AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca

Drug Studied: AZD4635

Study Purpose: This study was done to learn about the safety of AZD4635 in Japanese participants with advanced solid tumors.

Protocol Number: D8730C00005

Thank you

Thank you for taking part in the clinical study for the study drug AZD4635.

AstraZeneca 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 this study?

The researchers asked for the help of Japanese people with advanced solid tumors that either did not respond to standard therapy or did not have a standard therapy that existed for them.

The study included 10 participants in Japan.

Why was the research needed?

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

A "solid" tumor is a type of cancer that starts in an organ of the body. "Advanced" usually means that the cancer has spread to other parts of the body or has grown beyond the organ where it started. The study drug, AZD4635, is being developed to treat some cancers, including advanced solid tumors.

What was the purpose of this study?

In this study, the researchers wanted to learn about the safety of AZD4635 in Japanese participants with advanced solid tumors.

The main questions that 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 AZD4635 helps improve the health of people who have advanced solid tumors.

What treatments did the participants take?

In this study, all of the participants took AZD4635 as capsules by mouth.

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

The researchers wanted to learn about the safety of 2 different doses of AZD4635. The doses of AZD4635 were measured in milligrams, also known as "mg". The participants took either 50 mg or 75 mg of AZD4635 once a day until their cancer got worse or until they decided to stop taking the treatment.

What happened during this study?

The study started in July 2019 and ended in September 2020.

Before the participants took study treatment, they visited their study site 1 time. This part of the study lasted for up to 4 weeks. At this visit, the study doctors made sure the participants could join the study. They also:

- did a physical exam and asked about the participants' medications and any medical problems they were having
- took blood and urine samples
- took pictures of the participants' tumors using CT, MRI, PET, or bone scans
- used surgery to take a sample of the tumor, also known as a biopsy
- checked the participants' heart health using a type of heart scan called a MUGA scan, an echocardiogram, or an electrocardiogram, also called an ECG
- checked how well the participants were able to do their usual daily activities

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

While the participants were taking study treatment, they visited their study site 4 times in the first 4 days. During the first visit, the participants took their dose of AZD4635.

Then, the participants visited their study site 1 or 2 times a week for 7 weeks. After that, they visited their study site once every 3 weeks until they left the study. The participants took their dose of AZD4635 once a day until their cancer got worse, or they decided to stop taking the treatment.

After the participants took study treatment, they visited their study site up to 2 times. This part of the study lasted for up to 5 weeks. At these visits, the study doctors checked the health of the participants.

After this, the participants whose cancer did not get any worse at the end of AZD4635 treatment visited their study site once every 3 months to have their tumors measured. They visited until their cancer got worse, they started a new therapy, they left the study, or the researchers ended this study.

What were the results of this 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 a full report of 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 took AZD4635. The doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also checked the participants' heart health using certain tests and scans. These were ECGs and echocardiograms, which are ultrasound scans of the heart. The doctors also did a MUGA scan, which is a different type of scan that can measure how well the heart is pumping out blood.

Overall, the researchers found that from the start of the study, there were some small changes in the results of these tests and measurements. But, the researchers did not consider these to be meaningful.

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.

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. But, the participants had no serious adverse events or adverse events that led the participants to stop taking the study drug.

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". None of the participants had a DLT.

What medical problems happened during this 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 drug. A lot of research is needed to know whether a drug causes an adverse reaction.

The medical problems 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.

None of the participants had any serious adverse reactions, adverse reactions that led the participants to stop taking the study drug, or adverse reactions that resulted in death.

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of AZD4635 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 AZD4635 are ongoing.

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 **"NCT03980821"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D8730C00005"** 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 AZD4635 in Japanese Patients with Advanced Solid Malignancies

AstraZeneca Protocol Number: D8730C00005

National Clinical Trials Number: NCT03980821

AstraZeneca sponsored this study and has its headquarters at Cambridge, UK.

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.

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