

**Research Sponsor:** AstraZeneca AB

**Drug Studied:** Durvalumab and tremelimumab

**Study Title:** This study was done to learn how durvalumab with tremelimumab worked in participants with extensive-stage small-cell lung cancer

**Protocol Number:** D419QC00002

## Thank you

Thank you to the participants who took part in the clinical study for the study drugs durvalumab and tremelimumab.

All of the participants helped researchers learn more about durvalumab with tremelimumab to help people with extensive-stage small-cell lung cancer, also called ES-SCLC.

AstraZeneca AB sponsored this study and believes it is important to share the results of the study with the participants and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results. We hope it helps the participants understand and feel proud of their important role in medical research.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

This study happened in 3 groups. This summary shows the results from Group 1. The results from Groups 2 and 3 are in different summaries.

## Overview of this study



### Why was the research needed?

Researchers are looking for a better way to treat extensive-stage small-cell lung cancer, also called ES-SCLC. Before a drug can be approved for people to get, researchers do clinical studies to find out how safe it is and how it works. Sometimes researchers do a study of a drug in a small number of participants to decide if they should do a similar study in a larger number of participants.

This small study had 3 groups of participants. Each group got a different treatment. This summary shows the results from Group 1. The results from Groups 2 and 3 are in different summaries.



### What treatments did the participants take?

The participants in Group 1 of this study got durvalumab with tremelimumab.



### What were the results of this study?

The main questions the researchers wanted to answer for Group 1 in this study were:

- ▶ **Did the study treatments shrink the participants' tumors?**

Some participants in Group 1 had tumors that shrank after they got durvalumab and tremelimumab. But, the overall number of participants whose tumors shrank was small.

- ▶ **What medical problems did the participants have during this study?**

There were 46.3% of participants who had medical problems that the study doctors thought might be related to the study treatments during the study. The most common medical problem was high levels of thyroid hormones.

More details about the results of this study are included later in this summary.



### Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it also can be found on these websites.



## Who took part in the study?

The researchers asked for the help of men and women with ES-SCLC who had received chemotherapy that was no longer helping their cancer. The participants in Group 1 of this study were 40 to 76 years old when they joined.

Group 1 included 41 participants in Germany, Hungary, Poland, Spain, and Ukraine.



## Why was the research needed?

Researchers are looking for a better way to treat people who have ES-SCLC. Before a drug can be approved for people to get, researchers do clinical studies to find out how it works and how safe it is.

For Group 1 of this study, the researchers wanted to find out how durvalumab with tremelimumab worked in a small number of participants with ES-SCLC. If the drugs worked well, the researchers planned to do a similar study in a larger number of participants. The participants in this study had already received chemotherapy that was no longer helping their cancer. The researchers also wanted to find out what medical problems the participants had during the study.

In people with cancer, the body is not able to control the growth of cells. The extra cells can form tumors. When cancer reaches the “extensive stage”, tumors can spread to other parts of the body or grow beyond the organ where they started. Sometimes there are too many tumors, or they are too difficult to remove by surgery. This is also called “advanced” cancer.

Normally, the immune system can help stop tumors from growing by recognizing cancer cells as different from normal cells and then attacking and killing the cancer cells. But, in people with ES-SCLC, tumor cells can interfere with immune cells. This may stop the immune cells from recognizing the tumor cells and being able to attack them.

The study drugs, durvalumab and tremelimumab, were each designed to stop the tumor cells from interacting with some parts of the immune cells.

For Group 1 of this study, the researchers wanted to find out how well durvalumab and tremelimumab worked together in these participants.



## What was the purpose of this study?

The main questions the researchers wanted to answer for Group 1 of this study were:

- ▶ Did the study treatments shrink the participants' tumors?
- ▶ What medical problems did the participants have during the study?

The answers to these questions are important to know before larger studies can be done to find out if durvalumab with tremelimumab help improve the health of people with ES-SCLC.



## What treatments did the participants get?




All of the participants in Group 1 of this study got durvalumab with tremelimumab.

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what each participant was getting.

The participants got durvalumab and tremelimumab through a needle in a vein, also known as an IV infusion. The doses of the study drugs were measured in milligrams, also known as mg.

The participants got study treatment until they left the study, or until the study doctors thought the study treatments were not helping them.

The chart below shows the treatments that the participants in Group 1 got.

	<b>First 16 weeks of the study</b>	<b>Then, until the participants stopped study treatment</b>
	<ul style="list-style-type: none"><li>• 41 participants</li></ul>	<ul style="list-style-type: none"><li>• 41 participants</li></ul>
	<ul style="list-style-type: none"><li>• 1,500 mg durvalumab</li><li>• 75 mg tremelimumab</li><li>• By IV infusion</li></ul>	<ul style="list-style-type: none"><li>• 1,500 mg durvalumab</li><li>• By IV infusion</li></ul>
	<ul style="list-style-type: none"><li>• Once every 4 weeks</li></ul>	<ul style="list-style-type: none"><li>• Once every 4 weeks</li></ul>

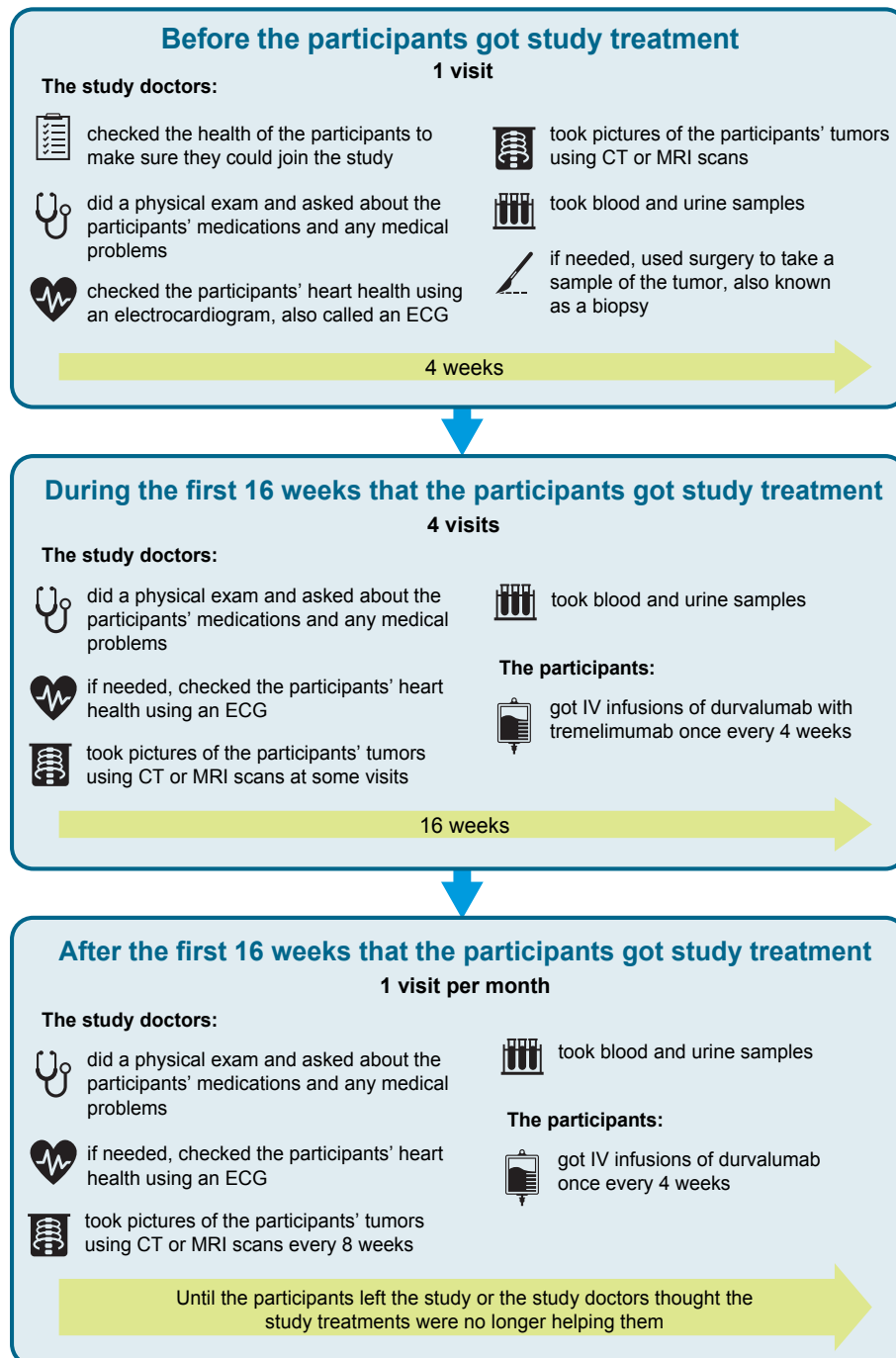


# What happened during the study?

The entire study took 3 years and 7 months to finish.

The study started in November 2016 and ended in June 2020.

The chart below shows what happened for Group 1 during the study.





## What were the results of the study?

This is a summary of the main results from Group 1 of this study. The results each participant had might be different and are not in this summary. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. When a full report of the study results is available, it can also be found on these websites.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

### **Did the study treatments shrink the participants' tumors?**

Some of the participants in Group 1 had tumors that shrank after they got durvalumab and tremelimumab. But, the overall number of participants whose tumors shrank was small.

To answer this question, the study doctors took pictures of the participants' tumors using CT or MRI scans. The study doctors measured the size of the participants' tumors before they took study treatment and throughout the study. The doctors then used a set of rules to calculate how much the tumors shrank. These rules are called Response Evaluation Criteria in Solid Tumors, or RECIST.

If a participant's tumor shrank by at least a third of its size, the participant was called a "responder". Participants whose tumors did not shrink or shrank by less than a third of their size were considered "non-responders". The researchers then calculated the percentage of responders.

In Group 1, 7.3% of the participants were responders. This was 3 out of 41 participants. The researchers decided that this number was too small for them to do a further study in a larger number of participants.



## What medical problems happened during the study?

This section is a summary of the medical problems the participants in Group 1 had during this study that the study doctors thought might be related to the study drugs. These medical problems are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse reactions may or may not be caused by the study drugs. A lot of research is needed to know whether a drug causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the study drugs.

The websites listed at the end of this summary may have other information about adverse reactions or other medical problems that happened during this study.

### Did any adverse reactions happen during this study?

	<b>Durvalumab with tremelimumab</b> (out of 41 participants)
How many participants had adverse reactions?	46.3% (19)
How many participants had serious adverse reactions?	19.5% (8)
How many participants stopped taking study treatments due to adverse reactions?	12.2% (5)

### What serious adverse reactions happened during this study?

The most common serious adverse reaction was diarrhea. The table below shows the serious adverse reactions that happened during the study.

Serious adverse reactions	
Serious adverse reaction	Durvalumab with tremelimumab (out of 41 participants)
Diarrhea	4.9% (2)
Bloody diarrhea caused by bacteria	2.4% (1)
Damage to the nerves outside the brain and spinal cord	2.4% (1)
Inflammation of the large intestine	2.4% (1)
Inflammation of the pancreas	2.4% (1)
Inflammation of the stomach and intestine caused by an infection	2.4% (1)
Increased levels of liver proteins	2.4% (1)
Pneumonia	2.4% (1)
Weakness of muscles and numbness in some areas of the body	2.4% (1)

There were 2.4% of participants who died because of a serious adverse reaction. This was 1 out of 41 participants. The serious adverse reaction was bloody diarrhea.



## What adverse reactions happened during this study?

The most common adverse reaction was high levels of thyroid hormones.

The table below shows the adverse reactions that happened in 2 or more participants during the study. There were other adverse reactions, but these happened in fewer participants.

Most common adverse reactions	
Adverse reaction	Durvalumab with tremelimumab (out of 41 participants)
High levels of thyroid hormones	9.8% (4)
Diarrhea	7.3% (3)
Fatigue	7.3% (3)
Low levels of thyroid hormones	7.3% (3)
Rash	4.9% (2)
Weakness of muscles and numbness in some areas of the body	4.9% (2)



## How has this study helped patients and researchers?

This study helped researchers learn more about how durvalumab and tremelimumab worked in participants with ES-SCLC who had received chemotherapy that was no longer helping their cancer.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with these study drugs for treatment of this type of ES-SCLC are not planned.



## Where can I learn more about this study?

You can find more information about this study on the websites listed below. If more information about the study results is available, it can also be found here.

- ▶ [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Once you are on the website, type **"NCT02937818"** into the search box and click **"Search"**.
- ▶ [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu). Once you are on the website, click **"Home and Search"**, then type **"2016-001202-42"** in the search box and click **"Search"**.
- ▶ [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type **"D419QC00002"** into the search box, and click **"Find a Study"**.

**Full Study Title:** A Phase II, Open-Label, Multi-Arm Study to Determine the Preliminary Efficacy of Novel Combinations of Treatment in Patients with Platinum Refractory Extensive-Stage Small-Cell Lung Cancer (BALTIC)

**AstraZeneca Protocol number:** D419QC00002

**National Clinical Trials number:** NCT02937818

**EudraCT number:** 2016-001202-42

**AstraZeneca AB** sponsored this study and has its headquarters at Södertälje, Sweden.

**The phone number** for the AstraZeneca Information Center is +1-877-240-9479.

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## Thank you

Clinical study participants and their families belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

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The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical studies, nor is it involved in conducting clinical studies.

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Version 1.0 2021\_06\_15

**Research Sponsor:** AstraZeneca AB

**Drug Studied:** Adavosertib and carboplatin

**Study Title:** This study was done to learn how adavosertib with carboplatin worked in participants with extensive-stage small-cell lung cancer

**Protocol Number:** D419QC00002

## Thank you

Thank you to the participants who took part in the clinical study for the study drugs adavosertib and carboplatin.

All of the participants helped researchers learn more about adavosertib with carboplatin to help people with extensive-stage small-cell lung cancer, also called ES-SCLC.

AstraZeneca AB sponsored this study and believes it is important to share the results of the study with the participants and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results. We hope it helps the participants understand and feel proud of their important role in medical research.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

This study happened in 3 groups. Each group got a different treatment. This summary shows the results from Group 2. The results from Groups 1 and 3 are in different summaries.

## Overview of this study



### Why was the research needed?

Researchers are looking for a better way to treat extensive-stage small-cell lung cancer, also called ES-SCLC. Before a drug can be approved for people to get, researchers do clinical studies to find out how safe it is and how it works. Sometimes researchers do a study of a drug in a small number of participants to decide if they should do a similar study in a larger number of participants.

This small study had 3 groups of participants. Each group got a different treatment. This summary shows the results from Group 2. The results from Groups 1 and 3 are in different summaries.



### What treatments did the participants take?

The participants in Group 2 of this study got adavosertib with carboplatin.



### What were the results of this study?

The main questions the researchers wanted to answer for Group 2 in this study were:

► **Did the study treatments shrink the participants' tumors?**

None of the participants in Group 2 had tumors that shrank by at least a third of its original size after they got adavosertib with carboplatin.

► **What medical problems did the participants have during this study?**

The medical problems that the participants in Group 2 had during this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities.

More details about the results of this study are included later in this summary.



### Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it also can be found on these websites.



## Who took part in the study?

The researchers asked for the help of men and women with ES-SCLC who had received chemotherapy that was no longer helping their cancer. The participants in Group 2 of this study were 48 to 78 years old when they joined.

Group 2 included 10 participants in Germany, Hungary, Poland, Spain, and Ukraine.



## Why was the research needed?

Researchers are looking for a better way to treat people who have ES-SCLC. Before a drug can be approved for people to get, researchers do clinical studies to find out how it works and how safe it is.

For Group 2 of this study, the researchers wanted to find out how adavosertib with carboplatin worked in a small number of participants with ES-SCLC. If the drugs worked well, the researchers planned to do a similar study in a larger number of participants. The participants in this study had already received chemotherapy that was no longer helping their cancer. The researchers also wanted to find out what medical problems the participants had during the study.

In people with cancer, the body is not able to control the growth of cells. The extra cells can form tumors. When cancer reaches the “extensive stage”, tumors can spread to other parts of the body or grow beyond the organ where they started. Sometimes there are too many tumors, or they are too difficult to remove by surgery. This is also called “advanced” cancer.

Certain proteins, which are substances in the body, can cause tumors to grow. Adavosertib was designed to stop 1 of these proteins from letting tumors grow and to cause tumor cells to die. The researchers thought that adavosertib might also make tumors more sensitive to chemotherapy with carboplatin, which would make them easier to treat.

For Group 2 of this study, the researchers wanted to find out how adavosertib and carboplatin worked together in these participants.



## What was the purpose of this study?

The main questions the researchers wanted to answer for Group 2 of this study were:

- ▶ Did the study treatments shrink the participants' tumors?
- ▶ What medical problems did the participants have during the study?

The answers to these questions are important to know before larger studies can be done to find out if adavosertib with carboplatin help improve the health of people with ES-SCLC.



## What treatments did the participants get?

All of the participants in Group 2 of this study got adavosertib with carboplatin.

This was an “open-label” study. This means the participants, researchers, study doctors, and other study staff knew what each participant was getting.

The participants took adavosertib as capsules by mouth and got carboplatin through a needle in a vein, also known as an IV infusion. The dose of adavosertib was measured in milligrams, also known as mg. Each participant's dose of carboplatin was as recommended by the study doctors.

The researchers planned for the participants to get study treatment for at least 9 weeks. Then, the participants could continue to get study treatment until they left the study, or until the study doctors thought the treatments were no longer helping them.

The chart below shows the treatments that the participants in Group 2 got.

	<ul style="list-style-type: none"><li>• 10 participants</li></ul>
	<ul style="list-style-type: none"><li>• 225 mg of adavosertib by mouth</li></ul>
	<ul style="list-style-type: none"><li>• carboplatin dose as recommended by the study doctor, by IV infusion</li></ul>
	Every 3 weeks: <ul style="list-style-type: none"><li>• adavosertib for 2.5 days, every 12 hours</li><li>• carboplatin 1 time</li></ul>

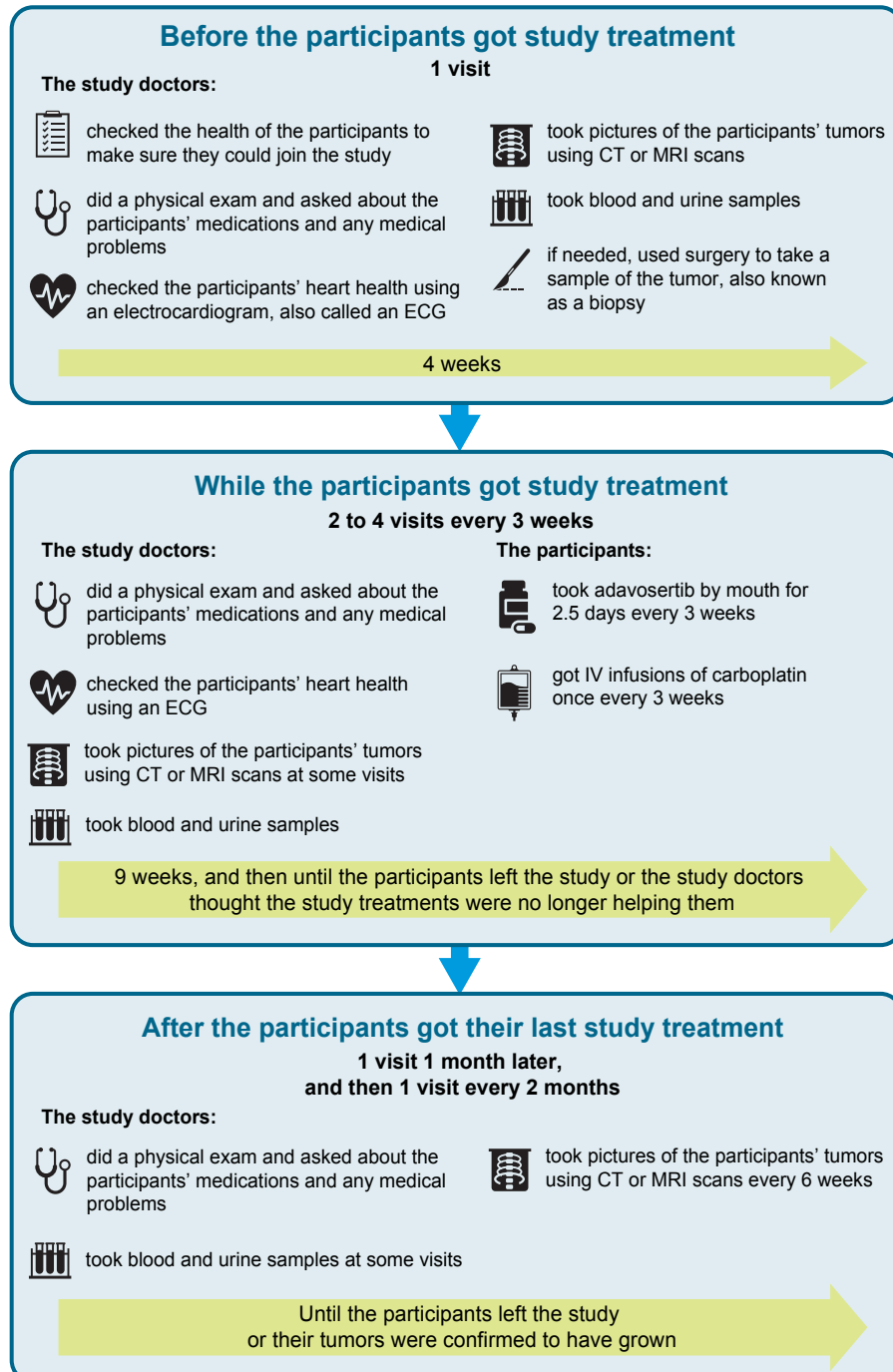


# What happened during the study?

The entire study took 3 years and 7 months to finish.

The study started in November 2016 and ended in June 2020.

The chart below shows what happened for Group 2 during the study.





## What were the results of the study?

This is a summary of the main results from Group 2 of this study. The results each participant had might be different and are not in this summary. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. When a full report of the study results is available, it can also be found on these websites.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

### **Did the study treatments shrink the participants' tumors?**

None of the participants in Group 2 had tumors that shrank by at least a third of its original size after they got adavosertib with carboplatin.

To answer this question, the study doctors took pictures of the participants' tumors using CT or MRI scans. The study doctors measured the size of the participants' tumors before they got study treatment and throughout the study. The doctors then used a set of rules to calculate how much the tumors shrank. These rules are called Response Evaluation Criteria in Solid Tumors, also called RECIST.

If a participant's tumor shrank by at least a third of its size, the participant was called a "responder". Participants whose tumors did not shrink or shrunk by less than a third of their size were considered "non-responders". The researchers then calculated the percentage of responders.

In Group 2, none of the participants were responders. For this reason, the researchers decided not to do a further study in a larger number of participants.





## What medical problems happened during the study?

The medical problems that the participants in Group 2 had during this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities.

The medical problems participants have during clinical studies that the study doctors think might be related to the study drugs are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study may or may not be caused by the study drugs. A lot of research is needed to know whether a drug causes an adverse reaction.



## How has this study helped patients and researchers?

This study helped researchers learn more about how adavosertib and carboplatin worked in participants with ES-SCLC who had received chemotherapy that was no longer helping their cancer.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with this combination of study drugs in this disease are not planned.



## Where can I learn more about this study?

You can find more information about this study on the websites listed below. If more information about the study results is available, it can also be found here.

- ▶ [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Once you are on the website, type **"NCT02937818"** into the search box and click **"Search"**.
- ▶ [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu). Once you are on the website, click **"Home and Search"**, then type **"2016-001202-42"** in the search box and click **"Search"**.
- ▶ [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type **"D419QC00002"** into the search box, and click **"Find a Study"**.

**Full Study Title:** A Phase II, Open-Label, Multi-Arm Study to Determine the Preliminary Efficacy of Novel Combinations of Treatment in Patients with Platinum Refractory Extensive-Stage Small-Cell Lung Cancer (BALTIC)

**AstraZeneca Protocol number:** D419QC00002

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Version 1.0 2021\_06\_15

**Research Sponsor:** AstraZeneca AB

**Drug Studied:** Ceralasertib and olaparib

**Study Title:** This study was done to learn how ceralasertib with olaparib worked in participants with extensive-stage small-cell lung cancer

**Protocol Number:** D419QC00002

## Thank you

Thank you to the participants who took part in the clinical study for the study drugs ceralasertib and olaparib.

All of the participants helped researchers learn more about ceralasertib with olaparib to help people with extensive-stage small-cell lung cancer, also called ES-SCLC.

AstraZeneca AB sponsored this study and believes it is important to share the results of the study with the participants and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results. We hope it helps the participants understand and feel proud of their important role in medical research.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

This study happened in 3 groups. This summary shows the results from Group 3. The results from Groups 1 and 2 are in different summaries.

## Overview of this study



### Why was the research needed?

Researchers are looking for a better way to treat extensive-stage small-cell lung cancer, also called ES-SCLC. Before a drug can be approved for people to get, researchers do clinical studies to find out how safe it is and how it works. Sometimes researchers do a study of a drug in a small number of participants to decide if they should do a similar study in a larger number of participants.

This small study had 3 groups of participants. Each group got a different treatment. This summary shows the results for Group 3. The results for Groups 1 and 2 are in different summaries.



### What treatments did the participants take?

The participants in Group 3 of this study took ceralasertib with olaparib.



### What were the results of this study?

The main questions the researchers wanted to answer for Group 3 in this study were:

#### ► Did the study treatments shrink the participants' tumors?

Some participants in Group 3 had tumors that shrank after they took ceralasertib with olaparib. But, the overall number of participants whose tumors shrank was small.

#### ► What medical problems did the participants have during this study?

There were 76.2% of participants who had medical problems that the study doctors thought might be related to the study treatments during the study. The most common medical problem was a low number of red blood cells.

More details about the results of this study are included later in this summary.



### Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it also can be found on these websites.



## Who took part in the study?

The researchers asked for the help of men and women with ES-SCLC who had already received chemotherapy that was no longer helping their cancer. The participants in Group 3 of this study were 34 to 76 years old when they joined.

Group 3 included 21 participants in Germany, Hungary, Poland, Spain, and Ukraine.



## Why was the research needed?

Researchers are looking for a better way to treat people who have ES-SCLC. Before a drug can be approved for people to get, researchers do clinical studies to find out how it works and how safe it is.

For Group 3 of this study, the researchers wanted to find out how ceralasertib with olaparib worked in a small number of participants with ES-SCLC. If the drugs worked well, the researchers planned to do a similar study in a larger number of participants. The participants in this study had received chemotherapy that was no longer helping their cancer. The researchers also wanted to find out what medical problems the participants had during the study.

In people with cancer, the body is not able to control the growth of cells. The extra cells can form tumors. When cancer reaches the “extensive stage”, tumors can spread to other parts of the body or grow beyond the organ where they started. Sometimes there are too many tumors, or they are too difficult to remove by surgery. This is also called “advanced” cancer.

The study drugs, ceralasertib and olaparib, were each designed to damage the DNA of the tumor cells. This causes the tumor cells to die.

For Group 3 of this study, the researchers wanted to find out how well ceralasertib and olaparib worked together in these participants.



## What was the purpose of this study?

The main questions the researchers wanted to answer in Group 3 of this study were:

- ▶ Did the study treatments shrink the participants' tumors?
- ▶ What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done to find out if ceralasertib with olaparib help improve the health of people with ES-SCLC.



## What treatments did the participants take?

All of the participants in Group 3 of this study took ceralasertib with olaparib.

This was an “open-label” study. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking.

In this study, treatment happened in 4 week periods called “cycles”.

The participants took ceralasertib and olaparib as tablets by mouth. The doses were measured in milligrams, also known as mg.

The participants took study treatment until they left the study, or the study doctors thought the treatments were no longer helping them.

The chart below shows the treatments that the participants in Group 3 took.

	<ul style="list-style-type: none"><li>• 21 participants</li></ul>
	<ul style="list-style-type: none"><li>• 160 mg of ceralasertib</li><li>• 300 mg of olaparib</li></ul>
	<ul style="list-style-type: none"><li>• ceralasertib once a day for the first week of the cycle</li><li>• olaparib twice a day for all 4 weeks of the cycle</li></ul>

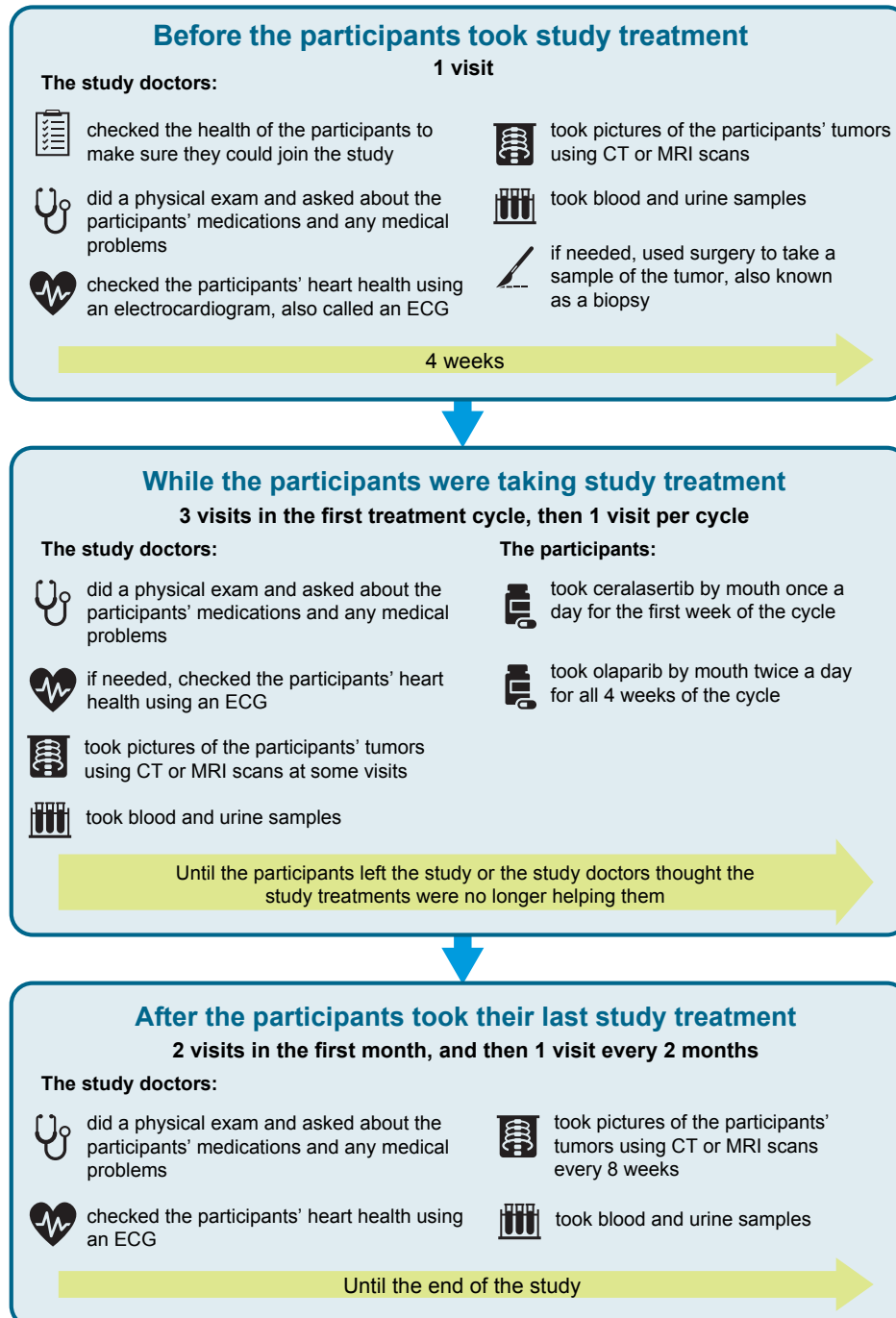


# What happened during the study?

The entire study took 3 years and 7 months to finish.

The study started in November 2016 and ended in June 2020.

The chart below shows what happened for Group 3 during the study.





## What were the results of the study?

This is a summary of the main results from Group 3 of this study. The results each participant had might be different and are not in this summary. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. When a full report of the study results is available, it can also be found on these websites.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

### **Did the study treatments shrink the participants' tumors?**

Some of the participants in Group 3 had tumors that shrank after they took ceralasertib with olaparib. But, the overall number of participants whose tumors shrank was small.

To answer this question, the study doctors took pictures of the participants' tumors using CT or MRI scans. The study doctors measured the size of the participants' tumors before they took study treatment and throughout the study. The doctors then used a set of rules to calculate how much the tumors shrank. These rules are called Response Evaluation Criteria in Solid Tumors, also called RECIST.

If a participant's tumor shrank by at least a third of its size, the participant was called a "responder". Participants whose tumors did not shrink or shrank by less than a third of their size were considered "non-responders". The researchers then calculated the percentage of responders.

In Group 3, 4.8% of the participants were responders. This was 1 out of 21 participants. The researchers decided that this number was too small for them to do a further study in a larger number of participants.





## What medical problems happened during the study?

This section is a summary of the medical problems the participants in Group 3 had during this study that the study doctors thought might be related to the study drugs. These medical problems are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse reactions may or may not be caused by the study drugs. A lot of research is needed to know whether a drug causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the study drugs.

The websites listed at the end of this summary may have other information about adverse reactions or other medical problems that happened during this study.

### Did any adverse reactions happen during this study?

	<b>Ceralasertib with olaparib</b> (out of 21 participants)
How many participants had adverse reactions?	76.2% (16)
How many participants had serious adverse reactions?	19.0% (4)
How many participants stopped taking study treatment due to adverse reactions?	0.0% (0)

### What serious adverse reactions happened during this study?

The most common serious adverse reaction was a low number of red blood cells. The table below shows the serious adverse reactions that happened during the study.

Serious adverse reactions	
Serious adverse reaction	Ceralasertib with olaparib (out of 21 participants)
Low number of red blood cells, which take oxygen to the entire body	19.0% (4)
Low number of platelets, which are blood cells that help wounds to heal	4.8% (1)

None of the participants in this study died due to serious adverse reactions.

### What adverse reactions happened during this study?

The most common adverse reaction was a low number of red blood cells.

The table below shows the adverse reactions that happened in 2 or more participants during the study. There were other adverse reactions, but these happened in fewer participants.

Most common adverse reactions	
Adverse reaction	Ceralasertib with olaparib (out of 21 participants)
Low number of red blood cells, which take oxygen to the entire body	57.1% (12)
Feeling sick	14.3% (3)
Low number of platelets, which are blood cells that help wounds to heal	9.5% (2)
Blood analysis showing a decreased number of platelets	9.5% (2)



## How has this study helped patients and researchers?

This study helped researchers learn more about how ceralasertib with olaparib worked in participants with ES-SCLC who had received chemotherapy that was no longer helping their cancer.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with these study drugs for treatment of this type of ES-SCLC are not planned.



## Where can I learn more about this study?

You can find more information about this study on the websites listed below. If more information about the study results is available, it can also be found here.

- ▶ [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Once you are on the website, type **"NCT02937818"** into the search box and click **"Search"**.
- ▶ [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu). Once you are on the website, click **"Home and Search"**, then type **"2016-001202-42"** in the search box and click **"Search"**.
- ▶ [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type **"D419QC00002"** into the search box, and click **"Find a Study"**.

**Full Study Title:** A Phase II, Open-Label, Multi-Arm Study to Determine the Preliminary Efficacy of Novel Combinations of Treatment in Patients with Platinum Refractory Extensive-Stage Small-Cell Lung Cancer (BALTIC)

**AstraZeneca Protocol number:** D419QC00002

**National Clinical Trials number:** NCT02937818

**EudraCT number:** 2016-001202-42

**AstraZeneca AB** sponsored this study and has its headquarters at Södertälje, Sweden.

**The phone number** for the AstraZeneca Information Center is +1-877-240-9479.

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## Thank you

Clinical study participants and their families belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

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The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical studies, nor is it involved in conducting clinical studies.

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