# 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-A317-305** |
| **Dates of Study** | **13 December 2018 to 27 August 2024** |
| **Title of This Study** | **Tislelizumab in Combination with Chemotherapy as First-Line Treatment in Adults With Inoperable, Locally Advanced or Metastatic Gastric or Gastroesophageal Junction Carcinoma** |
| **Date of This Report** | **April 2025** |

## Thank You!

BeiGene, who managed this study, thanks the study 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 stomach cancer (also called gastric cancer) or with cancer where the stomach connects with the esophagus (the tube that connects the throat to the stomach), also called gastroesophageal junction 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 advanced gastric or gastroesophageal (GE) junction carcinoma. Gastric or gastroesophageal junction cancer is cancer that starts in the stomach or the GE junction. Mutations or changes to the DNA can cause cells to grow out of control and form a tumor. The most common type of gastric and GE Junction cancer is called adenocarcinoma, which develops from the cells that form the innermost lining of the stomach (the mucosa). Most stomach and GE junction cancers do not cause symptoms until they have grown large or spread to an advanced stage. The symptoms and signs of GE junction cancer may include loss of appetite, difficulty swallowing, fatigue, unexplained weight loss, nausea and vomiting.

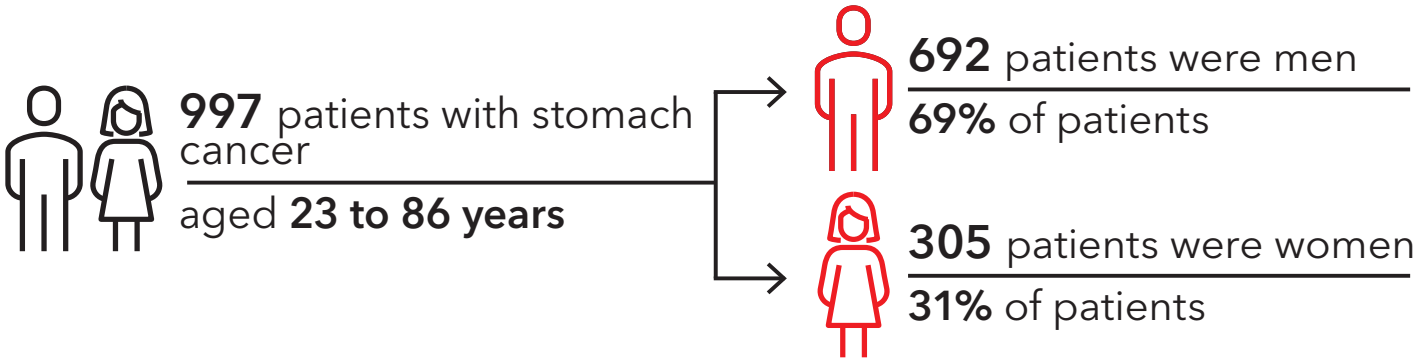
In this study, researchers wanted to learn more about how safe tislelizumab is when given with chemotherapy, and how it works in adult patients with locally advanced or metastatic stomach or GE junction cancer who have not received previous therapy for their cancer. Locally advanced means the cancer has spread into nearby tissue and muscles. Metastatic means that the cancer has spread from the place where it started to other areas of the body. Tislelizumab is a protein that strongly binds to a protein called PD-1 which is found on the surface of a type of immune cells called T-cells. When tislelizumab binds to PD-1 it helps the T-cells 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.

## Researchers in this study wanted to know:

- What adverse events would patients who took part in this study have?
- How long did patients in this study live after they started the study treatment?

# Who was in this study?




A total of 997 patients ranging in age from 23 to 86 years old participated in the study. There were 692 men (69%) and 305 women (31%).

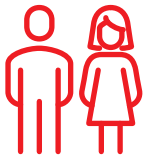
# When and where was this study done?

This study started in December 2018 and ended in August 2024. The study was conducted at 141 study centers in 13 countries and regions, including:

- Mainland China, with 499 patients
- Taiwan, with 17 patients
- Japan, with 101 patients
- South Korea, with 131 patients
- Spain, with 45 patients
- France, with 20 patients
- United Kingdom, with 8 patients
- Italy, with 18 patients
- Poland, with 18 patients
- Russia, with 98 patients
- Turkey, with 17 patients
- United States, with 25 patients

# How was this study done?

In this study, patients with stomach or GE junction cancer were randomly assigned to one of two treatment groups: either tislelizumab with chemotherapy or placebo and chemotherapy. Patients in the tislelizumab group received 200 milligrams (mg) of tislelizumab through an infusion into a vein plus chemotherapy every 3 weeks. Patients in the placebo group received placebo (saline solution) through an infusion into a vein plus chemotherapy once every 3 weeks. Neither the patient nor the study researchers knew whether each person was taking tislelizumab or placebo (this is called a double-blind study).



**498 patients**
received
**tislelizumab + chemotherapy**
treatment group

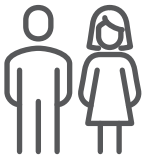
Patients received
**tislelizumab** once every three weeks
intravenously at

**200 mg**

**FOR 6 CYCLES**

**+ chemotherapy**

**tislelizumab**
until worsening or side effects



**494 patients**
received
**placebo + chemotherapy**
treatment group

Patients received
**placebo** once every three weeks
intravenously

**Placebo**

**FOR 6 CYCLES**

**+ chemotherapy**

**placebo**
until worsening or side effects

Chemotherapy was chosen by the study doctor, and consisted of either:

- Capecitabine (1000 mg/m$^2$ orally twice daily Days 1 through 14 (14 days total) of each 21-day cycle) and oxaliplatin (130 mg/m$^2$ IV once every 3 weeks), OR
- 5-fluorouracil (also called 5-FU, 800 mg/m$^2$/day intravenously using continuous infusion on Days 1 to 5 of each 21-day cycle) and cisplatin (80 mg/m$^2$ IV once every 3 weeks).

Participants received this study treatment for up to six treatment cycles (one cycle is 3 weeks). After that, participants could continue to receive tislelizumab or placebo until their cancer worsened, they developed side effects that could not be tolerated, or they chose not to continue participating int the study. The trial doctors continued to keep in touch with participants after they finished treatment to follow their status until the end of the study.

During the study, the trial doctors:

- Did physical exams and checked the participants' vital signs
- Took computed tomography (CT) scans or MRI to check the participants' tumors
- Asked if the participants could do their usual daily activities and how bad their symptoms were
- Monitored patients closely for any side effects
- Took blood and urine samples
- Did other tests such as electrocardiogram (ECG) and eye exams

Researchers looked at how long participants in the study lived. They compared patients who took tislelizumab + chemotherapy to those who took placebo + chemotherapy to see who lived longer. This is called **Overall Survival**. Researchers particularly looked at the results for participants who had a protein called PD-L1 (programmed death receptor ligand-1) on their tumor cells, who were called "**PD-L1 positive**" participants.

# 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 doctor, or leads to death. A total of 992 patients were evaluated for adverse events.

In this study:

- 99.4% of patients in the tislelizumab + chemotherapy group and 98.4% of patients in the placebo + chemotherapy group had at least 1 adverse event.
- 42.4% of patients in the tislelizumab + chemotherapy group and 36.2% of patients in the placebo + chemotherapy group had serious adverse events.
- 23.5% of patients in the tislelizumab + chemotherapy group and 13.8% of patients in the placebo + chemotherapy group of patients had adverse events that caused them to stop taking any of the study drugs (tislelizumab, placebo, or chemotherapy).

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?

Decreased platelet count was the most common serious adverse event. Platelets are tiny blood cells that help your body form clots to stop bleeding.

The most common serious adverse events that occurred in at least 2% of the patients in either of the groups are shown below.

| Serious adverse event | Tislelizumab + Chemotherapy (Out of 498 patients) | Placebo + Chemotherapy (Out of 494 patients) |
|---|---|---|
| Decreased levels of platelets | 3.2% (16 patients) | 3.4% (17 patients) |
| Pneumonia (a type of lung infection) | 2.4% (12 patients) | 2.8% (14 patients) |
| Death | 2.0% (10 patients) | 1.0% (5 patients) |
| Anemia (low levels of red blood cells) | 0.8% (4 patients) | 2.0% (10 patients) |

47 patients (9.4%) in the tislelizumab + chemotherapy group and 42 patients (8.5%) in the placebo + chemotherapy group had adverse events that led to death. 11 of these deaths in the tislelizumab + chemotherapy group and 4 deaths in the placebo + chemotherapy group were thought to be caused by the study treatment.

## What were the most common adverse events?

Nausea was the most common adverse event. The most common adverse events that occurred in at least 30% of the patients in this study are shown below.

| Adverse event | Tislelizumab + Chemotherapy (Out of 498 patients) | Placebo + Chemotherapy (Out of 494 patients) |
|---|---|---|
| Nausea | 50.4% (251 participants) | 48.4% (239 participants) |
| Decreased appetite | 41.6% (207 participants) | 42.3% (209 participants) |
| Anemia (low levels of red blood cells) | 40.2% (200 participants) | 42.3% (209 participants) |
| Vomiting | 36.3% (181 participants) | 36.2% (179 participants) |
| Decreased levels of platelets | 35.5% (177 participants) | 38.1% (188 participants) |
| Decreased levels of a type of white blood cell called neutrophils | 34.5% (172 participants) | 33.0% (163 participants) |
| Aspartate aminotransferase increased | 31.7% (158 participants) | 30.4% (150 participants) |

# What were the main results of the study?

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

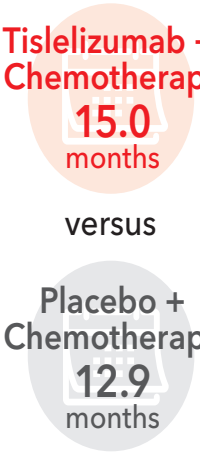
## How long did patients in this study live after they started the study treatment?

To answer this question, the researchers looked at overall survival during the study. Overall survival measures how long a participant lives. The researchers looked at the time from the start of the study treatment until February 2023 (up to approximately 50 months). Median overall survival time is the time point at which half of the participants in the study are still alive.

Median overall survival was 15.0 months for patients who took tislelizumab + chemotherapy and 12.9 months for patients who took placebo + chemotherapy. This shows an improvement of 2.1 months for the participants who took tislelizumab + chemotherapy compared to chemotherapy alone.

Researchers also looked at overall survival in participants who had PD-L1 protein on their tumor cells. The researchers looked at the time from the start of the study treatment to October 2021 (up to approximately 33 months).
In participants who were PD-L1-positive, the median overall survival was 17.2 months for patients who took tislelizumab + chemotherapy and 12.6 months for patients who took placebo + chemotherapy. This shows an improvement in median overall survival of 4.6 months for participants who were PD-L1-positive who took tislelizumab + chemotherapy compared to chemotherapy alone.

### Overall Survival




### PD-L1 Patients Overall Survival

# How has this study helped patients and researchers?

The results from this summary will help researchers and patients understand more about how tislelizumab works in patients with stomach or GE junction cancer and may provide additional treatment options for patients in the future.

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 Randomized, Double-Blind, Placebo-Controlled, Phase 3 Clinical Study Comparing the Efficacy and Safety of Tislelizumab (BGB-A317) plus Platinum and Fluoropyrimidine Versus Placebo plus Platinum and Fluoropyrimidine as First-Line Treatment in Patients with Locally Advanced Unresectable or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma

**The protocol number is**

BGB-A317-305

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:

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