Daiichi-Sankyo

# Clinical Results Summary

# A clinical study to learn about the safety and effect of food on the levels of Quizartinib in the blood of healthy participants

**Protocol number:** AC220-008

**Thank You!**

Daiichi Sankyo, Inc., the sponsor of this study, would like to thank the participants who took part in this study for quizartinib, also known as AC220. Each participant helped to advance medical research for people affected with acute myeloid leukemia. Their contribution to medicine and healthcare is greatly appreciated.

**Important note:** This summary only shows the results of a single study. Other studies may have different findings. Researchers and health authorities look at the results of many studies to understand which treatments work and how they work. It takes a lot of people in many studies around the world to advance medical science and healthcare.

Do not use the results of this study to make health decisions. Please talk to a doctor before changing any treatment you are taking or if you have any questions about these study results.

# What was the main purpose of this study?

## Acute myeloid leukemia (AML)

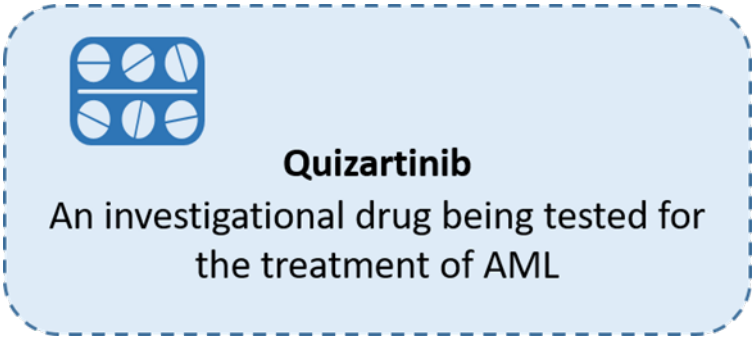
Quizartinib, also known as AC220, is an investigational drug being tested for the treatment of acute myeloid leukemia, or AML. Acute myeloid leukemia is a cancer of the blood and bone marrow.

Before a new drug can be given to patients, the researchers developing it perform many research studies to ensure that the drug is safe and effective. The first step in studying a new drug is to test it in healthy people. This means people without any health problems. This study involved healthy participants.

The presence of food in the stomach can affect how much of a drug that is taken by mouth is absorbed by the body. In this study, researchers wanted to know if there is any effect of food on quizartinib levels in the body when quizartinib is taken under fasted (no food present in the stomach) or fed (food present in the stomach) conditions. This will enable researchers to decide what dose of quizartinib should be given to people based on their food intake.

## Treatment given in this study

The treatment given in this study was:




## Main purpose of this study

The main question the researchers wanted to answer in this study was:

What was the effect of food on the levels of quizartinib and its active breakdown product AC886* in the blood of healthy participants?

**The body breaks down quizartinib into another product called AC886. AC886 has similar effects in the body to quizartinib.*

## Other purpose of this study

Researchers also wanted to answer the following question:

- What side effects could the participants develop during the study?

There were some additional questions that researchers wanted to answer but these are not discussed in this summary.

# How long was this study?

Study started Study ended

August 2011 March 2012

An individual participant could have been in this study for 3 to 6 weeks.

The study started in August 2011 and ended in March 2012. A study report was created. This summary is based on that report.

# Who was in this study?

This study included 58 participants from the United States.

**In Part 1 of this Study**

**8** participants took part

**38%** were women (3 out of 8)

**62%** were men (5 out of 8)

Participants had an average age of **26** years

**In Part 2 of this Study**

**50** participants took part

**34%** were women (17 out of 50)

**66%** were men (33 out of 50)

Participants had an average age of **33** years

Participants could take part in this study if they were healthy individuals and:

- were 18 to 50 years of age,
- had normal kidney and liver functions as measured by different blood tests, and
- were using effective birth control methods during the study or were unable to have children.

# What happened during this study?

This was a Phase 1 study. Phase 1 studies are done to find out how new study treatment works in a small number of healthy participants. This helps researchers understand what happens to the study treatment in the body, and if there are any side effects.

This study was “open label”. This means that both the researchers and the participants knew which treatment was given to which participants.

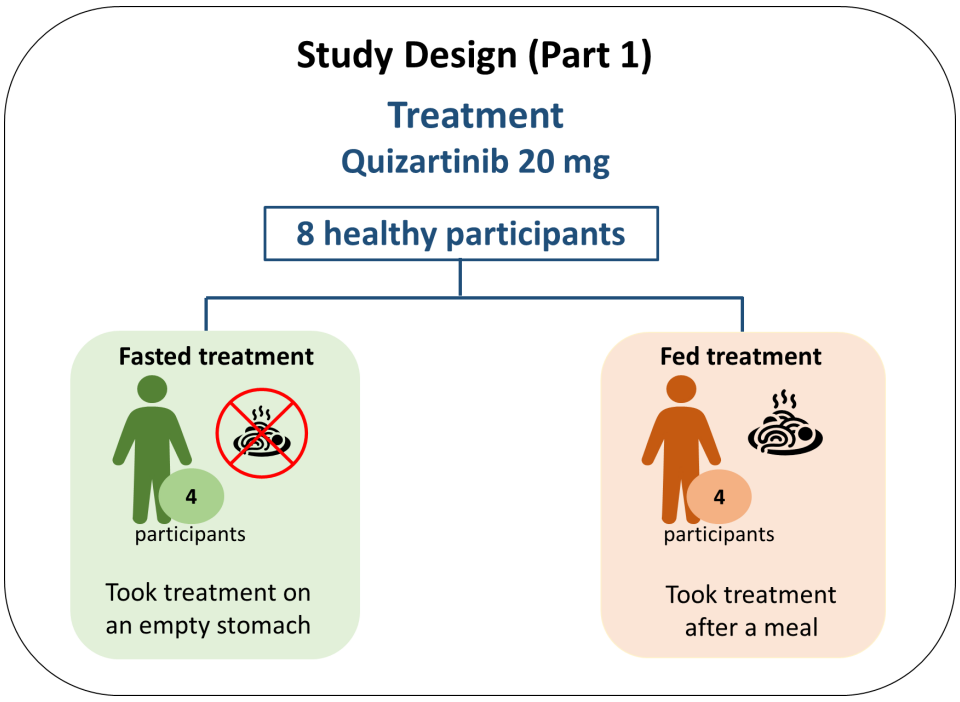
There were 2 situations in which the treatments were administered in the study:

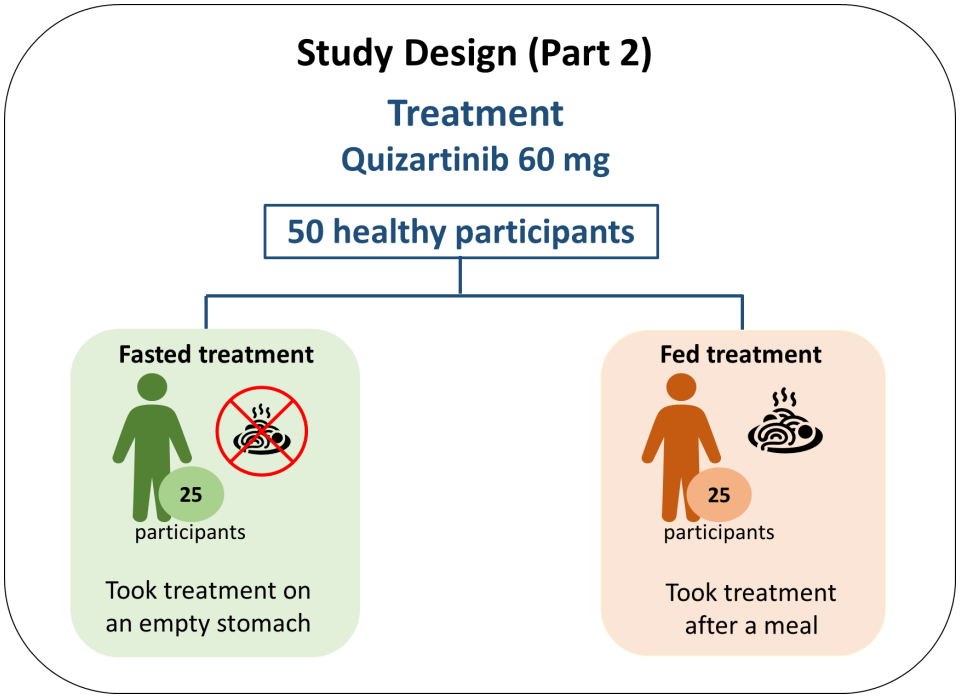
Quizartinib administered **without** food (**fasted conditions)**: participants fasted overnight for 10 hours and continued to fast for 4 hours after taking the study treatment

Quizartinib administered **with** food (**fed conditions)**: participants fasted overnight for 10 hours and then had a meal. Quizartinib was administered 30 minutes after the meal. Participants fasted for 4 hours after taking the study treatment.

**Part 1:** This part of the study was the dose selection part. It included 8 participants. Based on the results of this part, a higher or lower dose for the Part 2 was to be selected. Participants were randomly assigned to 1 of the 2 treatment arms (4 participants in each arm). On Day 1, 4 participants received a single dose of quizartinib 20 mg solution by mouth under fed conditions and 4 participants received the same dose under fasted conditions.

**Part 2:** This part of the study included 50 participants. Participants were randomly assigned to 1 of the 2 treatment arms (25 participants in each arm). On Day 1, 25 participants received a single dose of quizartinib 60 mg solution by mouth under fed conditions and 25 participants received the same dose under fasted conditions. The dose of quazirtinib was selected based on the analysis of Part 1 of the study.


Study Design (Part 1)
Treatment
Quizartinib 20 mg
8 healthy participants
Fasted treatment
4
participants
Took treatment on an empty stomach
Fed treatment
4
participants
Took treatment after a meal


Study Design (Part 2)
Treatment
Quizartinib 60 mg
50 healthy participants
Fasted treatment
25
participants
Took treatment on an empty stomach
Fed treatment
25
participants
Took treatment after a meal

# What were the key results of this study?

Key results from this study are shown for the total group of participants as average results. This summary does not show the results from each individual participant. An individual participant's results could be different from the total group of participants. A full list of the questions the researchers wanted to answer, and a detailed presentation of the results can be found on the websites listed at the end of this summary.

## What was the effect of food on the levels of quizartinib and its active breakdown product AC886 in the blood of healthy participants?

To answer this question, the researchers collected blood samples from the participants at defined timepoints over a period of time. They measured the levels of quizartinib and AC886 in the participants' blood during the study.

However, the blood samples from this study were not properly processed. Therefore**,** it was not possible to accurately measure the effects of food on the blood levels of quizartinib and its active breakdown product AC886. The effect of food on the blood levels of quizartinib was repeated in another study, AC220-019.

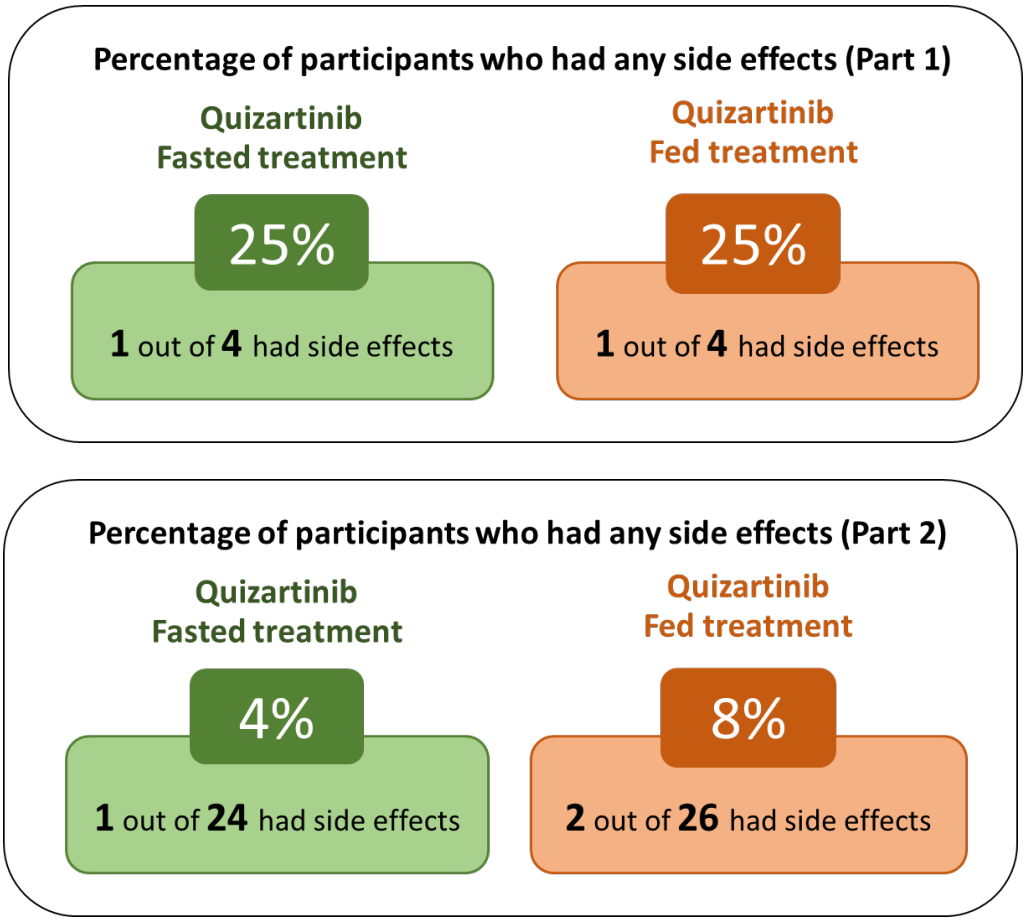
# What were the other results of this study?

## What side effects did the participants develop during the study?

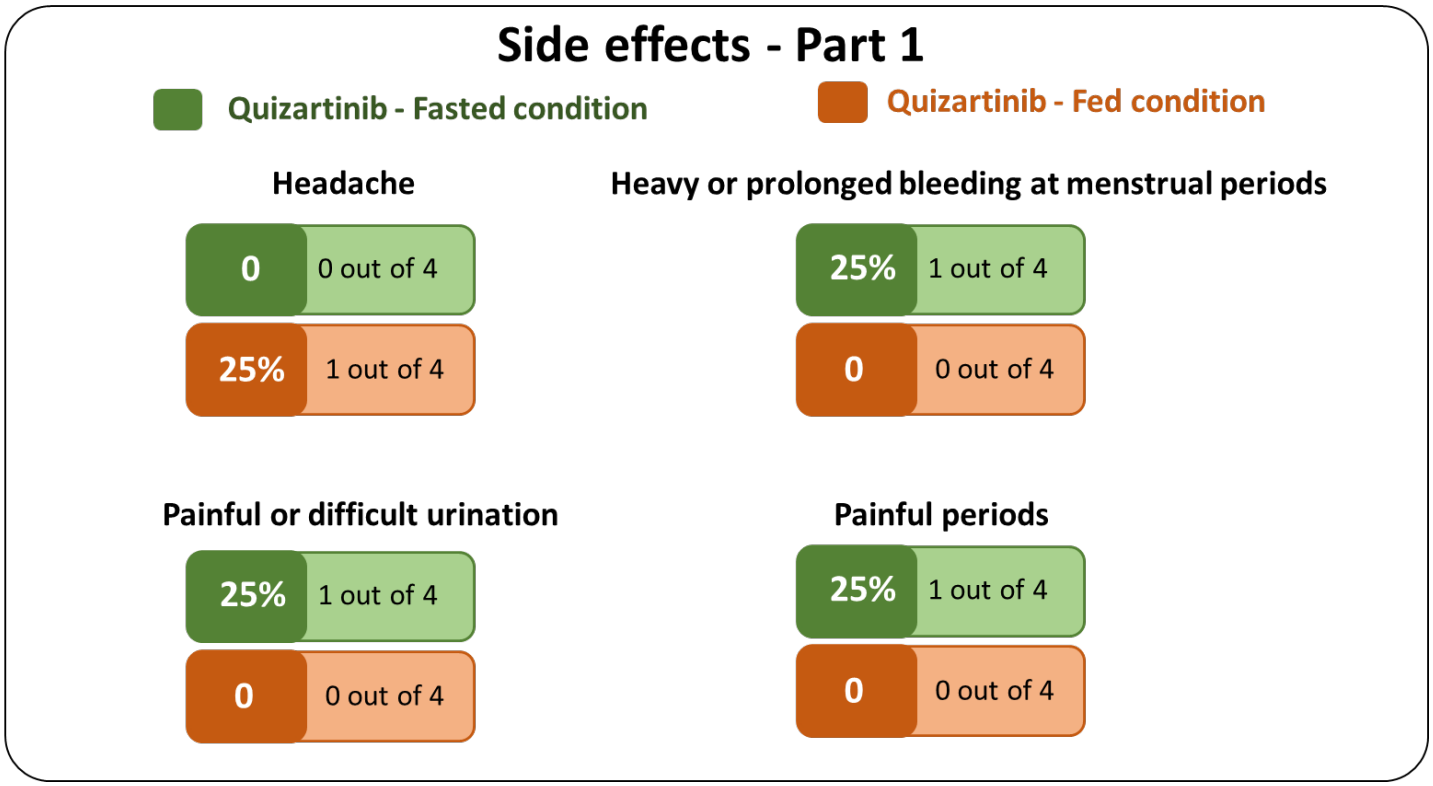
Side effects are medical problems (this may range from something mild such as feeling tired or something more severe like a severe infection or other medical problem) that happened during the study, which the study doctor thought could be related to the treatments in the study.

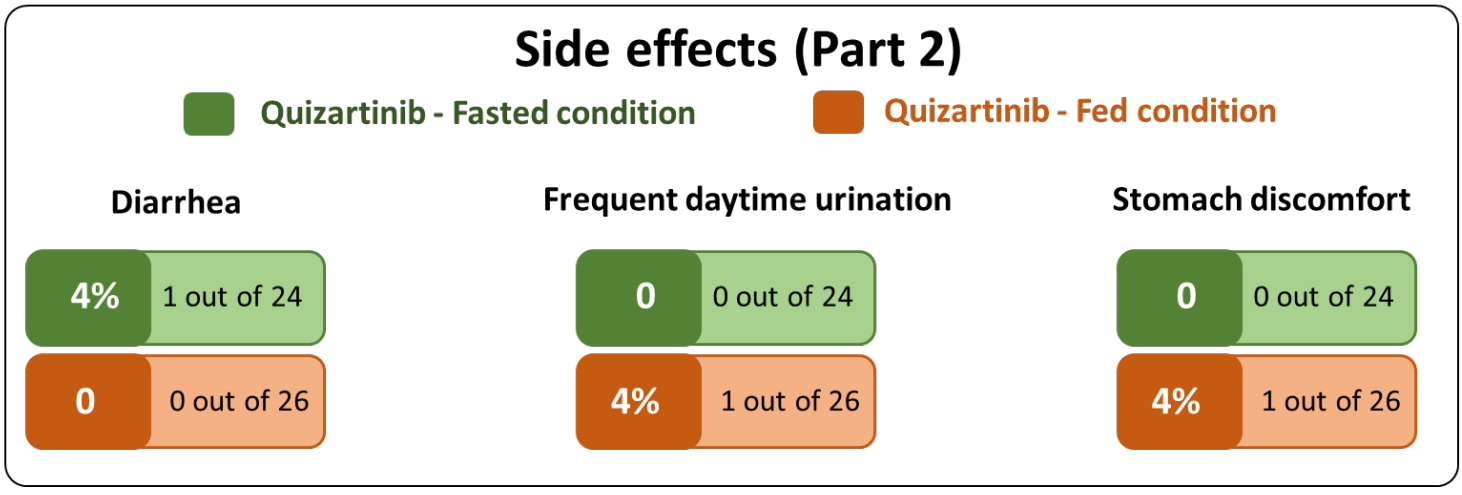
Side effects are considered serious if they cause death, are life-threatening, cause disability, cause lasting problems, cause birth defects, or require hospitalization. Some participants stopped study treatment because of side effects.

Side effects other than those related to quizartinib are not reported here. For more information on medical problems, please visit the websites listed at the end of this summary. The overall percentage (number) of participants who had any side effects in any group are presented below:



The most commonly reported side effects (part 1 and 2) are presented below:



## How was this study useful for patients and researchers?

This study was designed to help researchers understand the effect of food on the levels of quizartinib in blood and its breakdown product AC886 in healthy participants. However, it was not possible to determine this because of an issue with blood sample processing during the study.

Findings from this study may be used in other studies. Other studies for quizartinib are ongoing and the sponsor plans to conduct more studies in the future.

Please remember, this summary only shows the results of a single study. Other studies may have different findings. Please talk to a doctor before changing any treatment you are taking or if you have any questions about these study results.

## Where can I learn more about this study?

If you were a study participant and have questions about the results of this study, please speak with the doctor or staff at your study site.

**Full study title:** A Phase 1, Open-Label, randomized, Balanced, Single-Dose, Parallel Design AC220 Food Effect Study in Healthy Volunteers

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