CLINICAL TRIAL RESULTS

Researchers look at the results of many studies to decide which treatments may be best and safest 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 (BGB-A317)
Protocol Number	BGB-A317-312
Dates of Study	July 2019 to December 2023
Title of This Study	Study of Platinum Plus Etoposide With or Without Tislelizumab in Participants With Untreated Extensive-Stage Small Cell Lung Cancer
Date of This Report	October 2024

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 Extensive Stage Small Cell Lung Cancer (ES-SCLC).

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 exploring improved treatment options for ES-SCLC. ES-SCLC begins in the lungs and is characterized by aggressive growth and rapid spread due to genetic mutations that drive uncontrolled cell division. In its early stages, ES-SCLC often presents few or no symptoms, complicating early detection. As the disease advances, patients may experience persistent cough, chest pain, shortness of breath, or weight loss. In advanced cases, the cancer can block airways or invade surrounding tissues, necessitating prompt medical intervention and specialized therapies.

In this study, researchers wanted to learn how safe and helpful tislelizumab is for patients with ES-SCLC when combined with the chemotherapy drugs cisplatin, carboplatin, and etoposide. Tislelizumab helps the immune system fight cancer by blocking PD-1, which stands for Programmed Cell Death Protein 1. PD-1 is a protein on immune cells that acts as a brake, preventing them from attacking nearby cells. This is important for protecting healthy cells, but cancer cells can use PD-1 to hide from the immune system. By blocking PD-1, tislelizumab helps immune cells recognize and attack cancer cells. Cisplatin or carboplatin, often in combination with etoposide, is commonly used as a first-line treatment for ES-SCLC that has spread. This combination is standard because it helps to effectively target and kill cancer cells.

Before a new medical treatment can be approved for people to take, researchers must do clinical studies to learn how safe the treatment is by looking at adverse events, or side effects. Adverse events are unwanted medical problems that study participants can experience that may or may not be caused by the study drug. Researchers also must learn how the treatment works in people with the disease.

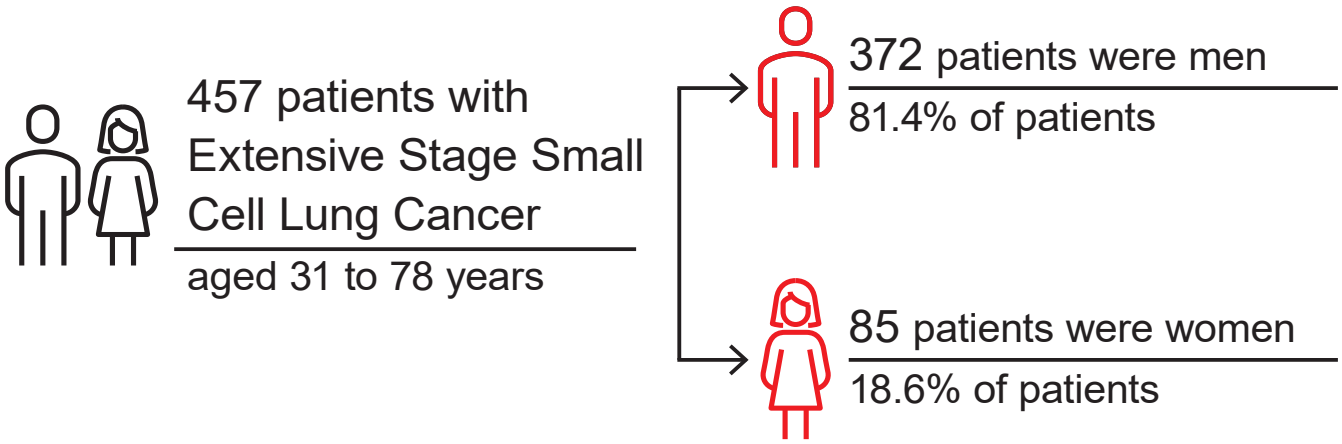
In this study, researchers compared the combination of tislelizumab with the standard chemotherapy treatment for ES-SCLC to a placebo with standard chemotherapy. A placebo is a harmless substance that looks like the real treatment but has no active medicine in it. This helps scientists see if adding tislelizumab to chemotherapy works better than chemotherapy alone..

Researchers in this study wanted to know:

- What adverse events would patients who took part in this study have?
- How long did patients participating in this study live after receiving this treatment?
- How long did patients participating in the study live without their cancer getting worse?

Who was in this study?

A total of 457 patients between the ages of 31 and 78 years were in the study. There were 372 men (81.4%) and 85 women (18.6%). All patients had a confirmed diagnosis of ES-SCLC and had not received any treatment for recurrent or metastatic ES-SCLC before. The patients did not have other medical conditions that could affect the study results.



When and where was this study done?

This study started in July 2019 and ended in December 2023. The study was conducted at 51 study centers in Mainland China.

How was this study done?

In this study, patients with ES-SCLC were randomly put into one of two groups: one group received tislelizumab with either cisplatin and etoposide or carboplatin and etoposide chemotherapy, while the other group received a placebo with the same chemotherapy options. Chemotherapy regimens were determined by the doctor. The patients in the tislelizumab group got 200 milligrams of tislelizumab through an intravenous infusion (IV) once every 3 weeks, along with the standard doses of cisplatin/carboplatin and etoposide. The placebo group got an injection that looked like tislelizumab but had no active ingredients, plus the standard doses of the other chemotherapy drugs. Randomly assigning patients to these groups helps ensure the groups are as similar as possible, so researchers can fairly compare the results.

227 patients
were assigned to the
tislelizumab + cisplatin + etoposide
or
tislelizumab + carboplatin + etoposide
treatment group

Patients were infused with
tislelizumab

200 mg

EVERY 3 WEEKS

+ cisplatin + etoposide infusion
or
+ carboplatin + etoposide infusion

230 patients
were assigned to the
placebo + cisplatin + etoposide
or
placebo + carboplatin + etoposide
treatment group

Patients were infused with
placebo

Placebo

EVERY 3 WEEKS

+ cisplatin + etoposide infusion
or
+ carboplatin + etoposide infusion

During this study, study doctors:

- Checked patients' overall health and took blood and urine samples
- Asked patients how they were feeling and what medicines they were taking
- Asked patients how well they could move and do their daily activities
- Measured how well patients' hearts were using an electrocardiogram machine
- Used a machine to take detailed images of patients' bodies to check on the tumor's condition

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 456 patients received at least one dose of study drug and were assessed for adverse events.

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.

- 99.6% of patients in the tislelizumab group and 99.6% of patients in the placebo group had at least 1 adverse event
- 41.4% of patients in the tislelizumab group and 30.6% of the patients in the placebo group had serious adverse events
- 13.2% of patients in the tislelizumab group and 3.1% of the patients in the placebo group had adverse events that caused them to stop the treatment.

What serious adverse events did patients have?

The most common serious adverse event in both groups was thrombocytopenia, a condition characterized by a lower-than-normal platelet count, which are the tiny cells in the blood that help stop bleeding, was the most common serious side effect in this study, affecting at least 7.5% of patients. The table below shows the most common serious adverse events that occurred in at least 5% of the patients in this study.

Most common serious adverse events		
Serious adverse event	Tislelizumab (227 Patients)	Placebo (229 Patients)
Thrombocytopenia	7.5% (17 patients)	7.9% (18 patients)
Neutrophil count decreased	7.0% (16 patients)	3.9% (9 patients)

A total of 14 patients (6.2%) in the tislelizumab group and 4 (1.7%) in the placebo group had adverse events that led to death. Eight (3.5%) of the adverse events leading to death in the tislelizumab group were possibly related to the study treatment.

What were the most common adverse events?

Anemia was the most common adverse event in both groups. The table below shows the most common adverse events that occurred in at least 50% of the patients in this study.

Most common adverse events		
Adverse event	Tislelizumab (227 Patients)	Placebo (229 Patients)
Anaemia	85% (193 patients)	84.7% (194 patients)
Alopecia (hair loss)	79.3% (180 patients)	79.5% (182 patients)
Neutrophil count decreased	68.7% (156 patients)	70.3% (161 patients)
White blood cell count decreased	55.9% (127 patients)	64.6% (148 patients)
Thrombocytopenia	49.8% (113 patients)	52.0% (119 patients)

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. Patients were followed for up to approximately 53 months from the time they started the trial to when their participation ended.

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 long did patients participating in this study live after receiving treatment?

Measuring **overall survival** is one way to determine how well a new cancer treatment works. The study compared patients in tislelizumab group to those in the placebo group to see who lived longer. In this study, a total of 457 patients were included in this analysis. Some patients lived for a shorter time, and some lived longer. Patients in the tislelizumab group had a median overall survival of about 15.5 month while patients in the placebo group had a median overall survival of about 13.5 months. Median is the middle number in a group of numbers.

How long do patients live without their cancer getting worse?

Researchers wanted to know how long patients survived without ES-SCLC getting worse after starting study treatment, also known as **progression free survival.** After about 14 months of follow-up, patients on tislelizumab plus chemotherapy had a 36% lower chance of their cancer growing or spreading compared with patients receiving placebo plus chemotherapy. During this time, the median length of time that patients survived without ES-SCLC getting worse was 4.7 months in the tislelizumab group and 4.3 months for patients in the placebo group. Median is the middle number in a group of numbers.

How has this study helped people and researchers?

The results from this study will help researchers understand more about how tislelizumab works in patients with ES-SCLC 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, can be found on the websites below:

The full title of this study is

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Platinum Plus Etoposide With or Without Tislelizumab (BGB-A317) in Patients With Untreated Extensive-Stage Small Cell Lung Cancer

The protocol number is

BGB-A317-312

For information about this study in the United States

Click here

For information about this study from China

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 patients in this study. 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