CLINICAL TRIAL RESULTS

Researchers look at the results of many studies to decide which treatments may offer patients improvements in terms of efficacy and safety. It takes people taking part in many studies around the world to help researchers decide this. This summary only shows the results from this study. Other studies might have different results.

Sponsor	**BeiGene, Ltd.**
Medicine(s) Studied	**Tislelizumab (BGB-A317) and BGB-30813**
Protocol Number	**BGB-A317-30813-101**
Dates of Study	**August 7th, 2023 to August 20th, 2025**
Title of This Study	**A Study of BGB-30813 Alone or in Combination With Tislelizumab in Participants With Advanced or Metastatic Solid Tumors**
Date of This Report	**16 July 2026**

Thank You!

BeiGene who managed this study, thanks the study patients for taking part in the clinical study for a new medical treatment called BGB-30813 and tislelizumab. In this study, researchers wanted to learn about the safety of BGB-30813 when given by itself or together with tislelizumab. They also wanted to find out how well these treatments worked in people with cancers that form solid tumors and had either spread to other parts of the body or grown into nearby tissues.

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 cancers that form solid tumors and have either spread to other parts of the body or grown into nearby tissues. Cancer begins when cells in the body grow and divide in an uncontrolled way. Solid tumors are masses of cancer cells that can form in organs or tissues, such as the lungs, breast, colon, liver, or pancreas. When cancer spreads to other parts of the body, it is called metastatic cancer. When cancer has grown into nearby tissues but has not spread far away, it is called locally advanced cancer. Symptoms can vary depending on where and how far the cancer has spread.

In this study, researchers wanted to learn more about how safe BGB-30813 is when given alone or together with tislelizumab and how well it works in people with advanced solid tumors that could not be removed with surgery or had spread to other parts of the body, whose cancer had gotten worse after standard treatment or for whom standard treatment was no longer available or had not worked.

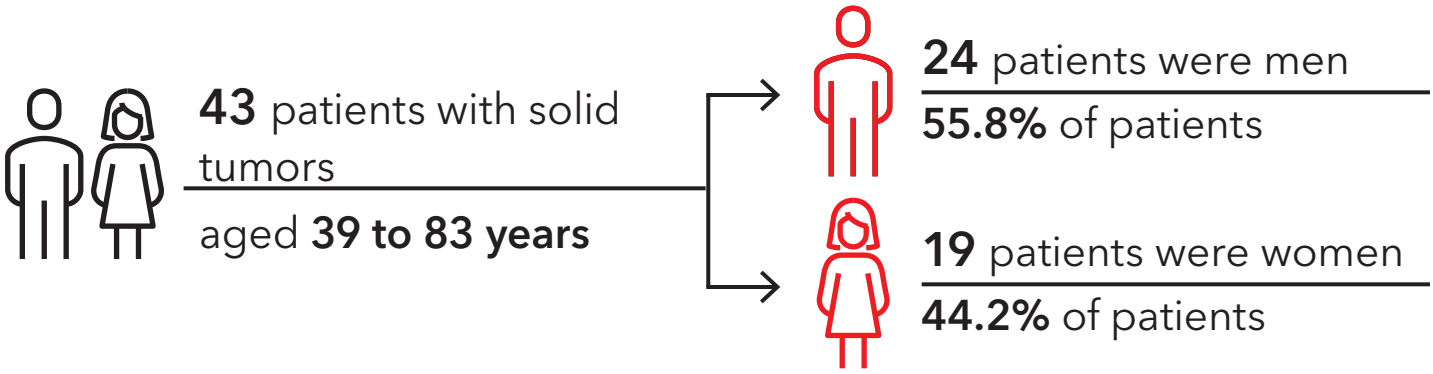
BGB-30813 is a new medicine that blocks a protein called diacylglycerol kinase zeta (DGKζ). Blocking this protein may help immune cells become more active so they can better recognize and attack cancer cells. Tislelizumab is an approved immunotherapy that blocks a protein called PD-1, which cancer cells can hide from the immune system. By blocking PD-1, tislelizumab helps the body's immune system find and destroy cancer cells.

Before a new medical treatment can be approved for use in patients, 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 would patients who took part in this study have?
- What is the maximum tolerated dose of BGB-30813?

A total of 43 patients ranging in age from 39 to 83 years were in the study. There were 24 men (55.8%) and 19 women (44.2%).



When and where was this study done?

This study started in August 2023 and ended in August 2025. The sponsor decided to stop the study early because the information collected showed that continuing the study was unlikely to provide additional benefit for participants. The study was conducted at multiple study centers in three countries, including:

- United States of America, with 8 patients
- Spain, with 25 patients
- Australia, with 10 patients

How was this study done?

In this study, participants with solid tumors received different doses and dosing schedules of BGB-30813 to help researchers find the dose that was safest and had the most potential benefit. The study was originally planned to have two parts. In the first part (Phase 1a), patients received BGB-30813 by mouth as a tablet at doses ranging from 20 milligrams (mg) to 240 mg, taken either once or twice a day. Some participants received BGB-30813 alone, while others received it together with tislelizumab, which was given as an infusion every 3 weeks.

The second part of the study (Phase 1b) was planned to include more patients receiving the selected dose of BGB-30813 to learn more about its safety and potential benefits. However, this part of the study did not begin because the study ended early.

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Patients received BGB-30813 to find the right dose and schedules

26 patients received BGB-30813 by mouth alone

- 20 mg once daily
- 60 mg once daily
- 120 mg once daily
- 240 mg once daily
- 120 mg twice daily

17 patients received BGB-30813 by mouth + tislelizumab by infusion together

- 10 mg once daily
- 20 mg once daily
- 30 mg twice daily

\+ Tislelizumab 200 mg by IV every 3 weeks

One of the main goals of this study was to find the maximum tolerated dose (MTD) of BGB-30813. MTD is the highest dose that most people can take without experiencing too many side effects. Researchers closely watched patients during the first 21 days of treatment to see if they had any dose limiting toxicities (DLTs), or what is known as a side effect serious enough to prevent giving a higher dose of the study drug. The MTD would be the highest dose at which fewer than about 3 out of every 10 patients experienced a DLT. Finding the MTD helps researchers choose to study in future clinical trials.

What adverse reactions did patients have?

Adverse reactions are unwanted medical problems that doctors think may be caused by the study treatment. An adverse reaction 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 doctor, or leads to death. A total of 43 patients were evaluated for adverse reactions.

The adverse reactions in this study that the doctors felt may have been caused by the study treatment are shown. It takes many studies for researchers to know if an adverse reaction is caused by the study treatment. The websites listed at the end of this summary may have more information about the adverse reactions that occurred in this study.

In this study:

- 80.8% of patients in monotherapy arms and 94.1% in the combination arms had at least 1 adverse reaction
- 11.5% of patients in monotherapy arms and 35.3% in the combination therapy group had serious adverse reaction
- 15.4% of patients in monotherapy arms and 35.3% in the combination therapy group had adverse reactions that caused them to stop treatment
- 11.8% (2 of 17 patients) in the combination therapy group had a serious adverse reaction that led to death. Two of the adverse reactions that led to death were thought to be caused by BGB-30813.

What serious adverse reactions did patients have?

Cytokine release syndrome (CRS) was the most common serious adverse reaction. CRS happens when the immune system overreacts and releases large amounts of cytokines into the bloodstream which can cause severe inflammation. The most common serious adverse reactions that occurred in at least 10% of the patients in either the BGB-30813 monotherapy group or the BGB-30813 + tislelizumab combination group are shown here.

Most Common Serious Adverse Reactions		
Serious Adverse Reaction	**Phase 1a: BGB-30813 Monotherapy (Out of 26 Patients)**	**Phase 1a: BGB-30813 + Tislelizumab Combination Therapy (Out of 17 Patients)**
Cytokine Release Syndrome (too many inflammatory proteins)	3.8% (1 patient)	17.6% (3 patients)
Haemophagocytic Lymphohistiocytosis (overactive immune system)	0% (0 Patients)	11.8% (2 patients)

What were the most common adverse reactions?

Diarrhea was the most common adverse reaction. The most common adverse reactions that occurred in at least 20% of the patients in either the BGB-30813 monotherapy group or the BGB-30813 + tislelizumab combination group are shown here.

Most Common Adverse Reactions		
Adverse reaction	**Phase 1a: BGB-30813 Monotherapy (Out of 26 Patients)**	**Phase 1a: BGB-30813 + Tislelizumab Combination Therapy (Out of 17 Patients)**
Diarrhea	42.3% (11 patients)	47.1% (8 patients)
Nausea	38.5% (10 patients)	11.8% (2% (2 patients)
Vomiting	23.1% (6 patients)	17.6% (3 patients)
Fatigue	34.6% (9 patients)	23.5% (4 patients)
Asthenia (weakness)	23.1% (6 patients)	0% (0 patients)
Dizziness	23.1% (6 patients)	0% (0 patients)
Cytokine release syndrome (too many inflammatory proteins)	3.8% (1 patient)	23.5% (4 patients)

What were the main results of the study?

The main results of the study are summarized here. The results for each patient in the study are not shown here and may be different from the overall results.

You can find a full list of the questions for this study on the websites listed on the last page of this summary. If there are results 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 their cancer burden?

Researchers looked for the maximum tolerated dose (MTD), which is the highest dose that most patients can take without too many serious side effects. When BGB-30813 was given alone, the MTD was 120 mg once daily. When BGB-30813 was given together with tislelizumab, researchers could not determine the MTD because the study ended early.

How has this study helped patients and researchers?

The results from this study will help researchers and patients understand more about how BGB-30813 works in patients with solid tumors.

More studies with BGB-30813 are not planned at this time.

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 found 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 1a/1b Study Investigating the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Antitumor Activity of the DGKζ Inhibitor BGB-30813, Alone or in Combination With the Anti-PD-1 Monoclonal Antibody Tislelizumab in Patients With Advanced or Metastatic Solid Tumors

The protocol number is

BGB-A317-30813-101

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 in China

Click here

For information about this study from BeiGene

Click here

Clinical study participants 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 patients in this study.

For more information about BeiGene:

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