AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca K.K.

Drug Studied: AZD9150 with durvalumab

Study Title: A study to learn about the safety of AZD9150 alone or with durvalumab in Japanese participants with advanced solid tumors

Thank you

Thank you for taking part in the clinical study for the study drugs AZD9150 and durvalumab.

AstraZeneca K.K. sponsored this study and believes it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you.

If you 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 people with advanced solid tumors. "Advanced" usually means that the cancer keeps growing even with treatment. The participants in this study may have already tried treatments for their cancer. They were 41 to 77 years old when they joined.

The study included 11 participants in Japan who had different types of advanced cancer. The participants could not have the most common type of liver cancer, which is called hepatocellular carcinoma or HCC.

Why was the research needed?

Researchers are looking for a better way to treat advanced solid tumors. 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.

In people with cancer, the body is not able to control the growth of cells. The extra cells can form tumors. Normally, the immune system fights infections or anything it does not recognize, and can help stop tumors from growing or surviving. But in people with advanced solid tumors, a protein on the tumor cells can interact with certain proteins on the immune cells. This stops the immune cells from attacking the tumor cells.

Durvalumab was designed to stop the tumor cells from interacting with some of these immune cell proteins. This lets the immune cells stop the tumor from growing. AZD9150 was designed to stop the tumor cells from surviving. It works by suppressing the genes that help the tumor cells to survive.

In this study, the researchers wanted to find out about the safety of AZD9150 alone or with durvalumab in Japanese participants with advanced solid tumors.

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 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 AZD9150 alone or with durvalumab will help improve the health of people with advanced solid tumors.

What treatments did the participants take?

The participants in this study got either AZD9150 alone or AZD9150 with durvalumab. Both study treatments were given through a needle into a vein, also known as an IV infusion. The doses were measured in milligrams, also known as mg.

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

There were 2 groups in this study. At the beginning of the study, the participants in both groups stayed overnight at their study site for 1 week to get 3 separate doses of AZD9150. After the first week:

- The participants in Group 1 got an infusion of AZD9150 every week.
- The participants in Group 2 got an infusion of AZD9150 every week and an infusion of durvalumab every 4 weeks.

The participants continued getting study treatment for as long as the study doctors thought it was helping them, or until they left the study.

The table below shows the treatments that the participants got.

	Group 1 (5 participants) 	**Group 2** (6 participants) 
Week 1	• 3 separate doses of 200 mg of AZD9150	• 3 separate doses of 200 mg of AZD9150
Week 2 onwards	• 200 mg of AZD9150 every week	• 200 mg of AZD9150 every week • 1,500 mg of durvalumab every 4 weeks

What happened during the study?

The study started in January 2018 and ended in April 2019.

Before the participants got study treatment, they visited their study site 1 time. The visit happened about 4 weeks before the participants got study treatment. At this visit, the study doctors made sure that the participants could join the study. The study doctors:

- did a physical exam and asked about the participants' medications and any medical problems they were having
- checked the participants' heart health using an electrocardiogram, also called an ECG
- did a procedure called a biopsy to take a sample of the participants' tumors, if needed
- took blood and urine samples

The study doctors also did these tests and measurements throughout the study.

While the participants were getting study treatment in Week 1, they stayed overnight at the study site for 1 week and got 3 doses of AZD9150.

While the participants were getting study treatment from Week 2 and onwards, they visited their study site once a week.

At each of these visits, the participants got their IV infusions of AZD9150. The participants in Group 2 got their IV infusions of durvalumab every 4 weeks.

The participants continued getting study treatment for as long as their cancer did not get worse.

After the participants got study treatment, they visited their study site 2 times. This part of the study lasted up to 1 month for the participants in Group 1 and up to 3 months for the participants in Group 2. At these visits, the study doctors checked the health of the participants.

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 change.

The websites listed at the end of this summary may have a full report of the study results.

Because there were a small number of participants in each group, the results for both groups are combined. This helps protect the participants' identities.

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 the study treatment. The study doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also did ECGs to check the participants' heart health.

Overall, the researchers found that there were no significant changes in the results of these tests and measurements.

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.

Later in this document, there will be a summary of the adverse events that the study doctors thought might be related to the study treatment. This section is a summary of all the adverse events, whether they might be related to the study treatment or not. 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 treatments in the study. A lot of research is needed to know whether a treatment causes an adverse event.

	Groups 1 and 2 (out of 11 participants)
How many participants had adverse events?	90.9% (10)
How many participants had serious adverse events?	9.1% (1)
How many participants stopped taking study treatment because of adverse events?	9.1% (1)

The serious adverse event was inflammation of the pancreas.

The most common adverse events were:

- Decreased numbers of blood cells that help form blood clots
- Liver not working normally
- Feeling generally unwell
- Fever
- Increased levels of the liver proteins called AST, ALT, and GGT
- Decreased numbers of a type of white blood cell called neutrophils
- Decreased appetite
- Nausea

The study doctors also counted the number of dose-limiting toxicities the participants had during the study. A dose-limiting toxicity is an adverse event that is severe enough to stop the study doctor from increasing the participant's dose of study treatment. A dose-limiting toxicity is also known as a DLT.

There was 9.1% of participants who had a DLT during the study. This was 1 out of 11 participants.

What medical problems happened during the study?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study drug. 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 drug. 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 drug.

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.

	Groups 1 and 2 (out of 11 participants)
How many participants had adverse reactions to either of the study drugs?	81.8% (9)
How many participants had serious adverse reactions to either of the study drugs?	0.0% (0)
How many participants stopped taking either of the study drugs because of adverse reactions?	9.1% (1)

What adverse reactions happened during this study?

The most common adverse reaction to either of the study drugs was a decreased numbers of blood cells that help form blood clots.

The adverse reactions below happened in 2 or more of all the participants. There were other adverse reactions to either study drug, but these happened in fewer participants.

Most common adverse reactions to either of the study drugs

Adverse reaction	Groups 1 and 2 (out of 11 participants)
Decreased numbers of blood cells that help form blood clots	45.5% (5)
Liver not working normally	27.3% (3)
Feeling generally unwell	18.2% (2)
Fever	18.2% (2)
Increased levels of a liver protein called GGT	18.2% (2)
Decreased numbers of a type of white blood cell called neutrophils	18.2% (2)

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of AZD9150 alone and with durvalumab in Japanese participants with advanced solid tumors.

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 AZD9150 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 Once you are on the website, type **"NCT03394144"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D5660C00017"** 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-tumor Activity of AZD9150 monotherapy and AZD9150 in combination with durvalumab in Japanese patients with Advanced Solid Malignancies

AstraZeneca Protocol Number: D5660C00017

National Clinical Trials number: NCT03394144

AstraZeneca K.K. sponsored this study and has its headquarters in Osaka, 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.

CISCRP

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.

CISCRP | One Liberty Square, Suite 1100 • Boston, MA 02109 | 1-877-MED-HERO | www.ciscrp.org

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