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	**Surzebiclimab (also called BGB-A425)** **Alcestobart (also called LBL-007)** **Tislelizumab (also called BGB-A317)**
Protocol Number	**BGB-900-102**
Dates of Study	**25 October 2018 to 06 February 2025**
Title of This Study	**Study of Surzebiclimab and Alcestobart in Combination With Tislelizumab in Advanced Solid Tumors**
Date of This Report	**15 December 2025**

Thank You!

BeiGene, who managed this study, thanks the study patients for taking part in the clinical study for two new medical treatments called surzebiclimab and alcestobart when given with another drug called tislelizumab.

In this study, researchers learned more about the safety and efficacy of surzebiclimab (also known as BGB-A425), and/or alcestobart (also known as LBL-007) when given together with tislelizumab (also known as BGB-A317), and how it may work in patients with solid tumors.

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 solid tumors. Solid tumors are cancerous lumps where cells grow uncontrollably. Some examples of solid tumors include breast cancer, lung cancer, head and neck cancer, and colorectal cancer.

In this study, researchers wanted to look at the safety and effectiveness of combining two or three experimental anticancer drugs called tislelizumab, surzebiclimab, and alcestobart. Adults with different kinds of advanced solid tumors participated in the study. Participants had previously received treatment for their cancer, but the cancer had returned or spread after that initial treatment.

Tislelizumab, surzebiclimab, and alcestobart are all antibodies that can attach to proteins called checkpoint proteins. Checkpoint proteins are found on some immune cells and work to regulate the immune system and prevent immune cells from attacking normal healthy cells. However, some cancer cells can trick the immune system by making checkpoint proteins. This helps them avoid being attacked by the immune system and allows the cancer to grow and spread. Tislelizumab, surzebiclimab, and alcestobart each work by blocking the checkpoint proteins on cancer cells and may help to reactivate the body's immune system to recognize and attack 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.

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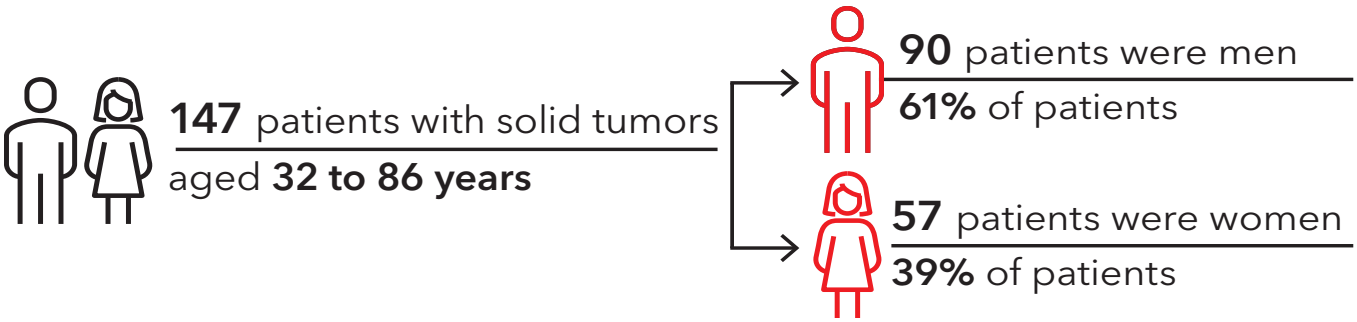
Researchers in this study wanted to know:

- What adverse events would patients who took part in this study have
- What is the safest and effective dose combination dose for participants with solid tumors
- Did patients in the study have improvements in the signs and symptoms of cancer?

Who was in this study?

A total of 147 patients ranging in age from 32 to 86 years were in the study. There were 90 men (61%) and 57 women (39%).



When and where was this study done?

This study started in October 2018 and ended in February 2025. The study was conducted in 6 countries, including 3 countries in the European Union and 3 other countries:

- Australia with 54 patients
- France with 7 patients
- Italy with 4 patients
- South Korea, with 24 patient
- Spain with 9 patients
- United States of America with 49 patients

How was this study done?

This study had three main parts:

Part 1 was called the Dose Escalation part. In this part of the study small groups patients with advanced solid tumors took a combination of tislelizumab and surzebiclimab. The first group of participants took a low dose of surzebiclimab with a standard dose of tislelizumab, the dose of surzebiclimab was very gradually increased in other groups of patients to find the safest dose combination of tislelizumab and surzebiclimab.

Part 2 was called the Safety Lead-in part. There were 2 main groups of patients in this part of the study:

- Patients who took alcestobart and tislelizumab
- Patients who took surzebiclimab, alcestobart, and tislelizumab

Part 3 was called the Dose Expansion part. Patients with certain types of cancer were treated as follows:

- Patients with head and neck squamous cell carcinoma (HNSCC) took surzebiclimab and tislelizumab
- Patients with non-small cell lung cancer (NSCLC) took surzebiclimab and tislelizumab
- Patients with head and neck squamous cell carcinoma took surzebiclimab, alcestobart, and tislelizumab
- Patients with non-small cell lung cancer took surzebiclimab, alcestobart, and tislelizumab

Patients could continue taking the treatment as long as there was no worsening of disease and there were no intolerable side effects.

Part 1: Dose Escalation

33 patients
were assigned to the
Surzebiclimab + Tislelizumab
treatment group

Part 2: Safety Lead-in

16 patients
were assigned to the
Alcestobart + Tislelizumab
treatment group

15 patients
were assigned to the
Surzebiclimab + Alcestobart + Tislelizumab
treatment group

Part 2: Dose Expansion

43 patients
were assigned to the
Alcestobart + Tislelizumab
treatment group

40 patients
were assigned to the
Surzebiclimab + Alcestobart + Tislelizumab
treatment group

The main purpose of Part 1 was to find the safest effective dose of surzebiclimab when taken together with tislelizumab in patients with solid tumors.

In Part 2, researchers wanted to find the safest effective dose of alcestobart when taken together with tislelizumab, and when taken together with surzebiclimab and tislelizumab.

In Part 3 researchers wanted to know whether the combinations of surzebiclimab taken together with tislelizumab, and alcestobart taken together with both surzebiclimab and tislelizumab shrank the size of the tumors in patients with non-small cell lung cancer of head and neck squamous cell carcinoma.

What adverse reactions did the study participants 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 147 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 below. 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:

- 61% of patients in Part 1, 55% of patients in Part 2, and 64% of patients in Part 3 had at least 1 adverse reaction.
- 9.1% of patients in Part 1, 16% of patients in Part 2, and 3.6% of patients in Part 3 had serious adverse reactions.
- 9.1% of patients in Part 1, 13% of patients in Part 2, and 1% of patients in Part 3 had adverse reactions that caused them to stop treatment.
- No patients had a serious adverse reaction that led to death during the study.

What serious adverse reactions did study participants have?

There were no serious adverse reactions that were experienced by more than 1 patient. All serious adverse reactions in this study are shown in the tables below.

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Most common serious adverse reactions In Part 1 and Part 2:

Serious adverse reaction	Part 1 Surzebiclimab + Tislelizumab (Out of 33 patients)	Part 2 Alcestobart + Tislelizumab (Out of 16 patients)	Part 2 Alcestobart + Surzebiclimab + Tislelizumab (Out of 15 patients)
Autoimmune myocarditis	3.0% (1 patient)	0.0% (0 patients)	0.0% (0 patients)
Diarrhea	3.0% (1 patient)	0.0% (0 patients)	0.0% (0 patients)
Pneumonitis	3.0% (1 patient)	0.0% (0 patients)	0.0% (0 patients)
Adrenal insufficiency	0.0% (0 patients)	0.0% (0 patients)	6.7% (1 patient)
Hypothyroidism	0.0% (0 patients)	0.0% (0 patients)	6.7% (1 patient)
Immune-mediated arthritis	0.0% (0 patients)	0.0% (0 patients)	6.7% (1 patient)
Colitis	0.0% (0 patients)	6.3% (1 patient)	0.0% (0 patients)
Troponin T increased	0.0% (0 patients)	6.3% (1 patient)	0.0% (0 patients)
Pleural effusion	0.0% (0 patients)	6.3% (1 patient)	0.0% (0 patients)
Capillary leak syndrome	0.0% (0 patients)	6.3% (1 patient)	0.0% (0 patients)

Most common serious adverse reactions In Part 3:

Serious adverse reaction	HNSCC Surzebiclimab + Tislelizumab (Out of 21 patients)	NSCLC Alcestobart + Tislelizumab (Out of 22 patients)	HNSCC Alcestobart + Surzebiclimab + Tislelizumab (Out of 20 patients)	NSCLC Alcestobart + Surzebiclimab + Tislelizumab (Out of 20 patients)
Immune-mediated encephalopathy	0.0% (0 patients)	0.0% (0 patients)	0.0% (0 patients)	5.0% (1 patient)
Swollen tongue	4.8% (1 patient)	0.0% (0 patients)	0.0% (0 patients)	0.0% (0 patients)
Pneumonia	4.8% (1 patient)	0.0% (0 patients)	0.0% (0 patients)	0.0% (0 patients)
Immune-mediated lung disease	4.8% (1 patient)	0.0% (0 patients)	0.0% (0 patients)	0.0% (0 patients)

What were the most common adverse reactions?

The most common adverse reactions that occurred in at least 20% of the patients in the treatment groups are shown here.

Most common adverse reactions In Part 1 and Part 2:

Adverse reaction	Part 1 Surzebiclimab + Tislelizumab (Out of 33 patients)	Part 2 Alcestobart + Tislelizumab (Out of 16 patients)	Part 2 Alcestobart + Surzebiclimab + Tislelizumab (Out of 15 patients)
Hypothyroidism	6.1% (2 patients)	18.8% (3 patients)	20% (3 patients)

Most common serious adverse reactions In Part 3:

Adverse reaction	HNSCC Surzebiclimab + Tislelizumab (Out of 21 patients)	NSCLC Alcestobart + Tislelizumab (Out of 22 patients)	HNSCC Alcestobart + Surzebiclimab + Tislelizumab (Out of 20 patients)	NSCLC Alcestobart + Surzebiclimab + Tislelizumab (Out of 20 patients)
Asthenia	4.8% (1 patient)	0.0% (0 patients)	5.0% (1 patient)	30.0% (6 patients)
Decreased appetite	4.8% (1 patient)	0.0% (0 patients)	10.0% (2 patients)	20.0% (4 patients)
Pruritus	9.5% (2 patients)	0.0% (0 patients)	10.0% (2 patients)	20.0% (4 patients)
Fatigue	47.6% (10 patients)	18.2% (4 patients)	15.0% (3 patients)	5.0% (1 patient)

What were the main results of the study?

The main results of the study are summarized here. The results for each individual 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.

What was the safest effective dose of surzebiclimab when taken together with tislelizumab?

None of the tested doses of surzebiclimab taken together with tislelizumab caused severe health problems. After reviewing the data, researchers decided that 600 mg of surzebiclimab taken together with 200 mg of tislelizumab was the dose that should be used in Part 3 of the study.

What was the safest effective dose of alcestobart when taken together with surzebiclimab and tislelizumab?

None of the tested doses of alcestobart when taken together with tislelizumab and surzebiclimab caused any severe health problems. Researchers decided that 600 mg of alcestobart was the dose that should be used in Part 3 of the study.

Part 3 – Did the size of the cancer shrink in patients with NSCLC or HNSCC?

One patient with NSCLC showed no evidence of tumors and 4 patients out of 83 showed a partial reduction in size of their tumors after study treatment.

How has this study helped patients and researchers?

The results from this summary will help researchers and patients understand more about how surzebiclimab and alcestobart, when taken together with tislelizumab, work in patients with advanced solid tumors and may provide additional treatment options for patients in the future.

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

Phase 1-2 Study Investigating Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Various Combinations of BGB-A425 and LBL-007 with Tislelizumab in Patients with Advanced Solid Tumors

The protocol number is

BGB-900-102

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

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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!