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**
Protocol Number	**BGB-A317-303**
Dates of Study	**November 2017 to January 2024**
Title of This Study	**Comparison of Efficacy and Safety of Tislelizumab (BGB-A317) Versus Docetaxel as Treatment in the Second- or Third-line Setting in Participants With Non-Small Cell Lung Cancer (NSCLC) (RATIONALE-303)**
Date of This Report	**March 2025**

Thank You!

BeiGene, who managed this study, thanks patients 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 Non–Small Cell Lung Cancer (NSCLC).

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 NSCLC. NSCLC is the most common type of lung cancer, beginning in the cells of the lungs and growing uncontrollably due to genetic changes. In its early stages, NSCLC often has no noticeable symptoms, making it difficult to detect. As the disease progresses, people may experience a persistent cough, shortness of breath, chest pain, and unexplained weight loss. In advanced cases, NSCLC can spread to other parts of the body, leading to severe complications that require immediate medical attention and personalized treatment approaches.

In this study, researchers wanted to better understand how safe tislelizumab is and how well it works in people with NSCLC whose cancer got worse during or after treatment with platinum-based chemotherapy. Tislelizumab is a protein that strongly binds to a cell surface protein called programmed cell death protein 1 (PD-1). By binding to PD-1, tislelizumab helps the body's natural immune cells (called T-cells) protect the body from infection and attack cancer cells.

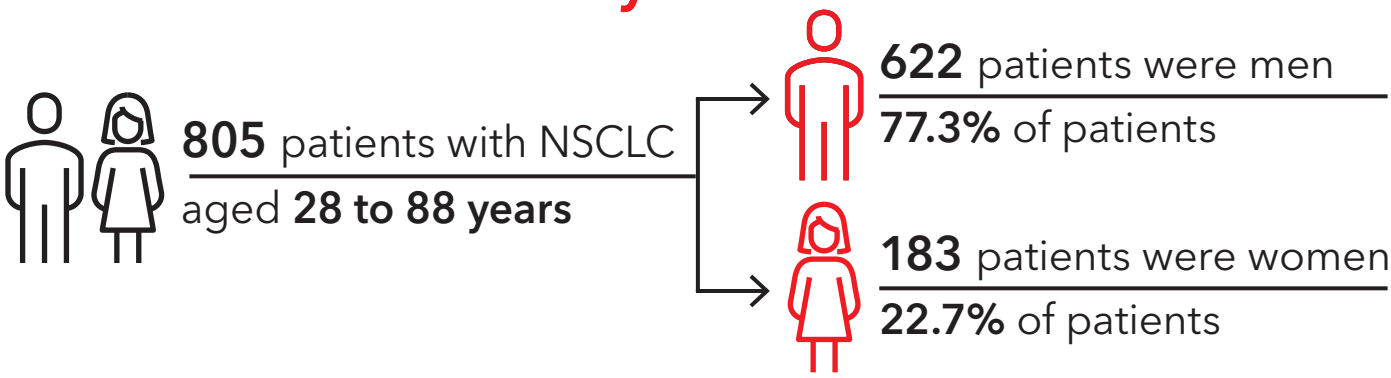
Before a new medical treatment can be approved for people to take, researchers must do clinical studies to learn how safe the treatment is by looking at adverse events, or side effects. Adverse events are unwanted medical problems that study patients can experience that may or may not be caused by the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

In this study, researchers compared tislelizumab to docetaxel, a common chemotherapy treatment for NSCLC, to see which works better.

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?

Who was in this study?



A total of 805 patients between the ages of 28 and 88 years were in the study. There were 622 men (77.3%) and 183 women (22.7%). All patients had a confirmed diagnosis of NSCLC and had already received at least one platinum-based treatment, but no more than two different rounds of cancer treatment for their disease. The patients did not have other medical conditions that could affect the study results.

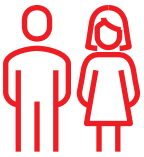
When and where was this study done?

This study started in November 2017 to January 2024. The study was done at 109 study centers in 10 countries, including:

- Mainland China, with 641 patients
- New Zealand, with 14 patients
- Bulgaria, with 2 patients
- Lithuania, with 5 patients
- Poland, with 4 patients
- Slovakia, with 5 patients
- Turkey, with 39 patients
- Brazil, with 25 patients
- Mexico, with 14 patients
- Russia, with 56 patients

How was this study done?

In this study, patients with NSCLC were randomly assigned to one of two treatment groups: either tislelizumab or docetaxel. Patients in the tislelizumab group received 200 milligrams (mg) of tislelizumab through an infusion into a vein every 3 weeks. Patients in the docetaxel group received 75 milligrams per square meter (mg/m^2) of docetaxel through an infusion every 3 weeks. The mg/m^2 means that the dose of docetaxel is based on the patient's body size, specifically their body surface area, which is a calculation that considers height and weight. Randomly putting patients into groups helps make sure the groups are balanced, allowing researchers to compare the results in the fairest way.

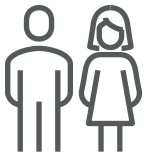


534 patients
were assigned to the
tislelizumab treatment group

Patients received
tislelizumab intravenously at

200 mg

ONCE EVERY 3 WEEKS



258 patients
were assigned to the
docetaxel treatment group

Patients received
docetaxel intravenously at

75 mg

ONCE EVERY 3 WEEKS

During this study, the 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
- Took pictures of the inside of the patients' bodies using two types of scans, CT (computed tomography) and MRI (magnetic resonance imaging) to help doctors see how the tumor is doing

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 792 patients were evaluated for this study.

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.

In this study:

- 97.0% of patients in the tislelizumab group and 98.4% of patients in the docetaxel group had at least 1 adverse event
- 36.0% of patients in the tislelizumab group and 32. 6% of the patients in the docetaxel group had serious adverse events
- 12.5% of patients in the tislelizumab group and 13.2% of the patients in the docetaxel group had adverse events that caused them to stop the treatment permanently.

What serious adverse events did patients have?

Pneumonia was the most common serious adverse event that occurred in the tislelizumab group.

Serious adverse event	Tislelizumab (534 patients)	Docetaxel (258 patients)
Pneumonia	7.3% (39 patients)	7.4% (19 patients)
Febrile neutropenia	0.0% (0 patients)	8.1% (21 patients)

A total of 35 patients (6.6%) in the tislelizumab group and 12 (4.7%) in the docetaxel group had adverse events that led to death. Eight (1.5%) of the adverse events leading to death in the tislelizumab group and 4 (1.6%) in the docetaxel group were possibly related to the study treatments.

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 20% of the patients in this study.

Adverse event	Tislelizumab (554 patients)	Docetaxel (258 patients)
Anemia	29.6% (158 patients)	45.3% (117 patients)
Cough	21.5% (115 patients)	15.5% (40 patients)
Liver Enzyme (Alanine aminotransferase) Increased	21.2% (113 patients)	15.1% (39 patients)
Liver Enzyme (Aspartate Aminotransferase) Increased	20.0% (107 patients)	12.4% (32 patients)
White blood cell counts decreased	3.9% (21 patients)	29.1% (75 patients)
Neutrophil (a type of white blood cells) count decreased	3.2% (17 patients)	36.8% (95 patients)
Decreased appetite	17% (91 patients)	24.0% (62 patients)
Weakness	14.2% (76 patients)	22.5% (58 patients)
Leukopenia (low white blood cell count)	3.2% (17 patients)	28.3% (73 patients)
Neutropenia (a type of low white blood cell count)	1.9% (10 patients)	31.4% (81 patients)
Hair Loss	1.3% (7 patients)	49.2% (127 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.

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.

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

Measuring **overall survival** helps us understand how well a new treatment works. Overall survival is the length of time from when a patient is randomly placed into treatment until they pass away from any cause. Median overall survival is the time, in months, when half of the people in the study are still alive, and the other half have passed away. In this study, some patients lived for a shorter time, and some lived longer. In the tislelizumab group median overall survival was 17.2 months, while in the docetaxel group median overall survival was 11.9 months. A total of 535 patients in the tislelizumab group and 270 patients in the docetaxel group were included in this analysis.

Overall Survival

For this study, overall survival in PD-L1-positive patients was one of the co-primary endpoints. PD-L1 is a protein found on the surface of some tumor cells. If a quarter (25%) or more of tumor cells have PD-L1, the tumor is referred to as PD-L1-positive. This information is important because PD-L1-positive tumors may respond differently to treatments that target the immune system, like tislelizumab, compared to other types of tumors.

In this study, patients with PD-L1-positive tumors were evaluated to see how long they lived after treatment. The results showed that for patients in the tislelizumab group median overall survival was 19.3 months, while for patients in the docetaxel group median overall survival was 11.5 months. A total of 227 patients in the tislelizumab group and 115 patients in the docetaxel group were included in this analysis.

PD-L1 Patients Overall Survival

How has this study helped patients and researchers?

The results from this study will help researchers understand more about how tislelizumab works in patients with NSCLC 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 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 3, Open-Label, Multicenter, Randomized Study to Investigate the Efficacy and Safety of BGB-A317 (Anti–PD1 Antibody) Compared With Docetaxel in Patients With Non–Small Cell Lung Cancer Who Have Progressed on a Prior Platinum-Containing Regimen

The protocol number is

BGB-A317-303

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 participants help advance science!