People were treated with **atezolizumab plus ipatasertib**
- **Control Group:** People were treated with **capecitabine**

In the **MORPHEUS-TNBC Study**, people received second-line treatment.

How do the medicines that were used to treat people in these subgroups work?

Some people in these subgroups from the **MORPHEUS-HR+ BC** and **MORPHEUS-TNBC Studies** were treated with a medicine called ‘atezolizumab’ (known by its brand name, TECENTRIQ®) taken together with additional medicines.

- **Atezolizumab** (you say this as ‘a – teh – zo – liz – oo – mab’)
 - This medicine is a type of immunotherapy.
 - The body’s immune system fights diseases like cancer. But cancer cells can block (stop) the immune system from attacking the cancer. Atezolizumab releases this blockage – meaning that the immune system again becomes able to fight the cancer cells.
 - When people take atezolizumab, their tumour (cancer) may get smaller.

Some people in these subgroups from the **MORPHEUS-HR+ BC** and **MORPHEUS-TNBC Studies** were treated with atezolizumab taken together with the medicine called ‘ipatasertib’.

- **Ipatasertib** (you say this as ‘eye – pat – a – sert – ib’)
 - Ipatasertib is a cancer drug called a ‘growth blocker’. It works by blocking a protein called ‘Akt’ that helps cancers grow.

Some people in the subgroups from the **MORPHEUS-HR+ BC Study** were treated with a medicine called ‘fulvestrant’ (known known by its brand name, Faslodex®) alone or in combination with other medicines.

- **Fulvestrant** (you say this as ‘ful – vuh – strant’)
 - This medicine is a type of hormonal therapy.
 - This medicine blocks the oestrogen receptors that may help breast cancer grow. This means the medicine can slow or stop the growth of breast cancer cells that need oestrogen to grow.

Some people in the **MORPHEUS-TNBC Study** were treated with a medicine called ‘capecitabine’ (known by its brand name, Xeloda®).

- **Capecitabine** (you say this as ‘ka – puh – sai – tuh – been’)
 - This medicine is a type of chemotherapy.
 - This medicine works by slowing or stopping the growth of cancer cells.

What kind of studies were these?

These subgroups are part of 2 larger studies called the **MORPHEUS-HR+ BC Study** and the **MORPHEUS-TNBC Study**. The MORPHEUS platform includes ‘Phase 1b/2’ studies (also known as early research studies) that look at how well a new combination of cancer medicines works and how safe the medicines are. Each subgroup contained a small number of people who took 1 of 3 different combinations of new medicines or an existing medicine (control). Researchers monitored these people to find out if taking a combination of medicines had any effect on treating their cancer.

In both studies, most people were ‘randomised,’ meaning that they were randomly put into different study subgroups by a computer (by chance, like rolling dice). The subgroups received different combinations of medicines.

Randomly putting people into these groups makes it more likely that the characteristics of the people in both groups (for example, age, race, how sick they are) will be similar at the start of the study. This makes it easier to compare the results.

This part of the study used an ‘open label’ design, which means that both the study researchers and the people in this subgroup knew which medicines people were taking. Apart from the different medicines being tested in the groups, all other aspects of care were the same between the 4 subgroups in the **MORPHEUS-HR+ BC Study** and 2 subgroups in **the MORPHEUS-TNBC Study**.

When and where did the study of these subgroups take place?

MORPHEUS-HR+ BC Study

For the **MORPHEUS-HR+ BC Study**, this summary includes results between December 2017 and June 2021. The study took place at 27 study centres in the Republic of Korea, Israel and the United States.

MORPHEUS-TNBC Study

For the **MORPHEUS-TNBC Study**, this summary includes results between March 2018 and March 2021. The study took place at 17 study centres in Australia, France, Germany, Israel, the Republic of Korea, Spain, the United Kingdom, and the United States.

4. Who took part in these subgroups?

MORPHEUS-HR+ BC Study

- 62 women with HR+ breast cancer took part.
- Most people (79%) were younger than 65 years.
- All people except for 1 had cancer that had spread to other parts of the body, and they had already been given treatments that had not worked or had stopped working.
- One person had cancer that had spread to nearby cells.

MORPHEUS-TNBC Study

- 53 women with TNBC took part.
- Most (87%) people were younger than 65 years.
- Five people had cancer that had spread to nearby cells.
- 48 people had cancer that had spread to other parts of the body.
- All people in the study had already been given treatments that had not worked or had stopped working.

5. What medicines were given to people in these subgroups?

MORPHEUS-HR+ BC Study

People from the **MORPHEUS-HR+ BC Study** were randomly put into the **Ipatasertib Group**, **Fulvestrant Group**, **Ipatasertib Plus Fulvestrant Group**, or **Control Group** by a computer and were given specific treatments. Each table shows what medicines were used to treat people in each subgroup, and when and how the medicines were taken.

Ipatasertib Group		
	Atezolizumab	Ipatasertib
Number of people taking this medicine	6	
When and how the medicines were taken	Injected into a vein every 2 weeks	Given by mouth on days 1-21 of every 28-day cycle
How long treatment was expected to last	Until their disease got worse or treatment was stopped for safety reasons	
Target end date of treatment	No target end date. People received treatment until their disease got worse	

Fulvestrant Group		
	Atezolizumab	Fulvestrant
Number of people taking this medicine	15	
When and how the medicines were taken	Injected into a vein every 2 weeks	Injected into a muscle on Cycle 1 Days 1 and 15, and Day 1 of each 28-day cycle afterwards
How long treatment was expected to last	Until their disease got worse or treatment was stopped for safety reasons	
Target end date of treatment	No target end date. People received treatment until their disease got worse	

Ipatasertib Plus Fulvestrant Group			
	Atezolizumab	Ipatasertib	Fulvestrant
Number of people taking this medicine	26		
When and how the medicines were taken	Injected into a vein every 2 weeks	Given by mouth on days 1-21 of every 28-day cycle	Injected into a muscle on Cycle 1 Days 1 and 15, and Day 1 of each

			28-day cycle afterwards
How long treatment was expected to last	Until their disease got worse or treatment was stopped for safety reasons		
Target end date of treatment	No target end date. People received treatment until their disease got worse		

Control Group	
	Fulvestrant
Number of people taking this medicine	15
When and how the medicines were taken	Injected into a muscle on Cycle 1 Days 1 and 15, and Day 1 of each 28-day cycle afterwards
How long treatment was expected to last	Until their disease got worse or treatment was stopped for safety reasons
Target end date of treatment	No target end date. People received treatment until their disease got worse

MORPHEUS-TNBC Study

People from the **MORPHEUS-TNBC Study** were randomly put into the **Ipatasertib Group** or **Control Group** by a computer and were given specific treatments. Each table shows what medicines were used to treat people in each subgroup, and when and how the medicines were taken.

Ipatasertib Group		
	Atezolizumab	Ipatasertib
Number of people taking this medicine	29	
When and how the medicines were taken	Injected into a vein every 2 weeks	Given by mouth on days 1-21 of every 28-day cycle
How long treatment was expected to last	Until their disease got worse or treatment was stopped for safety reasons	
Target end date of treatment	No target end date. People received treatment until their disease got worse	

Control Group	
	Capecitabine
Number of people taking this medicine	24
When and how the medicines were taken	Given by mouth on Days 1-14 of each 21-day cycle
How long treatment was expected to last	Until their disease got worse or treatment was stopped for safety reasons
Target end date of treatment	No target end date. People received treatment until their disease got worse

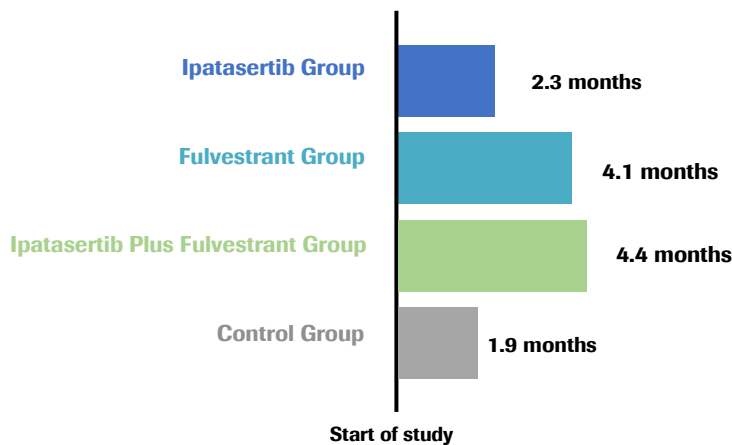
6. What were the results for these subgroups?

MORPHEUS-HR+ BC Study

After 75 weeks of treatment, researchers found that:

- Out of the 62 people, 9 people had their tumours shrink after receiving treatment:
 - 1 person in the **Ipatasertib Group**
 - 1 person in the **Fulvestrant Group**
 - 7 people in the **Ipatasertib Plus Fulvestrant Group**
- No one in the **Control Group** had their tumours shrink after receiving treatment.
- Researchers looked at how long it took for people's cancer to get worse on average. Some people's cancer got worse more quickly than this, and some people's cancer took longer to get worse.

On average, how long did it take for the cancer to get worse?



- Researchers looked at how long people in each subgroup lived on average. Some people lived longer than this, and some did not live as long.

On average, how long did people in each group live?



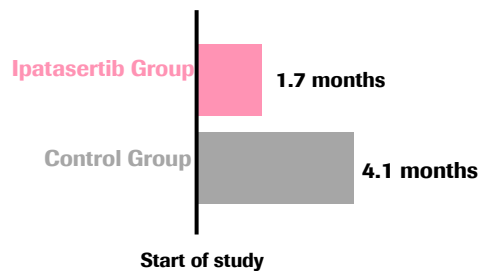
MORPHEUS-TNBC Study

After 72 weeks of treatment researchers found that:

- Out of the 53 people, 6 people had their tumours shrink as a result of their treatment:
 - 1 person in the **Ipatasertib Group**
 - 5 people in the **Control Group**

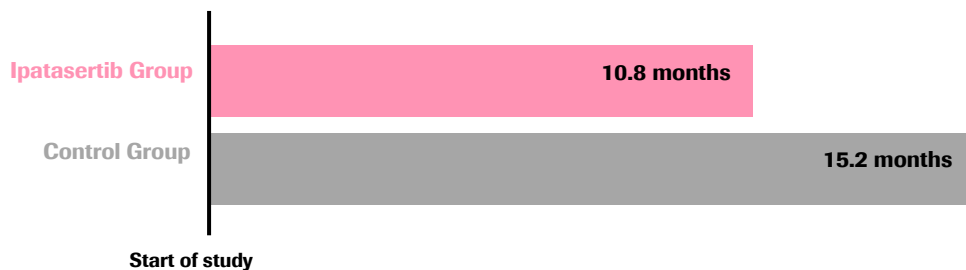
Researchers looked at how long it took for people's cancer to get worse on average. Some people's cancer got worse more quickly than this, and some people's cancer took longer to get worse.

On average, how long did it take for the cancer to get worse?



- Researchers looked at how long people in each subgroup lived on average. Some people lived longer than this, and some did not live as long.

On average, how long did people in each group live?



7. What side effects did people in these subgroups experience?

Side effects are unwanted medical problems (such as fever or headache) that happen during the study. It is important to note that:

- The side effects are described in the summary because the study researchers believe that the side effects may be related to the treatments in the study.
- Not all of the people in this study had all the side effects.
- Side effects may be mild to very serious and can be different from person to person.
- The side effects listed are the most common in the study and were seen in at least 20% of people who took part.

The side effects reported in this summary are from the people involved in this study only. This means that the side effects listed here may be different from those seen in other people, other

groups, and/or other studies of the same medicines. The side effects listed here may also be different from what is included in the patient leaflets, brochures, or websites for any of the medicines that are used in this study.

Information about common and serious side effects seen in this study are listed below.

MORPHEUS-HR+ BC Study

- All people in the **Ipatasertib**, **Fulvestrant**, and **Ipatasertib Plus Fulvestrant** subgroups had at least 1 side effect. In the **Control Group**, 13 out of 15 people (87%) had at least 1 side effect. These side effects could have happened for reasons other than the treatments

Most common treatment-related side effects in the MORPHEUS-HR+ BC Study

Ipatasertib Group (out of 6 people)	Fulvestrant Group (out of 15 people)	Ipatasertib Plus Fulvestrant Group (out of 26 people)	Control Group (out of 15 people)
<ul style="list-style-type: none"> Diarrhoea: 4 people (67%) Feeling sick (nausea): 4 people (67%) Being sick (vomiting): 3 people (50%) Feeling tired (fatigue): 3 people (50%) Decreased appetite: 3 people (50%) Dizziness: 2 people (33%) Cough: 2 people (33%) Flat or raised red rash: 2 people (33%) 	<ul style="list-style-type: none"> Low level of red blood cells (anaemia): 3 people (20%) Joint pain (arthralgia): 3 people (20%) Feeling tired (fatigue): 3 people (20%) 	<ul style="list-style-type: none"> Rash: 16 people (62%) Diarrhoea: 14 people (54%) Feeling sick (nausea): 11 people (42%) Feeling tired (fatigue): 7 people (27%) Being sick (vomiting): 6 people (23%) 	<ul style="list-style-type: none"> No treatment-related side effects

People taking the medicine combinations in these studies did not experience any new or unexpected side effects compared to people in other studies of each individual medicine.

Serious side effects

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

MORPHEUS-HR+ BC Study	
Subgroup	Number of people (%) with a serious side effect
Ipatasertib Group	3 out of 6 people (50%)
Fulvestrant Group	1 out of 15 people (7%)
Ipatasertib Plus Fulvestrant Group	10 out of 26 people (39%)
Control Group	2 out of 15 people (13%)

The serious side effects that the researchers thought were caused by the study medicines are shown below. Some people had more than 1 side effect — this means that they are included in more than 1 row in the table.

MORPHEUS-HR+ BC Study	
Subgroup	Number of people (%) with a treatment-related serious side effect
Ipatasertib Group	3 out of 6 people (50%)
Fulvestrant Group	1 out of 15 people (7%)
Ipatasertib Plus Fulvestrant Group	6 out of 26 people (23%)

Side effects that caused death

There were no deaths in the **MORPHEUS-HR+ BC Study** caused by side effects that may or may not have been related to 1 of the study medicines in the **Ipatasertib**, **Fulvestrant**, **Ipatasertib Plus Fulvestrant**, or **Control** groups.

Stopping the medicine because of side effects

During the study, some people decided to stop taking their medicine because of side effects that were related to 1 of the study medicines.

In the MORPHEUS-HR+ BC Study, the following number of people stopped taking their medicine because of a treatment-related side effect:

- 1 out of 6 people (17%) in the **Ipatasertib Group**
- 1 out of 15 people (7%) in the **Fulvestrant Group**
- 3 out of 26 people (12%) in the **Ipatasertib Plus Fulvestrant Group**
- 0 out of 15 people (0%) in the **Control Group**

MORPHEUS-TNBC Study

- All people in the **Ipatasertib Group** had at least 1 side effect. In the **Control Group**, 23 out of 24 people (96%) had at least 1 side effect. These side effects could have happened for reasons other than the treatments

Most common treatment-related side effects in the MORPHEUS-TNBC Study

Ipatasertib Group (out of 29 people)	Control Group (out of 24 people)
<ul style="list-style-type: none"> ▪ Diarrhoea: 14 people (48%) ▪ Rash: 12 people (41%) ▪ Feeling sick (nausea): 11 people (38%) ▪ Fever (pyrexia): 9 people (31%) ▪ Feeling tired (fatigue): 7 people (24%) 	<ul style="list-style-type: none"> ▪ Hand-foot syndrome (palmar-plantar erythrodysesthesia): 14 people (58%) ▪ Diarrhoea: 11 people (46%) ▪ Feeling sick (nausea): 7 people (29%)

People taking the medicine combinations in these studies did not experience any new or unexpected side effects compared to people in other studies of each individual medicine.

Serious side effects

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

MORPHEUS-TNBC Study	
Subgroup	Number of people (%) with a serious side effect
Ipatasertib Group	15 out of 29 people (52%)
Control Group	4 out of 24 people (17%)

The serious side effects that the researchers thought were caused by the study medicines are shown below. Some people had more than 1 side effect — this means that they are included in more than 1 row in the table.

MORPHEUS-TNBC Study	
Subgroup	Number of people (%) with a treatment-related serious side effect
Ipatasertib Group	12 out of 29 people (41%)
Control Group	1 out of 24 people (4%)

Side effects that caused death

In the **MORPHEUS-TNBC Study**, there was 1 death in the **Ipatasertib Group** and no deaths in the **Control Group** caused by side effects that may or may not have been related to 1 of the study medicines.

Stopping the medicine because of side effects

During the study, some people decided to stop taking their medicine because of side effects that were related to 1 of the study medicines.

In the MORPHEUS-TNBC Study, the following number of people stopped taking their medicine because of a treatment-related side effect:

- 2 out of 29 people (7%) in the **Ipatasertib Group**
- 1 out of 24 people (4%) in the **Control Group**

8. What do these results mean for people and researchers?

The information in this summary is from part of the larger **MORPHEUS-HR+ BC** and **MORPHEUS-TNBC Studies**.

These results have helped researchers learn more about how atezolizumab works with other medicines for the treatment of people with HR+ breast cancer and TNBC.

It is important to remember that **1 study cannot tell us everything we need to know about how safe a medicine is and how well it works**. It takes a lot of people in many studies to understand everything we need to know. The results from these studies may be different from

results from other studies of the same medicines. **This means that you should not make medical decisions based on this 1 summary. Always speak with your doctor before making any decisions about your treatment.**

9. Are there plans to add other people to these subgroups or to do other studies with these medicines?

No other studies are looking at the use of atezolizumab together with **ipatasertib**, **fulvestrant**, or **ipatasertib plus fulvestrant** to treat HR+ breast cancer or atezolizumab together with **ipatasertib** to treat TNBC.

10. Where can I find more information?

You can find more information about these studies on the following websites:

- <https://clinicaltrials.gov/ct2/show/NCT03280563> or <https://clinicaltrials.gov/ct2/show/NCT03424005>
- <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-000335-14> or <https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-002038-21>
- <https://forpatients.roche.com/en/trials/cancer/bc/a-study-of-multiple-immunotherapy-based-treatment-combinations-i.html> or
- <https://forpatients.roche.com/en/trials/cancer/bc/a-study-evaluating-the-efficacy-and-safety-of-multiple-immunother.html>

If you want to learn more about the results from these subgroups, see the following abstracts/posters:

- “Phase Ib/II Open-label, Randomized Trial of Atezolizumab With Ipatasertib Plus Fulvestrant vs Control in MORPHEUS-HR+ Breast Cancer and Atezolizumab With Ipatasertib vs Control in MORPHEUS Triple-Negative Breast Cancer.” The authors of the poster presented at the 2021 San Antonio Breast Cancer Symposium (SABCS) are Sara A. Hurvitz, Valentina Boni, Elizabeth Comen, Seock-Ah Im, Kyung Hae Jung, Sung-Bae Kim, Keun Seok Lee, Sherene Loi, Hope S. Rugo, Amir Sonnenblick, Melinda L. Telli, Kelly DuPree, Marcella Fassò, Ya-Chen Lin, Mina Nikanjam, Frauke Schimmoller, Xiaosong Zhang, Jing Zhu, and Peter Schmid. The link is here: https://aacrjournals.org/cancerres/article/82/4_Supplement/PD10-04/681385/Abstract-PD10-04-Phase-Ib-II-open-label-randomized.

Who can I contact if I have questions about these subgroups or the larger MORPHEUS-HR+ BC and MORPHEUS-TNBC Studies?

If you have more questions, visit the link below and fill out the contact form.

MORPHEUS-HR+ BC: <https://forpatients.roche.com/en/trials/cancer/bc/a-study-of-multiple-immunotherapy-based-treatment-combinations-i.html>

MORPHEUS-TNBC: <https://forpatients.roche.com/en/trials/cancer/bc/a-study-evaluating-the-efficacy-and-safety-of-multiple-immunother.html>

Who organised and paid for these subgroups and the larger MORPHEUS-HR+ BC and MORPHEUS-TNBC Studies?

The **MORPHEUS-HR+ BC Study** and **MORPHEUS-TNBC Study**, including the subgroups reported here, were organised and paid for by F. Hoffmann-La Roche Ltd whose headquarters are in Basel, Switzerland. The medicine fulvestrant was provided by F. Hoffmann-La Roche or purchased by study sites.

Full title of the study and other identifying information

The full titles of these studies are: “A Study of Multiple Immunotherapy-Based Treatment Combinations in Hormone Receptor (HR)-Positive Human Epidermal Growth Factor Receptor 2 (HER2)-Negative Breast Cancer (MORPHEUS HR+ BC)” and “A Study Evaluating the Efficacy and Safety of Multiple Immunotherapy-Based Treatment Combinations in Patients With Metastatic or Inoperable Locally Advanced Triple-Negative Breast Cancer (MORPHEUS-TNBC)”

- The protocol number for these studies are: CO39611 and CO40115.
- The ClinicalTrials.gov identifier for this study is: NCT03280563 and NCT03424005.
- The EudraCT number for this study is: 2017-000335-14 and 2017-002038-21.