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	Pamiparib (BGB-290)
Protocol Number	BGB-290-103
Dates of Study	July 2017 to May 2023
Title of This Study	A Study of Pamiparib (BGB-290) in Patients with Solid Tumors
Date of This Report	May 2024

Thank You!

BeiGene, who managed this study, thanks the study patients for taking part in the clinical study for a new medical treatment called pamiparib (BGB-290) to treat people with solid tumors, which is also called cancer. This trial studied patients with breast, ovarian, prostate, stomach, and lung cancer. In this study, scientists wanted to know if pamiparib, when used with another medicine called temozolomide or TMZ (which is already used for cancer), could help people with advanced solid tumors live longer without their cancer getting worse. They also wanted to check if it is safe for patients to take both medicines together.

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 patients with solid tumors that have spread to other parts of the body or cannot be treated with surgery. Solid tumors are growths of cells that start either in a particular organ or in nearby tissues. Symptoms of solid tumor cancers may include pain in the affected area, trouble breathing, an urge to vomit, feeling extremely tired, and weight loss.

In this study, researchers wanted to learn more about pamiparib. Pamiparib works by blocking cancer cells from repairing damage to their DNA, which causes cancer cells to die. TMZ causes cells to die by changing part of their DNA. This stops the cells from growing. When pamiparib is used together with TMZ, there is even more damage to the DNA, causing more cells to die or stop growing.

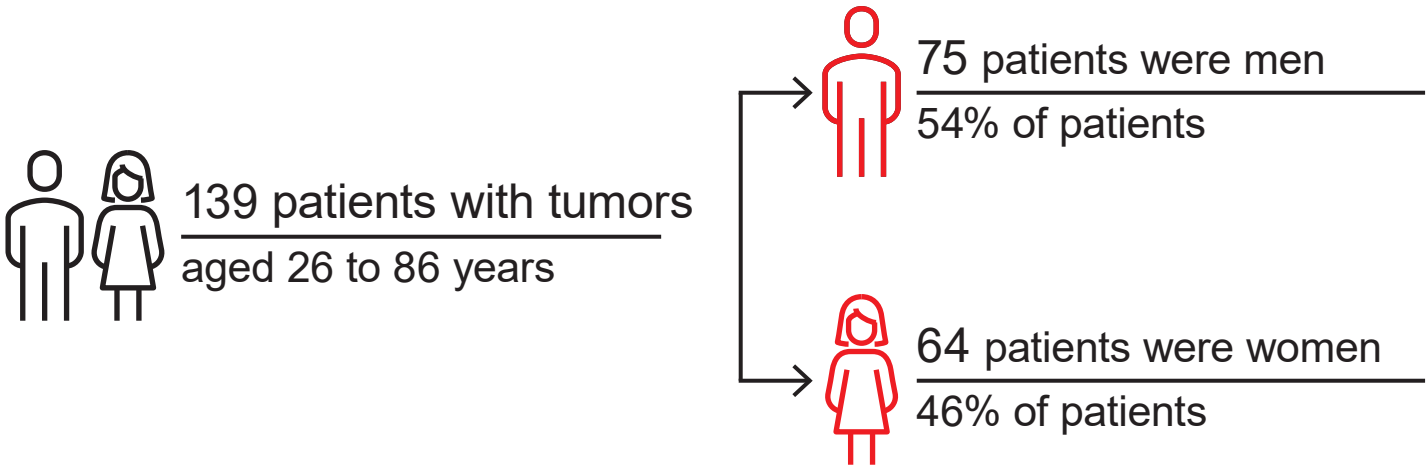
Before a new medical treatment can be approved for people to take, researchers must do clinical studies to learn how safe the treatment is by looking at adverse events. Adverse events are unwanted medical problems study patients can experience that may or may not be caused by the study drug. Researchers also must learn how the treatment works in people with the disease. In this study, researchers looked at how pamiparib works in the body with TMZ. Researchers did medical tests on men and women before and after they took pamiparib and TMZ to learn how the treatment moved through the body.

Researchers in this study wanted to know:

- What adverse events did patients have?
- How much pamiparib can be given without causing too many side effects when used with TMZ?
- How well does pamiparib work against tumors when it is used with TMZ?

Who was in this study?

A total of 139 patients between the ages of 26 and 86 years joined the study. There were 75 (54.0%) men and 64 (46.0%) women. All patients had a solid tumor cancer that spread to other organs (metastasized) and had responded to previous cancer treatment.



When and where was this study done?

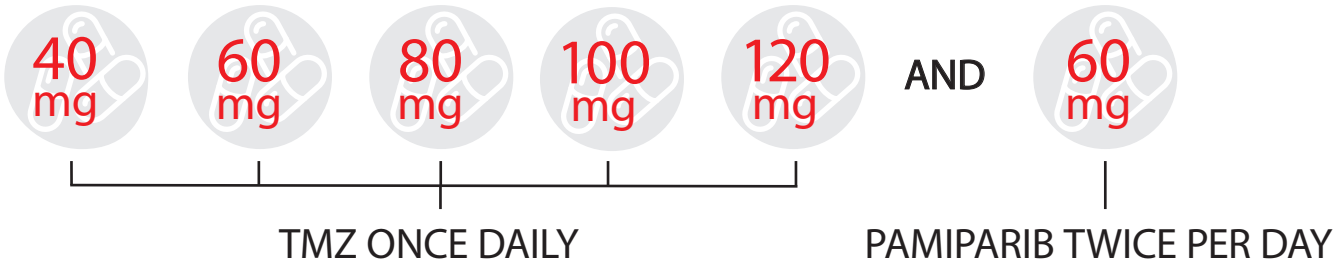
This study started in July 2017 and ended in May 2023. The study was conducted at multiple study centers in countries worldwide, including:

- Australia, with 8 patients
- Spain, with 43 patients
- United Kingdom, with 14 patients
- United States, with 74 patients

How was this study done?

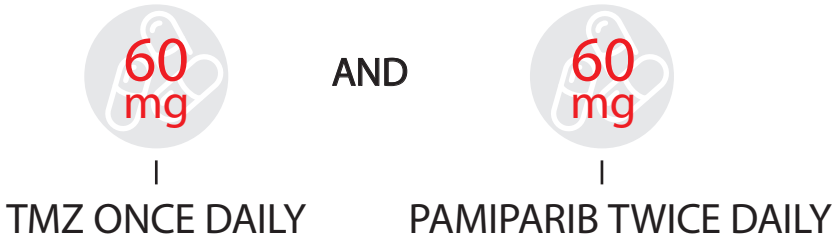
This study was done in 2 parts.

Part 1 Patients were given increasing amounts of TMZ with pamiparib at a dose of 60 milligrams twice per day .



Researchers monitored the overall health of patients to check the safety of each dose level.

Part 2 Scientists looked more closely at how safe and effective the combination of medicines was for patients with certain types of solid tumors based on what they learned from the first part of the study



In this study, 139 patients with solid tumor cancers were enrolled. At first, patients were given increasing amounts of TMZ with pamiparib at a dose of 60 milligrams twice per day in what is called the dose escalation phase. After, in what is called the dose expansion phase, scientists looked more closely at how safe and effective the combination of medicines was for patients with certain types of solid tumors based on what they learned from the first part of the study.

This study was open label, which means the patients, doctors, and people helping with the study knew which treatment each person was receiving.

During this study, study doctors:

- Asked patients to take capsules daily
- Checked patient's overall health and took blood and urine samples
- Took images of patients with an X-ray machine to determine the tumor status
- Asked patients how they were feeling and what medicines they were taking

What adverse events did patients have?

Adverse events, or side effects, are unwanted 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.

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 happened in this study.

- 36%, or 50 out of 139 patients, had a serious adverse event
- 98.6%, or 137 out of 139 patients, had at least one adverse event
- 7.2%, or 10 out of 139 patients, had adverse events that caused them to stop treatment

What serious adverse events did patients have?

Stomach pain was the most common serious adverse event in this study. The table below shows the most common serious adverse events in this study that occurred in at least 3% of the patients in this study.

Most common serious adverse events			
Serious adverse event	Dose Escalation Phase (Out of 66 patients)	Dose Expansion Phase (Out of 73 patients)	Total (Out of 139 patients)
Stomach pain	4.5% (3 patients)	4.1% (3 patients)	4.3% (6 patients)

4 out of 139 (2.9%) patients in this study had a serious adverse event that led to death. None of the adverse events that led to death were thought to be caused by the study treatments.

What were the most common adverse events?

Low red blood cell count (anemia) was the most common adverse event in this study. The table below shows the most common adverse events that occurred in at least 20% of the patients in this study.

Most common adverse events			
Adverse event	Dose Escalation Phase (Out of 66 patients)	Dose Expansion Phase (Out of 73 patients)	Total (Out of 139 patients)
Low red blood cell count (Anemia)	56.1% (37 patients)	63.0% (46 patients)	59.7% (83 patients)
Feeling an urge to vomit (Nausea)	54.5% (36 patients)	49.3% (36 patients)	51.8% (72 patients)
Lack of energy (Fatigue)	48.5% (32 patients)	47.9% (35 patients)	48.2% (67 patients)
Decreased appetite	30.3% (20 patients)	35.6% (26 patients)	33.1% (46 patients)
Low white blood cell count (Neutropenia)	33.3% (22 patients)	30.1% (22 patients)	31.7% (44 patients)
Low platelet count (Thrombocytopenia)	36.4% (24 patients)	26.0% (19 patients)	30.9% (43 patients)
Vomiting	25.8% (17 patients)	31.5% (23 patients)	28.8% (40 patients)
Low blood clotting cells (platelet count decreased)	18.2% (12 patients)	32.9% (24 patients)	25.9% (36 patients)
Diarrhea	25.8% (17 patients)	19.2% (14 patients)	22.3% (31 patients)
Low white blood cell count (Neutrophil count decreased)	18.2% (12 patients)	26.0% (19 patients)	22.3% (31 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.

How much pamiparib can be given without causing too many side effects when it is used with TMZ?

This study looked at how many patients had a dose limiting toxicity (DLT), which is an adverse effect or side effect of a medication that is severe enough to prevent an increase in dosage. There was a total of 4 patients (out of 66) with a DLT event in the dose escalation phase. For all 4 patients, the events were resolved.

How well does pamiparib work against tumors when it is used together with TMZ?

Measuring the Objective Response Rate (ORR) is one way to determine how well a new treatment works. In this study, the ORR was 12.6% (16 out of 127 patients evaluated for this outcome). This is the percentage of patients with solid tumors who no longer had evidence of cancer or had some improvement in the signs and symptoms of active disease after treatment.

How has this study helped people and researchers?

The results from this summary will help researchers and patients learn more about how pamiparib may help people with different solid tumor cancers that cannot be operated on and has spread to other parts of the body. More studies with pamiparib are ongoing.

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 1b Study to Assess the Safety, Tolerability and Clinical Activity of BGB-290 in Combination With Temozolomide (TMZ) in Subjects With Locally Advanced or Metastatic Solid Tumors

The protocol number is

BGB-290-103

For information about this study in the United States

Click here

For information about this study in the European

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

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