

Summary of Clinical Study Results for Participants

A study to evaluate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and preliminary anti-tumor activity of RO7616789 in participants with advanced small cell lung cancer and other neuroendocrine carcinomas

Definitions of key medical terms can be found at the end of this summary in the Glossary.

Title of the Study:	An open-label, multicenter Phase I study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary anti-tumor activity of RO7616789 in participants with advanced small cell lung cancer and other neuroendocrine carcinomas
Protocol Number:	BP44382 (TRIDENIS)
Study Identifier:	2023-506354-20-00 (EU CT) and NCT05619744 (ClinicalTrials.gov)
Medicine(s) Studied:	RO7616789
Study Start and End Date:	January 23, 2023 to March 04, 2025
Date of Summary:	October 15, 2025
Status of This Study:	This study stopped early in March 2025 because the sponsor, Roche, decided to focus on the development of other, potentially more impactful medicines. This summary was written after the study ended and includes an analysis of all the data collected throughout the study.
Disease Studied:	Small cell lung cancer – a type of very fast-growing lung cancer, and other neuroendocrine carcinomas – types of cancer that start in glands or nerve cells
Type of Study:	This study was a Phase 1, open-label study of RO7616789. Phase 1 is an important step in the research process where a treatment is tested in a small number of people. The purpose of this phase is to see how safe the treatment is. An open-label study means everyone involved, including the participant and the study doctor, know which study treatment the participant is given.

Thank you to our participants

We would like to thank all the individuals who took part in this study and their families, as well as carers who supported their participation.

Study participants belong to a large community of individuals around the world who have made it possible for researchers to answer important health questions and discover new medicines. We hope you feel proud of the critical role you have played in medical research.

As the company that has organised and funded this research, we believe it is important for you, and people like you, to know the results of this study. If you have questions about the information in this summary, please speak with the doctor or nurse at the clinic where you participated in the study.

It is important to note that the information presented in this summary is from one study. Remember that one study cannot tell us everything about the possible effects of a study medicine and how well it may or may not work. It takes a lot of people, participating in many studies to learn as much as we can about new medicines. This is why the results of this study may be different from the results of other studies of the same medicine.



Why was this study needed?

The neuroendocrine system is a complex network of glands and nerve cells in the body that work together to regulate and coordinate various processes by producing hormones. There are neuroendocrine cells in most organs of our body, including the lungs. Small cell lung cancer (SCLC) is a type of neuroendocrine cancer (known as 'neuroendocrine carcinoma', or NEC).

Standard first treatment of SCLC and other NECs includes medicines that kills cancer cells (chemotherapy) and/or medicines that help a person's natural defence (immune system) attack cancer cells (known as 'immunotherapy'). However, new treatments are needed that improve health outcomes for people living with SCLCs that have grown or spread to other parts of the body (also called 'advanced SCLC') or with other fast-growing (also known as 'poorly differentiated') NECs.

This study is testing a medicine called RO7616789. It is being developed to treat SCLC and other NECs. RO7616789 is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved RO7616789 for treating any type of cancer.

What was the main purpose of the study? What did researchers want to find out?

This study looked at how safe RO7616789 was, which researchers measured by counting how many people had unwanted effects when taking the medicine during the study and how severe these effects were.

Researchers also wanted to find out well RO7616789 worked in people with SCLC and other NECs.

The main questions researchers were trying to answer were:

- How many participants had unwanted effects, and how serious were they?
- What was the highest amount of RO7616789 that could be given to participants safely?
- What happened to RO7616789 at different doses in the body?
- How many participants had a reduction of their cancer after treatment?
- How many participants had tumours that didn't grow or actually shrank after receiving treatment?
- How much time was there between participants' cancer first responding to treatment and the cancer getting worse?
- How long did participants live without their cancer getting worse?
- How long did participants live?

Who took part in the study?



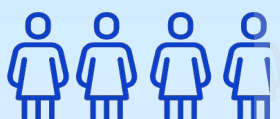
41 people living with
SCLC or other NECs



At 16 centres



In Denmark, Japan, Poland, Spain
and the United States



39% were women



61% were men



Participants had been given at least 1 treatment
for SCLC or other NECs before the study



Participants were between
24 and 77 years of age

Additionally, people had:

- To be at least 18 years old
- To have healthy blood with a certain level of oxygen and working organs
- To have cancer that could be measured at the start of the study
- To test negative for HIV

The following people could not take part in this study:

- People with certain other medical conditions, such as severe heart or immune disease, liver disease or uncontrolled type 2 diabetes
- People being treated with certain cancer, heart medicines or medicines similar to RO7616789
- People who had serious immune system unwanted effects from past treatments
- People who were pregnant or breastfeeding
- People with cancer that started in, or spread to the brain or spinal cord and requires treatment or causes symptoms and needs treatment
- People with untreated spinal cord compression
- People who had a live vaccine in the last 4 weeks
- People allergic to RO7616789 or tocilizumab

What medicine was used in this study?

RO7616789 immunotherapy was used in this study to help the body’s immune cells find and destroy cancer cells.

RO7616789

More than 2 in 3 people with NEC have cancer cells that contain a protein called DLL3, which helps cancer cells to grow.

RO7616789 attaches to DLL3 on cancer cells and, at the same time, attaches to immune cells.

RO7616789 works by bringing the two types of cells closer together and activating the immune cells to fight cancer cells.

Another medicine, called ‘tocilizumab’, was also given, if needed, to treat an unwanted effect called ‘cytokine release syndrome’, or ‘CRS’. CRS happens when the immune system reacts in an unusual way to an infection or cancer immunotherapy. During this reaction, substances called cytokines are released into the body. This can cause a variety of symptoms, such as a fever, nausea, headache, and rash. The person can also have a fast heartbeat, low blood pressure, and trouble breathing.

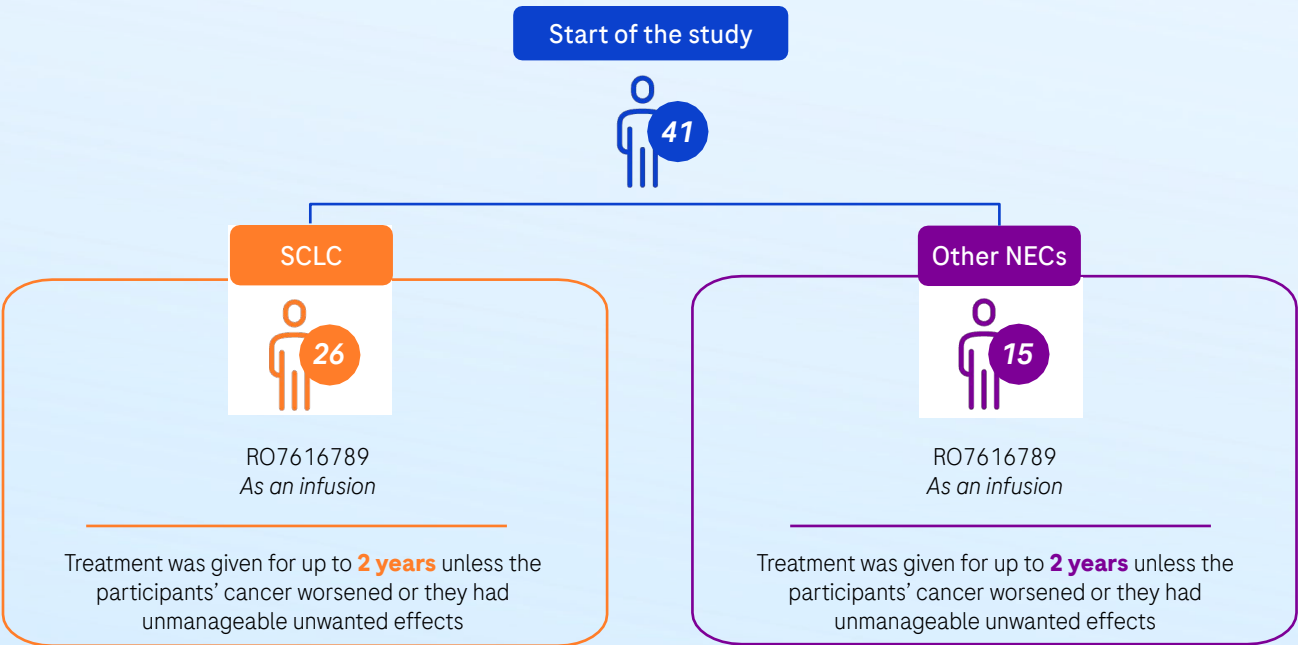
How was the study conducted?

The study had 3 parts. RO7616789 was given to people for the first time in this study, so researchers first checked how safe RO7616789 was, the most effective dose to use and how often to give it in Parts 1 and 2.

Part 1: small groups of participants received different doses of RO7616789 once a week as a drip into a vein (infusion). Some were given the full dose each time, while others started with a lower dose that increased over time.

Part 2: participants received RO7616789 every 3 weeks as an infusion. This part also tested different doses, starting with a lower dose and increasing to the full dose.

Part 3: researchers planned to give a larger number of people RO7616789 using information from Parts 1 and 2 to choose the most effective doses and timing. The study was stopped before this part began.



What were the results of the study?

Overall, RO7616789 was well tolerated at all doses without unmanageable unwanted effects. Some participants benefited from treatment, particularly those with SCLC.

1. What unwanted effects did the participants experience?

Unwanted effects (also called “adverse reactions”) are medical problems that happen during a study. They are described in this summary because the study doctor believes the unwanted effects were related to the medicine(s) used in the study. Unwanted effects may be mild to very serious and can be different for each person. Not all the people in this study experienced all the unwanted effects noted below.

Common unwanted effects are those that are experienced by at least 1 in every 20 participants (5% of participants). Mild unwanted effects are medical problems that do not impact a participant’s daily routine. Moderate unwanted effects are those that are not life threatening, but that may impact a participant’s day-to-day life. In these cases, the participant may need to have their study medicine dose adjusted or may need additional treatment. Serious unwanted effects are those that may result in death, may require a participant to be hospitalised, or may extend a participant’s time in hospital.

In this study, researchers looked at the safety of RO7616789 by measuring the number and type of unwanted effects related to RO7616789 experienced by all the people who participated in the study. This information is listed below.

RO7616789	
Effect	Number of participants impacted
Serious unwanted effects	
Cytokine release syndrome	7 out of 41 (17%)
The kidneys suddenly stop working properly	1 out of 41 (2%)
Blood clots throughout the body	1 out of 41 (2%)
Changes to awareness or consciousness	1 out of 41 (2%)
Inflammation involving the immune system that causes damage to nerves	1 out of 41 (2%)
Other common unwanted effects	
Cytokine release syndrome	19 out of 41 (46%)
Feeling tired or weak	11 out of 41 (27%)
Itching	5 out of 41 (12%)
A low number of red blood cells	4 out of 41 (10%)
A feeling of coldness that makes the body shiver	4 out of 41 (10%)
Feeling less hungry than usual	4 out of 41 (10%)
Loose, watery and more frequent stools	4 out of 41 (10%)
Not having energy or strength	3 out of 41 (7%)
Changes in the sense of taste (making food taste strange or causing a strange taste in the mouth)	3 out of 41 (7%)
Pain or discomfort in the head	3 out of 41 (7%)
A reaction to the infusion	3 out of 41 (7%)

What were the results of the study?

2. What was the highest amount of RO7616789 that could be given to participants safely?

The study was stopped before researchers could determine the highest dose of RO7616789 that could be given safely.

Two participants (5% of all participants) had an unwanted effect that meant they could no longer be given their intended dose of RO7616789:

- In Part 1, 1 participants’ kidneys suddenly stopped working properly due to cytokine release syndrome after being given RO7616789 once a week
- Another participant in Part 1 had inflammation of the pancreas (which plays an important role in digestion and blood sugar regulation) after being given RO7616789.

3. What happens to RO7616789 at different doses in the body?

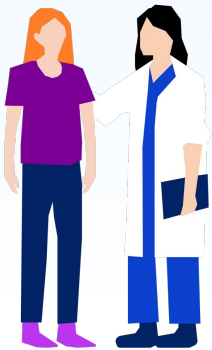
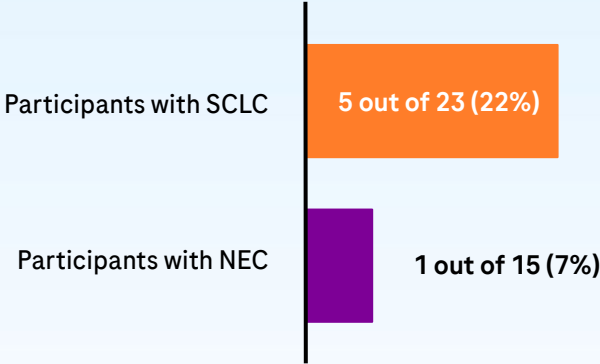
RO7616789 levels in the blood were highest in participants given the highest doses. It took about 2 to 4 days for the amount of RO7616789 in the blood to drop by half.

When participants were started with a lower dose of RO7616789 that was gradually increased, fewer had an unwanted effect of cytokine release syndrome – when the immune system reacts in an unusual way to cancer immunotherapy.

4. How many participants had a reduction of their cancer after treatment?

Researchers checked if participants’ cancer had shrunk by at least one third with no signs the cancer had grown anywhere else in the body, or if no cancer was detectable on tests or scans after treatment. Information was available from 38 of the 41 participants.

How many participants had a reduction of their cancer after treatment?



What were the results of the study?

5. How many participants had tumours that didn't grow or actually shrank after receiving treatment?

Researchers also checked the number of participants whose tumours didn't grow or actually shrank after receiving treatment – known as ‘disease control’.

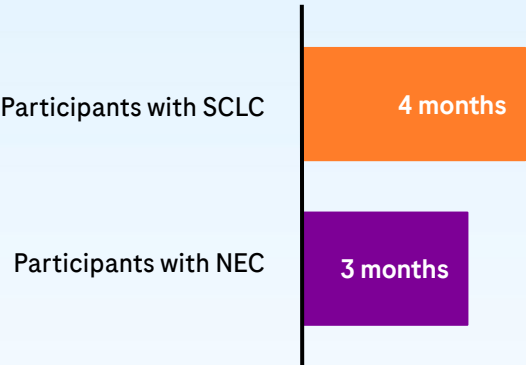
How many participants had disease control after treatment?



6. How much time was there between participants’ cancer first responding to treatment and the cancer getting worse?

Researchers checked how long a response to treatment lasted by seeing when cancer worsened, if this happened.

How long did a response to treatment last?

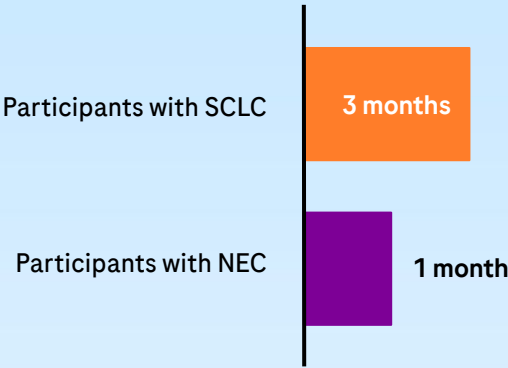


What were the results of the study?

7. How long did participants live without their cancer getting worse?

Researchers checked how much time passed from starting treatment for cancer to worsen, if this happened.

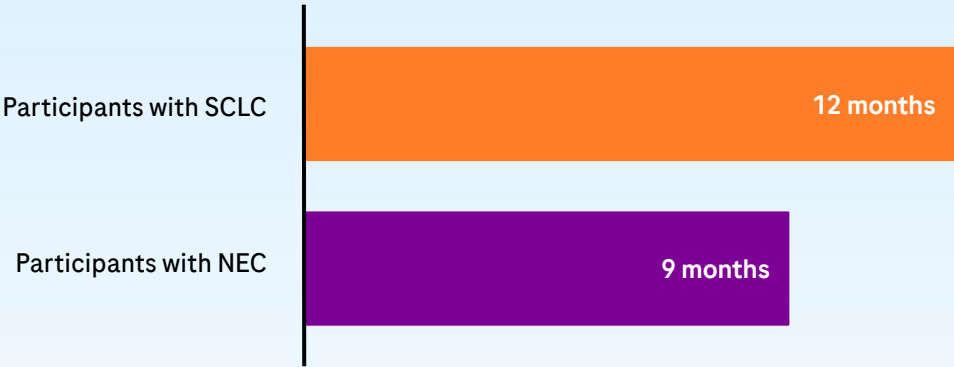
How long did participants live without their cancer getting worse?



8. How long did participants live?

Researchers also looked at how long participants lived after starting treatment.

How long did participants live?



How has this study helped research?

This study helped researchers understand more about RO7616789 as a treatment for cancers that have a protein called DLL3, such as NECs.

The results showed that RO7616789 was well tolerated at all doses. This means that participants did not experience unmanageable unwanted effects. More participants with SCLC had a response to treatment than those with other types of NECs.

Where can I find more information about this study?

For more information about this study, visit:

[A clinical trial to look at how safe and well RO7616789 works at different doses in people with small cell lung cancer \(SCLC\) that has spread or any neuroendocrine cancer \(NEC\), and how the body processes RO7616789 – ForPatients](#)

Learn about the purpose, design, and participant information on the Roche ForPatients site.

[TRIDENIS Study – ClinicalTrials.gov](#) Explore official registration details, eligibility criteria, and study updates.

[TRIDENIS Study – EU Clinical Trials Register](#) View the EU listing with regulatory and trial data.

What other studies are being conducted for this medicine?

At the time of writing this summary, no additional studies are planned for RO7616789 for treating cancer.

Sponsor(s):

This study was paid for and conducted by F. Hoffmann-La Roche Ltd (Roche).

Contact details:

If you have any further questions after reading this summary, please visit [ForPatients.Roche.com](https://forpatients.roche.com) and click on the 'Talk to us' link at the top of the page.

If you took part in this study and have questions about the results, please speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment, please speak with the doctor in charge of your treatment.

Glossary of key medical terms

Chemotherapy: a medicine that kills cancer cells

Cytokine release syndrome (CRS): when the immune system reacts in an unusual way to an infection or cancer immunotherapy. During this reaction, substances called cytokines are released into the body. This can cause a variety of symptoms, such as a fever, nausea, headache, and rash. The person can also have a fast heartbeat, low blood pressure, and trouble breathing

Immune system: the body's natural defence, which protects the body from foreign or harmful substances such as bacteria and viruses

Immunotherapy: a type of medicine that helps a person's own immune system attack cancer cells

Infusion: a drip into a vein

Neuroendocrine carcinomas (NECs): cancers of the neuroendocrine system – a complex network of glands and nerve cells in the body that work together to regulate and coordinate various processes

Open-label study: when everyone involved, including the participant and the study doctor, know which study treatment the participant is given

Phase 1: an important step in the research process where a treatment is tested in a small number of people. The purpose of this phase is to see how safe the treatment is

RO7616789: the experimental medicine studied here

Small cell lung cancer (SCLC): a type of very fast-growing lung cancer. It happens when some cells in the lungs start growing in a harmful way

