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	**Zanubrutinib and Obinutuzumab**
Protocol Number	**BGB-3111-212**
Dates of Study	**November 2017 to December 2024**
Title of This Study	**An International, Phase 2, Open-Label, Randomized Study of BGB-3111 Combined With Obinutuzumab Compared With Obinutuzumab Monotherapy in Relapsed/ Refractory Follicular Lymphom**
Date of This Report	**28 October 2025**

Thank You!

BeiGene, who managed this study, thanks all participants for taking part in this clinical study for a new medical treatment called zanubrutinib, also known as BGB-3111. In this study, researchers learned more about the safety and efficacy of zanubrutinib, and how it may work in patients with a type of cancer called relapsed/refractory follicular 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 working to find better ways to help people with different types of cancer, including follicular lymphoma (FL). FL is a type of non-Hodgkin lymphoma; a blood cancer that begins in the lymphatic system and affects a kind of white blood cell called a B lymphocyte. FL typically develops slowly, and in early stages, many people may not notice any symptoms. Over time, it can cause painless swollen lymph nodes, fatigue, fever, unexplained weight loss, and night sweats. In some cases, FL can return after treatment (relapsed) or stop responding to therapy (refractory), requiring new or more targeted treatment approaches to help manage the disease.

In this study, researchers wanted to better understand how safe zanubrutinib is when taken in combination with obinutuzumab and how well it works in people with FL. Zanubrutinib blocks a specific protein in cells known as Bruton's Tyrosine Kinase (BTK), which plays a role in cell development and survival. Blocking BTK function can stop cancer cells from 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, 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.

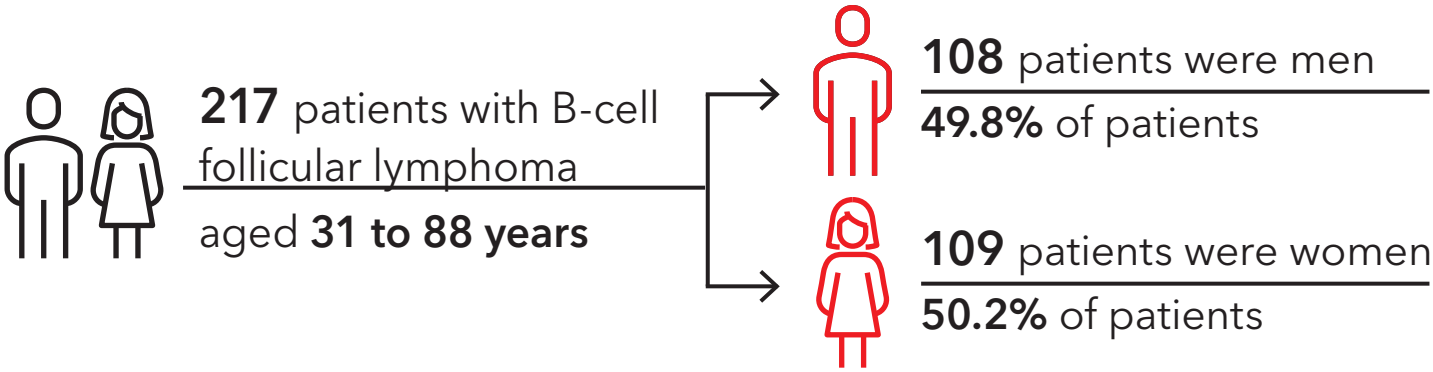
In this study, researchers compared obinutuzumab, a common treatment for FL, with a combination of zanubrutinib plus obinutuzumab to see whether the combination could provide better outcomes for people with FL.

Researchers in this study wanted to know:

- What adverse reactions would patients who took part in this study have?
- How many patients who took part in the study no longer had evidence of cancer or had some improvement in their cancer burden?

Who was in this study?

A total of 217 participants took part in the study. Their ages ranged from 31 to 88 years old. About half were men (108 participants, 49.8%) and half were women (109 participants, 50.2%). All participants had B-cell follicular lymphoma that had come back or did not respond after two or more previous treatments. No one had any other serious illness that would prevent them from joining the study.



When and where was this study done?

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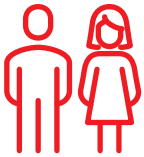
- Australia, with 20 patients
- Belarus, with 4 patients
- Bulgaria, with 4 patients
- Canada, with 4 patients
- Mainland China, with 33 patients
- Czechia, with 17 patients
- France, with 27 patients
- Germany, with 1 patient
- Italy, with 25 patients
- Korea, Republic of, with 7 patients
- New Zealand, with 7 patients
- Poland, with 7 patients
- Russian Federation, with 11 patients
- Spain, with 26 patients
- Taiwan Region, with 7 patients
- United Kingdom, with 10 patients
- United States, with 7 patients

How was this study done?

In this study, participants with FL were randomly assigned to one of the two treatment groups. One group received obinutuzumab through a vein (intravenous infusion) at a dose of 1000 mg. The other group received zanubrutinib by mouth at 160 mg twice a day, together with 1000 mg of obinutuzumab given through a vein. Treatment continued until the cancer got worse, the side effects became too hard to manage, another cancer treatment was needed, the patient or their doctor decided to stop, a medication that couldn't be used with the study drug was needed, the patient chose to leave the study, or the patient became pregnant. Randomly putting people into groups helps make sure the comparison between treatments is as fair and accurate as possible.

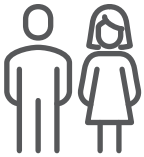


145 patients
were assigned to
zanubrutinib and obinutuzumab combination treatment group

143 patients
were given with
zanubrutinib orally

160mg
TWICE A DAY

+ obinutuzumab 1000mg
+ intravenously



72 patients
were assigned to
obinutuzumab monotherapy treatment group

71 patients
were infused with
obinutuzumab intravenously

1000mg

EVERY 28 DAYS

36 patients
crossed over to
combination treatment

The primary endpoint of this study was to measure how many patients' cancers responded to the treatment, called the **Overall Response Rate (ORR).** This means the study looked at the percentage of people whose cancer either completely went away (complete response) or got much smaller (partial response). To determine this, doctors who were not part of the study team independently reviewed the scans. A complete response meant no signs of cancer on the scans and no new areas of disease. A partial response meant the cancer had shrunk by at least half or showed much less activity, with no new growths. This measure shows how well the treatment worked to shrink or eliminate cancer, and it was evaluated in all patients who were randomly assigned to treatment groups

What adverse reactions did patients have?

Adverse reactions are unwanted medical problems that doctors think may be caused by the study treatment. An adverse reaction 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 214 patients were evaluated for adverse reactions.

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:

- 69% of patients in the obinutuzumab arm and 76.9% of patients in the zanubrutinib and Obinutuzumab combination arm had at least 1 adverse reaction
- 11.3% of patients in the obinutuzumab arm and 20.3% of patients in the zanubrutinib and Obinutuzumab combination arm had at least 1 serious adverse reaction
- 4.2% of patients in the obinutuzumab arm and 9.8% of patients in the zanubrutinib and Obinutuzumab combination arm had adverse reactions that caused them to stop treatment

What serious adverse reactions did patients have?

Pneumonia was the most common serious adverse reaction. The most common serious adverse reactions that occurred in at least 3% of the patients in either treatment group are shown here.

Most Common Serious Adverse Reactions			
Serious Adverse Reaction	**Obinutuzumab (Out of 71 Patients)**	**Zanubrutinib + Obinutuzumab (Out of 143 Patients)**	**Total (Out of 214 Patients)**
Pneumonia	1.4% (1 Patient)	6.3% (9 Patients)	4.7% (10 Patients)
COVID-19 Pneumonia	0% (0 Patients)	3.5% (5 Patients)	2.3% (5 Patients)

1 patient in the obinutuzumab arm (1.4%) and 2 patients in the combination zanubrutinib and obinutuzumab arm (1.4%) had a serious adverse reaction that led to death. All the adverse reactions that led to death were thought to be caused by zanubrutinib and obinutuzumab.

What were the most common adverse events?

Platelet count decrease was the most common adverse reaction. The most common adverse reactions that occurred in at least 10% of the patients in either, treatment group are shown here.

Most Common Adverse Reactions		
Serious Adverse Reaction	**Obinutuzumab (Out of 71 Patients)**	**Zanubrutinib + Obinutuzumab (Out of 143 Patients)**
Platelet count decrease (cells that help the blood clot)	12.7% (9 Patient)	18.2% (26 Patients)
Thrombocytopenia (a very low number of cells that help the blood clot)	9.9% (7 patients)	17.5% (25 patients)
Neutropenia (a very low number of infections fighting cells)	15.5% (11 patients)	11.9% (17 patients)

Most Common Adverse Reactions		
Serious Adverse Reaction	**Obinutuzumab (Out of 71 Patients)**	**Zanubrutinib + Obinutuzumab (Out of 143 Patients)**
Neutrophil count decrease (low infection fighting cells)	8.5% (6 patients)	15.4% (22 patients)
White blood cell count decreased	4.2% (3 patients)	11.9% (17 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 many patients who took part in the study no longer had evidence of cancer or had some improvement in their cancer burden?

One way to see how well a new cancer treatment works is by measuring the **overall response rate**, which shows the percentage of people whose cancer either went away or improved after treatment. In this study, results were reviewed from the first dose of the study drug until October 8, 2021, or until participants started another cancer treatment or switched treatments. After about 12 and a half months of follow-up (the median; meaning half the people were followed for less time and half for longer), doctors found that 45.8% of people with follicular lymphoma who received obinutuzumab alone showed improvement or no signs of cancer, compared to 68.3% of people who received the combination of zanubrutinib and obinutuzumab.

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 FL 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 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

An International, Phase 2, Open-Label, Randomized Study of BGB-3111 Combined With Obinutuzumab Compared With Obinutuzumab Monotherapy in Relapsed/ Refractory Follicular Lymphoma

The protocol number is

BGB-3111-212

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 Hopewell, NJ, USA
- Our phone number is +1 (877) 828-5568
- Our email address is ClinicalTrials@beigene.com

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