CLINICAL TRIAL RESULTS

Researchers look at the results of many studies to decide if a study treatment works, how it works, and if it is safe for patients. It takes people taking part in many studies around the world to help researchers make these decisions. This summary only shows the results from this study. Other studies might have different results.

Sponsor	**BeiGene, Ltd.**
Medicine(s) Studied	**Tislelizumab**
Protocol Number	**BGB-A317-208**
Dates of Study	**April 2018 to July 2022**
Title of This Study	**Safety and Efficacy of Tislelizumab in Patients With Hepatocellular Carcinoma**
Date of This Report	**July 2023**

Thank You!

BeiGene, who managed this study, thanks participants for taking part in the clinical study for a new medical treatment called tislelizumab. In this study, researchers learned more about the safety and efficacy of tislelizumab, also called BGB-A317, and how it may work in patients with a type of cancer called hepatocellular carcinoma.

BeiGene thinks it is important to share the results of the study with the public. If you participated in the study and have questions about the results, please speak with the doctor or staff at your study center.

Why was this study done?

Researchers are looking for better ways to help people with different types of cancer, including hepatocellular carcinoma (HCC) which is a type of liver cancer. HCC starts in the cells of the liver, which is a football-sized organ located in the upper-right part of the body just above the stomach. Mutations or changes to the DNA can cause liver cells to grow out of control and form a tumor. Symptoms of HCC may include weight loss, upper abdominal pain, and yellow discoloration of the skin.

In this study, researchers wanted to learn more about how safe tislelizumab is and how it works in patients with HCC who have been treated with chemotherapy or other drugs that target liver cancer and who are not eligible for surgery. Tislelizumab is a protein that strongly binds to a cell surface receptor protein called PD-1. Binding to these receptors may help immune system cells, called T cells, protect the body from infection and attack tumor cells.

Before a new medical treatment can be approved for humans, researchers must conduct clinical studies to learn how safe the treatment is by looking at adverse events, or side effects, and how well the treatment works. Adverse events are unwanted medical problems patients can experience that may or may not be caused by the treatment.

Researchers in this study wanted to know:

- What adverse events patients who received study treatment would have
- How many patients who received study treatment would no longer have evidence of cancer or would have some improvement in the signs and symptoms of cancer

BeiGene

Who was in this study?

249 HCC patients
aged **28 to 90 years**

217 patients were men
87.1% of patients

32 patients were women
12.9% of patients

When and where was this study done?

This study started in April 2018 through July 2022. The study was conducted at 73 study centers in multiple countries, including:

Mainland China
104 patients

Taiwan China
18 patients

France
77 patients

United Kingdom
21 patients

Italy
14 patients

Spain
7 patients

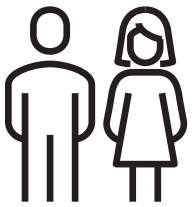
Germany
4 patients

Poland
4 patients

BeiGene

How was this study done?

In this study, patients with HCC were given 200 milligrams of tislelizumab as an infusion through a vein once every 3 weeks.



All patients with HCC were infused with **tislelizumab**

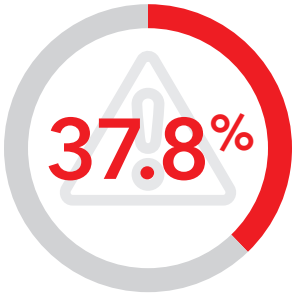
EVERY 3 WEEKS

Researchers determined how many patients responded to the treatment using the "overall response rate" or ORR. ORR is used to describe the number of patients with complete and partial responses to treatment, also called remission. Complete response means that patients no longer had evidence of cancer and partial response means that there was an improvement in the signs and symptoms of cancer.

What adverse events did patients have?

Adverse events are medical problems that may or may not be caused by the study treatment. An adverse event is called "serious" if it causes long-lasting problems, puts the patient in the hospital, is life-threatening, is considered medically important by the study researcher, or leads to death. A total of 249 patients were assessed for adverse events.

of patients had at least 1 adverse event



of patients had serious adverse events

of patients had adverse events that caused them to stop treatment

Below are the adverse events that patients had in this study. The websites listed at the end of this summary may have more information about the adverse events that occurred in this study.

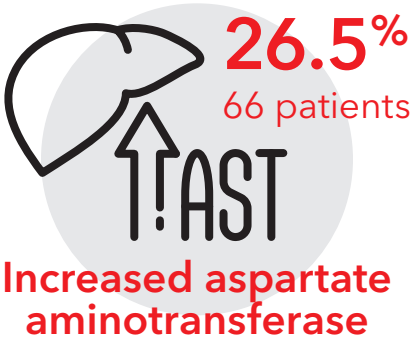
What serious adverse events did patients have?

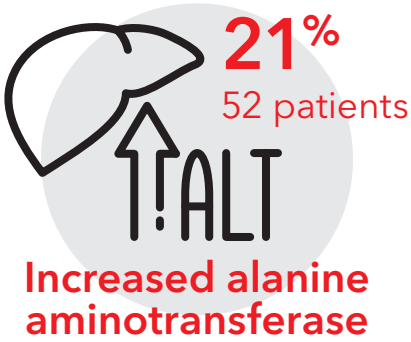
Excess abdominal fluid was the most common serious adverse event that occurred in at least 3% of patients in this study.

Twenty-six patients (10.4%) had adverse events that led to death. None of the adverse events that led to death were caused by tislelizumab.

What were the most common adverse events?

Increased laboratory values were the most common adverse events. The figure below shows the most common adverse events that occurred in at least 20% of the patients in this study.



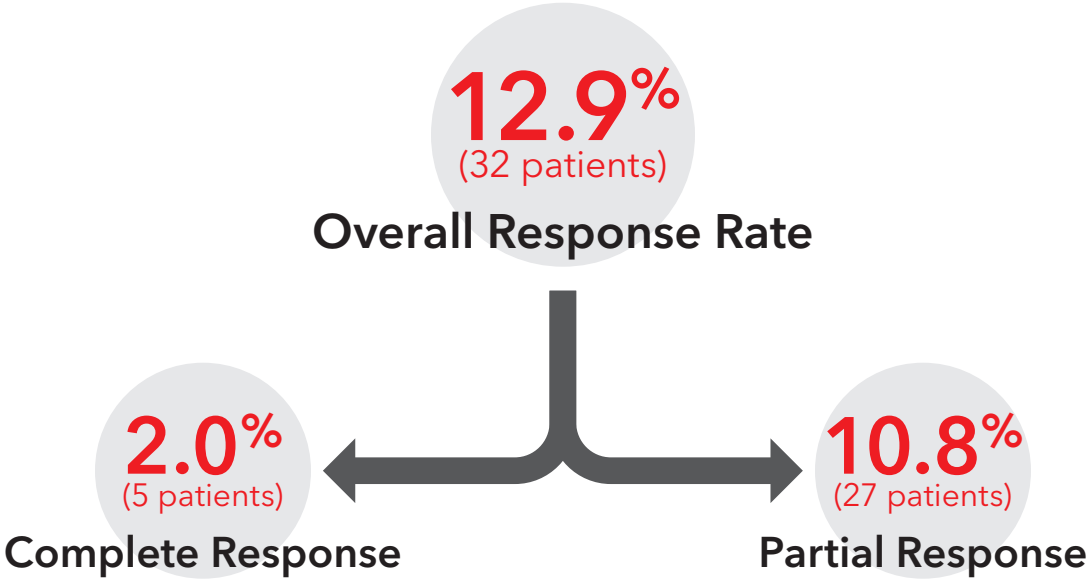


What were the main results of the study?

Below is a summary of the main results of this study. The results for each patient in the study are not shown here and may be different from the overall results shown below. You can find a full list of the questions for this study on the websites listed on the last page of this summary. If results are already available, they will also be found on these websites.

How many patients who took part in the study no longer had evidence of cancer or had some improvement in the signs and symptoms of cancer?

Measuring ORR is one way to determine how well a new treatment works. The percentage of patients with HCC who no longer had evidence of cancer or had an improvement in the signs and symptoms of cancer after treatment is shown below. A total of 249 patients were included in this analysis.



How has this study helped people?

The results from this study will help researchers understand more about how tislelizumab works in patients with HCC and may provide additional treatment options for patients in the future. More studies with tislelizumab are ongoing and planned.

The results in this summary come from this one study. Other studies may show different results. If you participated in this study and have questions about the results, please speak to the doctor or staff at your study center. You should not make changes to your treatments based on the results of this study.

Where can I find out more about this study?

More information about this study, including any available results, is found below:

The full title of this study is
A Phase 2, Open-Label, Multicenter Study to Investigate the Efficacy, Safety, and Pharmacokinetics of the Anti-PD-1 Monoclonal Antibody BGB-A317 in Patients With Previously Treated Hepatocellular Unresectable Carcinoma

The protocol number is
BGB-A317-208

For information about this study in the United States
Click here

For information about this study in the European Union
Click here

For information about this study from BeiGene
Click here

Clinical study patients help researchers make important discoveries that may lead to new medical treatments worldwide. BeiGene sponsored this study and is thankful for the help of the study patients.

For more information about BeiGene:

- Our main office is located in San Mateo, CA, USA
- Our phone number is +1 (877) 828-5568
- Our email address is ClinicalTrials@beigene.com

BeiGene thanks all the participants for their time and effort that went into making this study possible. Clinical study participants help advance science!