Plain Language Summary of Study Results

Astellas is grateful to the people who took part in this clinical study.

Thank you!

Study Sponsor: **Astellas**

Medicine Studied: **ASP2215**

Study Number: **2215-CL-1101**

What was the study called?

A study of ASP2215 (gilteritinib) given with atezolizumab in people with acute myeloid leukemia.

Why was the study needed?

Acute myeloid leukemia, or AML, is a type of cancer when bone marrow makes too many abnormal white blood cells. These cells are called leukemia cells. The main treatment offered for people with acute myeloid leukemia is chemotherapy. However, chemotherapy might not work well in some people.

ASP2215 (also known as gilteritinib) when given with atezolizumab, is being studied as a potential new treatment for people with acute myeloid leukemia. This study provided more information on this combined treatment.

The study started in June 2019 and stopped in June 2021. The study stopped earlier than planned for business reasons. Astellas reviewed all the study information and created a report of the results. This is a summary of that report.

What were the main questions this study helped answer?

- Did people in the study have any medical problems from taking gilteritinib together with atezolizumab?

What kind of study was this and who took part in it?

This study was designed to learn which doses of atezolizumab, when given with gilteritinib, resulted in the fewest medical problems.

Each person in the study and the study doctors knew which dose of atezolizumab that person received.

People with acute myeloid leukemia (AML) who also had a faulty FLT3 gene were in this study. Their cancer had not responded to chemotherapy, or their cancer came back some time after chemotherapy.

Information on people who took part in the study
11 people from 20 to 87 years old took part
7 men 4 women
They were all treated with gilteritinib and atezloizumab

Where did the study take place?

This study took place at 6 clinics in the United States.

What happened during the study?

The study doctors did a check-up to make sure each person could be in the study before they received their assigned treatment.

Assigned treatment
120 mg **gilteritinib** and 420 mg **atezolizumab** OR 120 mg **gilteritinib** and 840 mg **atezolizumab**

mg = milligrams

People taking part in the study took a 120 mg tablet gilteritinib once a day. They did this on continuous 28-day cycles.

They were given a diary on the first day of every cycle with gilteritinib. This was to record information such as any medical problems with gilteritinib during the cycle.

They also received an infusion of atezolizumab once every 2 weeks.

People returned to the study clinic for their atezolizumab infusions. During these visits, they also had a check-up and were asked if they had any medical problems.

People stayed on this treatment until it was no longer helping them or caused any medical problems. Once treatment stopped, they returned to the clinic 30 days later for a final check-up. After this, the clinic staff phoned them every 3 months to check for any medical problems.

What were the study results?

- Did people in the study have any medical problems from taking gilteritinib together with atezolizumab?

What adverse reactions did people have in this study?

A lot of research is needed to know whether a medicine causes a medical problem. When new medicines are being studied, researchers keep track of all medical problems that people have while they are in the study. These problems are called adverse events and are recorded whether or not they might be caused by the treatment taken.

An adverse reaction is any medical problem or adverse event that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

10 out of 11 people (90.9%) had adverse reactions in this study.

The next table shows the most common **adverse reactions** that people reported.

	gilteritinib with atezolizimab (11 people)
fever caused by a dangerously low level of a type of white blood cell (neutrophil)	6 (54.5%)
fatigue	4 (36.4%)
diarrhea	3 (27.3%)
decreased appetite	3 (27.3%)
nausea	3 (27.3%)

Did any of the people in this study have serious adverse reactions?

An adverse reaction is considered serious when it is life-threatening, causes lasting problems or needs hospital care.

9 people had serious adverse reactions in this study. The most common serious adverse reaction was fever caused by a dangerously low level of a type of white blood cell (neutrophil). This happened in 6 people.

6 people passed away; 3 during the study and 3 during the follow-up after they had left the study. None of the deaths were thought to be caused by their treatment in this study.

Where can I learn more about this study?

This document is a short summary of the main results from this study.

The full name for the study is: A Phase 1/2 Study of ASP2215 (Gilteritinib) Combined with Atezolizumab in Patients with Relapsed or Treatment Refractory FLT3 Mutated Acute Myeloid Leukemia.

You can find this summary and more information about this study at

https://www.trialsummaries.com

Further information can be found at the following websites:

https://clinicaltrials.gov/ ClinicalTrials.gov Identifier: NCT03730012

Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. This summary only shows the results of this 1 study. Your doctor may help you understand more about the results of this study.

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This summary was written by Astellas in April 2022.