CLINICAL TRIAL RESULTS

Researchers look at the results of many studies to decide if a treatment works, how it works, and if it is safe 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	**Zanubrutinib**
Protocol Number	**BGB-3111-214**
Dates of Study	**February 2019 to May 2022**
Title of This Study	**Safety and Efficacy of Zanubrutinib in Patients with Marginal Zone Lymphoma**
Date of This Report	**April 25, 2023**

Thank You!

BeiGene, who managed this study, thanks participants for taking part in the clinical study for a new medical treatment called zanubrutinib. In this study, researchers learned more about the safety and efficacy of zanubrutinib, also called BGB-3111 and Brukinsa, and how it may work in patients with a type of cancer called marginal zone lymphoma.

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 lymphomas or blood cancers, including marginal zone lymphoma. This type of cancer starts in white blood cells called lymphocytes, which are part of the immune system. Normal B-lymphocytes (B-cells) protect the body from germs by making antibodies. If abnormal B-cells are produced, the unhealthy cells can make it harder to fight off infections.

In this study, researchers wanted to learn more about how safe zanubrutinib is and how it works in patients with marginal zone lymphoma. Zanubrutinib blocks the function of a specific protein in cells known as Bruton's tyrosine kinase (or BTK), which plays a role in how cells grow and survive. Blocking BTK function can stop cancer cells from growing.

Before a new medical treatment can be approved for use in patients, 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 patients can experience that may or may not be caused by the treatment. Researchers also must learn how well the treatment works in people.

Researchers in this study wanted to know:

- What adverse events or side effects would patients who took part in this study have
- How many patients who took part in the study would no longer have evidence of cancer or would have some improvement in the signs and symptoms of cancer

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Who was in this study?

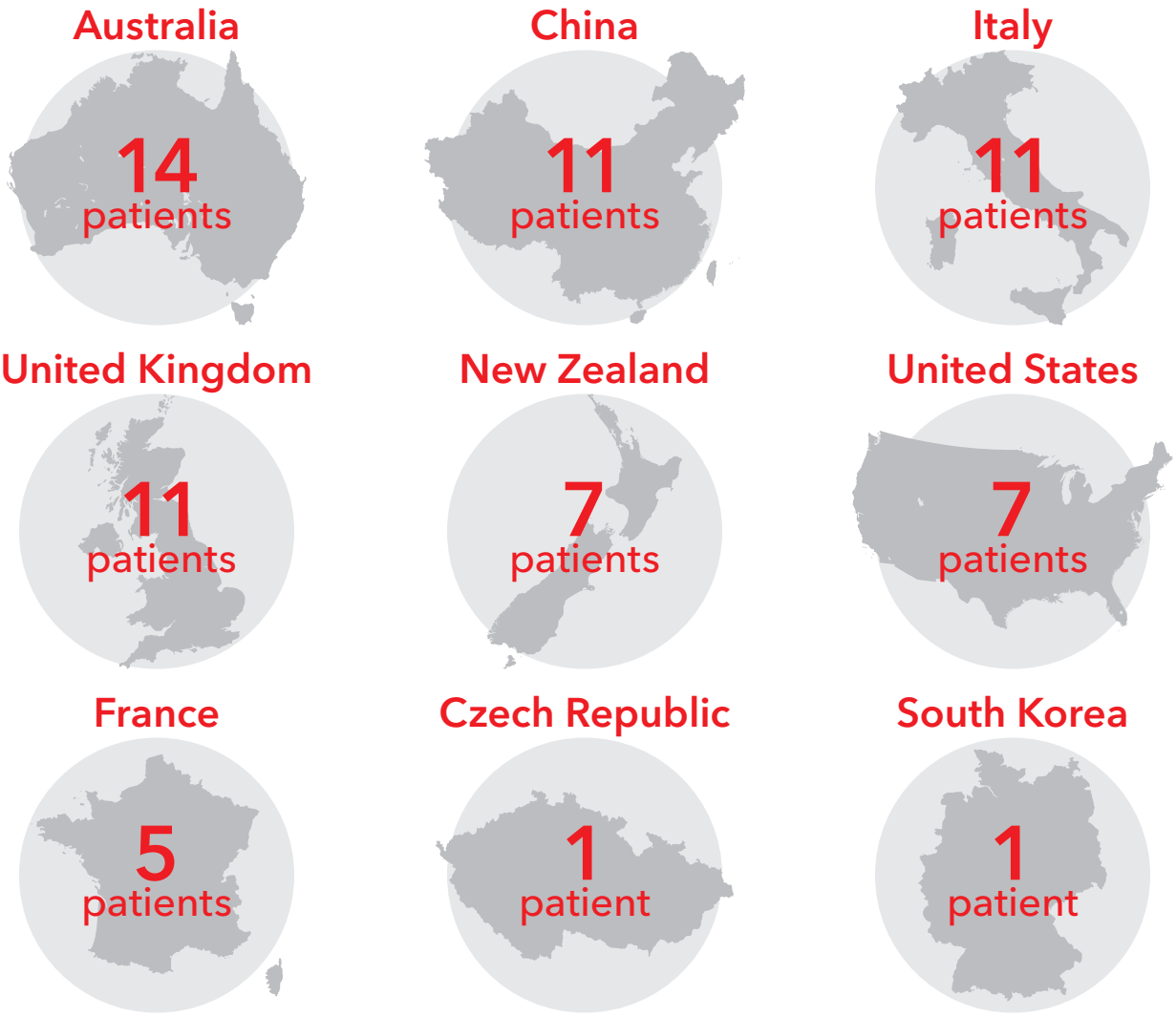
68 MZL patients
aged **37 to 95 years**

36 patients were men
52.9% of patients

32 patients were women
47.1% of patients

When and where was this study done?

This study started in February 2019 and ended in May 2022. The study was conducted at 31 study centers in 9 countries, including:



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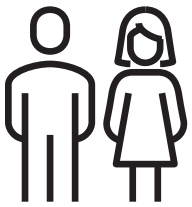
How was this study done?

In this study, patients with marginal zone lymphoma were given 160 milligrams of zanubrutinib orally twice daily in the form of 80 milligram capsules.



All patients with MZL were given **zanubrutinib**

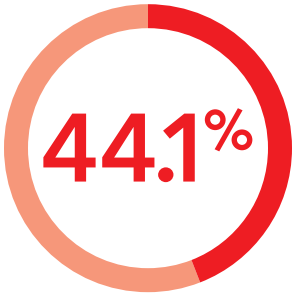
TWICE DAILY

Researchers determined how many patients responded to the treatment using "overall response rate" or ORR. ORR is used to describe the number of patients with complete and partial responses to treatment, also called remission. Complete response means that patients no longer had evidence of cancer and partial response means that there was an improvement in the signs and symptoms of cancer.

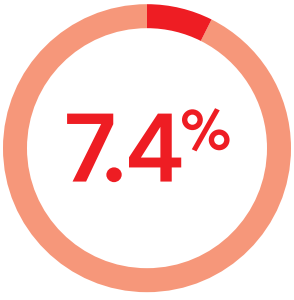
What adverse events did patients have?

Adverse events are unwanted medical problems that may or may not be caused by 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 68 patients were assessed for adverse events.

of patients had at least 1 adverse event



of patients had serious adverse events

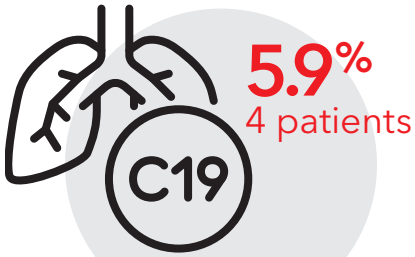


of patients had adverse events that caused them to stop treatment

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.

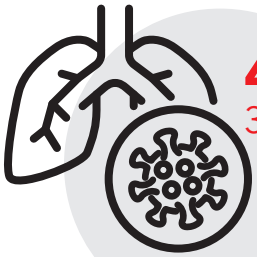
What serious adverse events did patients have?

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



5.9%
4 patients

Pneumonia related to COVID-19



4.4%
3 patients

Pneumonia

4.4%
3 patients

Fever

Five patients had adverse events that led to death. None of the adverse events that led to death were caused by zanubrutinib.

What were the most common adverse events?

Bruising was the most common adverse event. The figure below shows the most common adverse events that occurred in at least 20% of the patients in this study.

23.5%
16 patients

Bruising

22.1%
15 patients

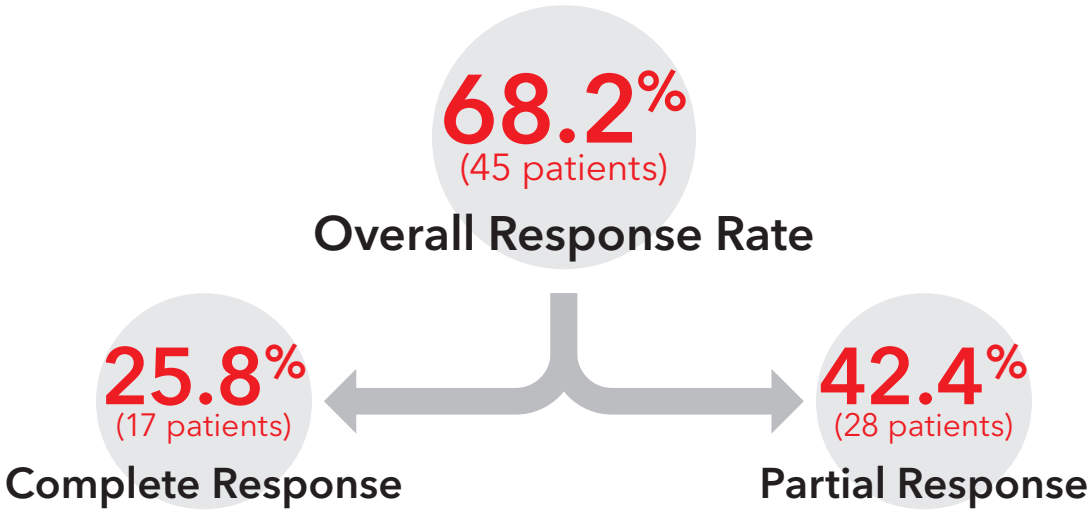
Diarrhea

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 many patients who took part in the study no longer had evidence of cancer or had some improvement in the signs and symptoms of cancer?

Measuring overall response rate is one way to determine how well a new treatment works. The percentage of patients with marginal zone lymphoma who had a complete response or a partial response after treatment is shown below. A total of 66 patients with a confirmed diagnosis of marginal zone lymphoma were included in this analysis.



How has this study helped patients and researchers?

The results from this study will help researchers understand more about how zanubrutinib works in patients with marginal zone lymphoma and may provide additional treatment options for patients in the future. More studies with zanubrutinib 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 treatment 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, is found below:

The full title of this study is
A Phase 2, Open-Label Study of Zanubrutinib (BGB-3111) in Patients with Relapsed or Refractory Marginal Zone Lymphoma

The protocol number is
BGB-3111-214

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 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 study patients.

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!