

# Clinical Study Results



**Research Sponsor:** AstraZeneca K.K.

**Drugs Studied:** MEDI9447 (oleclumab)

**Study Title:** A study to learn about the safety of MEDI9447 in Japanese men and women who have advanced cancers

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## ***Thank you!***

Thank you to the participants who took part in the clinical study for the study drug MEDI9447, also called oleclumab, and to the families of the participants. AstraZeneca K.K. sponsored this study and thinks it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results.

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

## Who took part in the study?

The researchers asked for the help of men and women with advanced cancer.

The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

## Why was the research needed?

Researchers are looking for a better way to treat advanced cancer. Before a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

Cancer is a disease that happens when the body cannot control the growth of cells. Many of these extra cells come together to form tumors, which can start in any part of the body. “Advanced” means that the tumors are unlikely to be completely removed by surgery.

There are treatments available for people who have advanced cancer. But, these treatments may not stop cancer cells from growing or spreading. They may also cause medical problems.

The study drug, MEDI9447, is being developed to help treat cancer. Researchers think that MEDI9447 may be able to help the body’s immune system fight cancer cells and keep them from growing or spreading.

In this study, the researchers wanted to learn more about the safety of MEDI9447 in people who have advanced cancer. They also wanted to study the number of dose limiting toxicities the participants had during the study. A dose-limiting toxicity is a medical problem that is severe enough to stop the study doctor from increasing the participant’s dose of study drug. Dose-limiting toxicities are also known as DLTs.

## What was the purpose of this study?

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

- What signs and symptoms did the participants have during the study?
- What medical problems happened during the study?

The answers to these questions are important to know before other studies can be done to find out if MEDI9447 helps improve the health of people who have advanced cancer.

## What treatments did the participants get?

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

In this study, the participants got 1 of 2 MEDI9447 treatments through a needle into a vein. This is also known as an intravenous infusion, also called an IV infusion. The 2 treatment doses were measured in milligrams, also called mg:

- 1,500 mg of MEDI9447
- 3,000 mg of MEDI9447

## What happened during the study?

The study started in November 2018 and ended in June 2019.

During the study, the participants got MEDI9447 in 4-week periods called “cycles”. The participants could take part in as many cycles as they wanted unless:

- the study doctors thought that the treatment was not working
- the participants’ cancer got worse
- the participants had medical problems that caused them to stop taking study treatment

If their cancer got worse, the participants stopped the treatment cycles. If the study treatment was helping the participants’ cancer at the end of the study, the participants could choose to continue treatment.

The chart below shows what happened during the study.

### Before the participants got study treatment

1 visit

The study doctors checked to make sure the participants could join the study.

The study doctors:



did a physical examination and checked the participants' vital signs



checked the participants' heart health using an electrocardiogram, also called an ECG



checked blood and urine test results



asked the participants about their medical history, how they were feeling, and what medications they were taking

About 4 weeks



### While the participants were getting study treatment

up to about 2 cycles

The study doctors:



continued checking the participants' health and asking them how they were feeling



kept track of any DLTs that happened



The participants got either:  
1,500 mg of MEDI9447  
2 times each cycle  
Each cycle lasted 4 weeks



3,000 mg of MEDI9447  
2 times each cycle  
Each cycle lasted 4 weeks

Up to about 2 months



### After the participants got their last dose of study treatment

2 visits



The doctors checked the health of the participants.

About 3 months

## What were the results of the study?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary.

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.

The websites listed at the end of this summary may have more information about the study results.

## What signs and symptoms did the participants have during the study?

To answer this question, the study doctors did tests and measurements before and after the participants got MEDI9447. Then, the researchers compared the results.

The study doctors recorded:

- any changes in the participants' health
- any DLTs that happened

Overall, the researchers found that there were some changes in the participants' health. But, these changes were too small for the researchers to consider them to be meaningful. They also found that none of the participants had a DLT.

The study doctors also kept track of the “adverse events” that the participants had. An adverse event is any sign or symptom that participants have during a study. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatment. An adverse event is considered “serious” when it is life-threatening, causes lasting problems, or the participant needs hospital care. Adverse events may or may not be caused by the treatment in the study. A lot of research is needed to know whether a treatment causes an adverse event.

The adverse events that the participants 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.

## What medical problems happened during the study?

The medical problems participants have during clinical studies that the study doctors think might be related to the study drug 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 treatment. A lot of research is needed to know whether a treatment causes an adverse reaction.

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

## How has this study helped patients and researchers?

This study helped researchers learn about the safety of MEDI9447 in people who have advanced 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 MEDI9447 are 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 “**NCT03736473**” into the search box, and click “**Search**”.
- [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type “**D6070C00006**” into the search box, and click “**Find a Study**”.

**Full Study Title:** A Phase I, Open-label Study to Assess the Safety, Tolerability, Pharmacokinetics and Anti-tumour Activity of MEDI9447 (Oleclumab) in Japanese Patients with Advanced Solid Malignancies

**AstraZeneca Protocol Number:** D6070C00006

**AstraZeneca K.K.** sponsored this study and has its headquarters at Grand Front Osaka Tower B 3-1, Ofuka-cho, Kita-ku, Osaka 530-0011, Japan.

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

## *Thank you!*

Clinical study participants 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.



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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