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COMPLETED ⓘ

Efficacy and Safety of Zanubrutinib in Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

ClinicalTrials.gov ID ⓘ NCT03206918

Sponsor ⓘ BeiGene

Information provided by ⓘ BeiGene (Responsible Party)

Last Update Posted ⓘ 2021-10-04

Study Details Tab

Study Overview

Brief Summary

This was a single-arm, open-label, multi-center Phase 2 study in participants with histologically documented CLL/SLL who have relapsed after or refractory to ≥ 1 prior treatment regimen(s). The study is composed of an initial screening phase, a single-arm treatment phase, and a follow-up phase.

Official Title

A Single-Arm, Open-Label, Multicenter Phase 2 Study to Evaluate Safety and Efficacy of BGB-3111, a Bruton's Tyrosine Kinase (BTK) Inhibitor in Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)

Conditions ⓘ

Relapsed or Refractory Chronic Lymphocytic Leukemia

Pharmacyclics LLC
Exhibit 2090
BeiGene v. Pharmacyclics
PGR2024-00009

EX2090.0001



Intervention / Treatment ⓘ

- Drug: Zanubrutinib

Other Study ID Numbers ⓘ

- BGB-3111-205
- CTR20160890 (Registry Identifier) (REGISTRY: ChinaDrugTrials.org)

Study Start (Actual) ⓘ

2017-03-09

Primary Completion (Actual) ⓘ

2018-06-15

Study Completion (Actual) ⓘ

2020-09-10

Enrollment (Actual) ⓘ

91

Study Type ⓘ

Interventional

Phase ⓘ

Phase 2

Resource links provided by the National Library of Medicine

[MedlinePlus](https://medlineplus.gov/) (https://medlineplus.gov/) related topics: [Chronic Lymphocytic Leukemia](https://medlineplus.gov/chroniclymphocyticleukemia.html) (https://medlineplus.gov/chroniclymphocyticleukemia.html), [Leukemia](https://medlineplus.gov/leukemia.html) (https://medlineplus.gov/leukemia.html), [Lymphoma](https://medlineplus.gov/lymphoma.html) (https://medlineplus.gov/lymphoma.html).

[Genetic and Rare Diseases Information Center](https://rarediseases.info.nih.gov/gard) (https://rarediseases.info.nih.gov/gard) resources: [Lymphosarcoma](https://rarediseases.info.nih.gov/diseases/6946/lymphosarcoma) (https://rarediseases.info.nih.gov/diseases/6946/lymphosarcoma), [Chronic Lymphocytic Leukemia](https://rarediseases.info.nih.gov/diseases/6104/chronic-lymphocytic-leukemia) (https://rarediseases.info.nih.gov/diseases/6104/chronic-lymphocytic-leukemia), [Chronic Graft Versus Host Disease](https://rarediseases.info.nih.gov/diseases/10964/chronic-graft-versus-host-disease) (https://rarediseases.info.nih.gov/diseases/10964/chronic-graft-versus-host-disease).

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>), available for: [Zanubrutinib](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Zanubrutinib) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Zanubrutinib>).

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>).

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

China

Beijing Locations

-  **Beijing, Beijing, China, 100082**
Peking University People's Hospital
-  **Beijing, Beijing, China, 100730**
Peking Union Medical College Hospital

Fujian Locations

-  **Fuzhou, Fujian, China, 350001**
Fujian Medical University Union Hospital

[Click to view interactive map](#)

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](https://clinicaltrials.gov/study-basics/learn-about-studies) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Key Inclusion Criteria:

1. Confirmed diagnosis with at least one criterion for treatment according to International workshop on chronic lymphocytic leukemia (IWCLL)
2. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
3. Measurable disease by contrast enhanced computerized tomography / magnetic resonance imaging (CT/MRI).
4. Previously treated with a minimum of 1 prior line of standard chemotherapy-containing regimen (with completion of ≥ 2 treatment cycles).
5. Documented failure to achieve at least partial response (PR) or documented disease progression after response to the most recent treatment regimen. Refractory disease is defined as treatment failure (stable disease, non-response, progressive disease [PD]) or disease progression within 6 months after the most recent prior therapy (Hallek et al, 2008).
6. Neutrophils $\geq 0.75 \times 10^9/L$ independent of growth factor support within 7 days of study entry
7. Platelets $\geq 50 \times 10^9/L$, independent of growth factor support or transfusion within 7 days of study entry
8. Creatinine clearance of ≥ 30 ml/min (as estimated by the Cockcroft-Gault equation or estimated glomerular filtration rate [eGFR] from the Modification of Diet in Renal Disease [MDRD])
9. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) $\leq 3 \times$ ULN
10. Bilirubin $\leq 2 \times$ ULN (unless documented Gilbert's syndrome)
11. International normalized ratio (INR) ≤ 1.5 and activated partial thromboplastin time (APTT) $\leq 1.5 \times$ ULN.
12. Participants may be enrolled who relapse after autologous stem cell transplant if they are at least 6 months after transplant.
13. Life expectancy of >4 months
14. Echocardiogram (ECHO) must demonstrate left ventricular ejection fraction (LVEF) $\geq 50\%$; (AHA, 2016)

Key Exclusion Criteria:

1. Current or history of central nervous system (CNS) lymphoma
2. Prior exposure to a Bruton's tyrosine kinase (BTK) inhibitor
3. Prior corticosteroids given in excess of prednisone 10 mg/day or its equivalent with antineoplastic intent within 7 days.
4. Major surgery within 4 weeks of screening
5. Not recovered from toxicity of any prior anti-cancer therapy to $< \text{Grade } 1$ (except for alopecia, absolute neutrophil count (ANC) and platelets).

6. History of other active malignancies within 2 years of study entry, with exception of (1) adequately treated in-situ carcinoma of cervix; (2) localized basal cell or squamous cell carcinoma of skin; (3) previous malignancy confined and treated locally (surgery or other modality) with curative intent
7. Currently active clinically significant cardiovascular disease
8. QTcF >480 msec based on Fridericia's formula or other significant electrocardiogram abnormalities including second degree atrioventricular (AV) block Type II, or third degree AV block
9. Unable to swallow capsules or disease significantly affecting gastrointestinal function such as malabsorption syndrome, resection of the stomach or small bowel, symptomatic inflammatory bowel disease, or partial or complete bowel obstruction
10. Active infection including infections requiring oral or intravenous anti-microbials
11. Known human immunodeficiency virus (HIV), or active hepatitis B or hepatitis C infection (detected positive by polymerase chain reaction [PCR]).
12. Has received allogenic hematopoietic stem cell transplantation prior to enrollment
13. Any life-threatening illness, medical condition or organ system dysfunction which, in the investigator's opinion, could compromise the participants's safety, or put the study at risk
14. Requires ongoing treatment with any medication which is a strong cytochrome P450, family 3, subfamily A (CYP3A) inhibitor or strong CYP3A inducer
15. Known or clinically suspected Richter's transformation at the time of study entry
16. History of stroke or intracranial hemorrhage within 6 months prior to enrollment

NOTE: Other protocol defined Inclusion/Exclusion criteria may apply.

Ages Eligible for Study ⓘ

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment
Allocation ⓘ : N/A
Interventional Model ⓘ : Single Group Assignment
Masking ⓘ : None (Open Label)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: Zanubrutinib	Drug: Zanubrutinib - Zanubrutinib 160 mg (two - 80 mg white opaque capsules) taken by mouth (PO) twice a day (BID) - Other Names: - BGB-3111

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Overall Response Rate (ORR) by Independent Review Committee (IRC)	ORR is defined as the number of participants who achieve a best response of CR or, CRi, Nodular Partial Response, PR, and PR with Lymphocytosis as assessed by IRC per the modified IWCLL Guidelines in participants with CLL and the Revised Criteria for Response for Malignant Lymphoma in participants with SLL.	Up to 1 year and 4 months

Outcome Measure	Measure Description	Time Frame
Progression-free Survival (PFS): Percentage of Participants Progression/Death Event Free	PFS is defined as the time from treatment initiation to first documentation of progression by International workshop on chronic lymphocytic leukemia (IWCLL) criteria/revised criteria for response for malignant lymphoma or death, whichever is earlier.	6, 12, 24, and 36 months
Duration of Response (DOR): Event Free Rate - Percentage of Participants Who Remained Event Free	DOR is defined as the time from the date that response criteria are first met to the date that progressive disease (PD) is objectively documented or death, whichever occurs first	6, 12, 24, and 36 months
Time to Response (TTR)	TTR is defined as the time from treatment initiation to first signs of response	Up to 3.5 years
Overall Response Rate as Determined by the Investigator	Overall response was defined as achieving a best overall response of CR, CRi, nodular partial response (nPR), PR, or partial response with lymphocytosis (PR-L).	up to 3.5 years
Number of Participants Experiencing Adverse Events (AEs)	An adverse event (AE) was defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. All AEs were monitored per the National	Up to 3.5 years

Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE version [v] 4.03 2010). A treatment emergent adverse event (TEAE) is defined as an adverse event that has an onset date or a worsening in severity from baseline (pretreatment) on or after the date of first dose of study drug up to 30 days following study drug discontinuation or initiation of new anticancer therapy, whichever occurs first.

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

BeiGene

Investigators ⓘ

- Principal Investigator: Study Director, BeiGene

Publications

Study Results

These publications are provided voluntarily by the person who enters information about the study and are about the study results.

- [Xu W, Yang S, Zhou K, Pan L, Li Z, Zhou J, Gao S, Zhou D, Hu J, Feng R, Huang H, Ji M, Guo H, Huang J, Novotny W, Feng S, Li J. Treatment of relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma with the BTK inhibitor zanubrutinib: phase 2, single-arm, multicenter study. J Hematol Oncol. 2020 May 11;13\(1\):48. doi: 10.1186/s13045-020-00884-4.](https://pubmed.ncbi.nlm.nih.gov/32393328/) (https://pubmed.ncbi.nlm.nih.gov/32393328).

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- [Xu W, Yang S, Tam CS, Seymour JF, Zhou K, Opat S, Qiu L, Sun M, Wang T, Trotman J, Pan L, Gao S, Zhou J, Zhou D, Zhu J, Song Y, Hu J, Feng R, Huang H, Su D, Shi M, Li J. Zanubrutinib Monotherapy for Naive and Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: A Pooled Analysis of Three Studies. Adv Ther. 2022 Sep;39\(9\):4250-4265. doi: 10.1007/s12325-022-02238-7. Epub 2022 Jul 28. 5900694](https://pubmed.ncbi.nlm.nih.gov/35900694/)).

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2017-06-29

First Submitted that Met QC Criteria ⓘ

2017-06-29

First Posted ⓘ

2017-07-02

Results Reporting Dates

Results First Submitted ⓘ

2020-08-10

Results First Submitted that Met QC Criteria ⓘ

2020-09-04

Results First Posted ⓘ

2020-09-25

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2021-09-29

Last Update Posted ⓘ

2021-10-04

Last Verified ⓘ

2021-09

More Information

Terms related to this study

Keywords Provided by BeiGene

Bruton's tyrosine kinase
Chronic lymphocytic leukemia
Relapsed/refractory
Zanubrutinib

Additional Relevant MeSH Terms

Neoplasms by Histologic Type
Neoplasms
Lymphoproliferative Disorders
Lymphatic Diseases
Immunoproliferative Disorders
Immune System Diseases
Hematologic Diseases
Leukemia, B-Cell
Chronic Disease
Disease Attributes
Pathologic Processes
Lymphoma
Leukemia
Leukemia, Lymphoid
Leukemia, Lymphocytic, Chronic, B-Cell
Tyrosine Kinase Inhibitors
Protein Kinase Inhibitors
Enzyme Inhibitors
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents
Zanubrutinib

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

No

Study Documents ⓘ Provided by BeiGene

- [Study Protocol \(https://cdn.clinicaltrials.gov/large-docs/18/NCT03206918/Prot_001.pdf\)](https://cdn.clinicaltrials.gov/large-docs/18/NCT03206918/Prot_001.pdf) [PDF, 8.28MB, 2017-10-25]
- [Statistical Analysis Plan \(https://cdn.clinicaltrials.gov/large-docs/18/NCT03206918/SAP_000.pdf\)](https://cdn.clinicaltrials.gov/large-docs/18/NCT03206918/SAP_000.pdf) [PDF, 2.8MB, 2018-03-16]



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ClinicalTrials.gov ID ⓘ NCT03206918

Sponsor ⓘ BeiGene

Information provided by ⓘ BeiGene (Responsible Party)

Last Update Posted ⓘ 2021-10-04

Researcher View Tab

Trial Contacts

Contacts

ICMJE

Contact information is only displayed when the study is recruiting subjects

Study Record Dates

First Submitted

ICMJE

2017-06-29

First Posted

ICMJE

Feedback

2017-07-02

Results First Submitted

ICMJE

2020-08-10

Results First Posted

ICMJE

2020-09-25

Last Update Posted

2021-10-04

Last Verified *

2021-09

Outcome Measures

Change History

[See all versions of this study.](#)

Primary (Current) *

ICMJE

(Submitted: 2021-09-29)

- Overall Response Rate (ORR) by Independent Review Committee (IRC) [Time Frame: Up to 1 year and 4 months]
 - ORR is defined as the number of participants who achieve a best response of CR or, CRi, Nodular Partial Response, PR, and PR with Lymphocytosis as assessed by IRC per the modified IWCLL Guidelines in participants with CLL and the Revised Criteria for Response for Malignant Lymphoma in participants with SLL.

Primary (Original) *

ICMJE

(Submitted: 2017-06-29)

- Objective response rate (ORR) [Time Frame: Up to 3 years]

Secondary (Current) [*]

ICMJE

(Submitted: 2021-08-30)

- Progression-free Survival (PFS): Percentage of Participants Progression/Death Event Free [Time Frame: 6, 12, 24, and 36 months]

- PFS is defined as the time from treatment initiation to first documentation of progression by International workshop on chronic lymphocytic leukemia (IWCLL) criteria/revised criteria for response for malignant lymphoma or death, whichever is earlier.
- Duration of Response (DOR): Event Free Rate - Percentage of Participants Who Remained Event Free [Time Frame: 6, 12, 24, and 36 months]
 - DOR is defined as the time from the date that response criteria are first met to the date that progressive disease (PD) is objectively documented or death, whichever occurs first
- Time to Response (TTR) [Time Frame: Up to 3.5 years]
 - TTR is defined as the time from treatment initiation to first signs of response
- Overall Response Rate as Determined by the Investigator [Time Frame: up to 3.5 years]
 - Overall response was defined as achieving a best overall response of CR, CRi, nodular partial response (nPR), PR, or partial response with lymphocytosis (PR-L).
- Number of Participants Experiencing Adverse Events (AEs) [Time Frame: Up to 3.5 years]
 - An adverse event (AE) was defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. All AEs were monitored per the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE version [v] 4.03 2010). A treatment emergent adverse event (TEAE) is defined as an adverse event that has an onset date or a worsening in severity from baseline (pretreatment) on or after the date of first dose of study drug up to 30 days following study drug discontinuation or initiation of new anticancer therapy, whichever occurs first.

Secondary (Original) [*]

ICMJE

(Submitted: 2017-06-29)

- Progression-free survival (PFS) [Time Frame: Up to 3 years]
- Duration of response (DOR) [Time Frame: Up to 3 years]
- Time to response (TTR) [Time Frame: Up to 3 years]
- The safety and tolerability of BGB-3111, measured by the incidence, timing, and severity of AEs [Time Frame: Up to 3 years]

Other Pre-specified (Current)

Not provided

Other Pre-specified (Original)

Not provided

Trial Description

Brief Title *	ICMJE
Efficacy and Safety of Zanubrutinib in Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma	
Official Title *§	ICMJE
A Single-Arm, Open-Label, Multicenter Phase 2 Study to Evaluate Safety and Efficacy of BGB-3111, a Bruton's Tyrosine Kinase (BTK) Inhibitor in Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)	
Brief Summary *	
This was a single-arm, open-label, multi-center Phase 2 study in participants with histologically documented CLL/SLL who have relapsed after or refractory to ≥ 1 prior treatment regimen(s). The study is composed of an initial screening phase, a single-arm treatment phase, and a follow-up phase.	
Detailed Description	
Not provided	
Study Type *	ICMJE
Interventional	
Study Phase *	ICMJE
Phase 2	
Study Design *§	ICMJE
Allocation N/A Interventional Model Single Group Assignment Masking None (Open Label) Primary Purpose Treatment	
Condition *	ICMJE
- Relapsed or Refractory Chronic Lymphocytic Leukemia - Relapsed or Refractory Small Lymphocytic Lymphoma	

Intervention *

ICMJE

- Drug: Zanubrutinib
 - Zanubrutinib 160 mg (two - 80 mg white opaque capsules) taken by mouth (PO) twice a day (BID)
 - Other Names:
 - BGB-3111

Study Arms *

ICMJE

- Experimental: Zanubrutinib
 - Interventions:
 - Drug: Zanubrutinib

Publications

(Includes general and study results' publications, and Pubmed publications referencing this study by ClinicalTrials.gov Identifier (NCT Number))

- [Xu W, Yang S, Zhou K, Pan L, Li Z, Zhou J, Gao S, Zhou D, Hu J, Feng R, Huang H, Ji M, Guo H, Huang J, Novotny W, Feng S, Li J. Treatment of relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma with the BTK inhibitor zanubrutinib: phase 2, single-arm, multicenter study. J Hematol Oncol. 2020 May 11;13\(1\):48. doi: 10.1186/s13045-020-00884-4.](https://pubmed.ncbi.nlm.nih.gov/32393328/) (https://pubmed.ncbi.nlm.nih.gov/32393328).
- [Xu W, Yang S, Tam CS, Seymour JF, Zhou K, Opat S, Qiu L, Sun M, Wang T, Trotman J, Pan L, Gao S, Zhou J, Zhou D, Zhu J, Song Y, Hu J, Feng R, Huang H, Su D, Shi M, Li J. Zanubrutinib Monotherapy for Naive and Relapsed/Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: A Pooled Analysis of Three Studies. Adv Ther. 2022 Sep;39\(9\):4250-4265. doi: 10.1007/s12325-022-02238-7. Epub 2022 Jul 28.](https://pubmed.ncbi.nlm.nih.gov/35900694/) (https://pubmed.ncbi.nlm.nih.gov/35900694).

Recruitment Information

Recruitment Status *

ICMJE

Completed

Enrollment (Actual) *§

ICMJE

(Submitted: 2018-03-14)

91

Original Enrollment (Estimated) *§

ICMJE

(Submitted: 2017-06-29)

80

Study Start Date (Actual) *§

ICMJE

2017-03-09

Primary Completion Date (Actual) *

2018-06-15 (Final data collection date for primary outcome measure)

Study Completion Date (Actual) *§

ICMJE

2020-09-10

Eligibility Criteria *

ICMJE

Key Inclusion Criteria:

1. Confirmed diagnosis with at least one criterion for treatment according to International workshop on chronic lymphocytic leukemia (IWCLL)
2. Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
3. Measurable disease by contrast enhanced computerized tomography / magnetic resonance imaging (CT/MRI).
4. Previously treated with a minimum of 1 prior line of standard chemotherapy-containing regimen (with completion of ≥ 2 treatment cycles).
5. Documented failure to achieve at least partial response (PR) or documented disease progression after response to the most recent treatment regimen. Refractory disease is defined as treatment failure (stable disease, non-response, progressive disease [PD]) or disease progression within 6 months after the most recent prior therapy (Hallek et al, 2008).
6. Neutrophils $\geq 0.75 \times 10^9/L$ independent of growth factor support within 7 days of study entry
7. Platelets $\geq 50 \times 10^9/L$, independent of growth factor support or transfusion within 7 days of study entry
8. Creatinine clearance of ≥ 30 ml/min (as estimated by the Cockcroft-Gault equation or estimated glomerular filtration rate [eGFR] from the Modification of Diet in Renal Disease [MDRD])
9. Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) $\leq 3 \times$ ULN

10. Bilirubin $\leq 2 \times$ ULN (unless documented Gilbert's syndrome)
11. International normalized ratio (INR) ≤ 1.5 and activated partial thromboplastin time (APTT) $\leq 1.5 \times$ ULN.
12. Participants may be enrolled who relapse after autologous stem cell transplant if they are at least 6 months after transplant.
13. Life expectancy of >4 months
14. Echocardiogram (ECHO) must demonstrate left ventricular ejection fraction (LVEF) $\geq 50\%$; (AHA, 2016)

Key Exclusion Criteria:

1. Current or history of central nervous system (CNS) lymphoma
2. Prior exposure to a Bruton's tyrosine kinase (BTK) inhibitor
3. Prior corticosteroids given in excess of prednisone 10 mg/day or its equivalent with antineoplastic intent within 7 days.
4. Major surgery within 4 weeks of screening
5. Not recovered from toxicity of any prior anti-cancer therapy to $<$ Grade 1 (except for alopecia, absolute neutrophil count (ANC) and platelets).
6. History of other active malignancies within 2 years of study entry, with exception of (1) adequately treated in-situ carcinoma of cervix; (2) localized basal cell or squamous cell carcinoma of skin; (3) previous malignancy confined and treated locally (surgery or other modality) with curative intent
7. Currently active clinically significant cardiovascular disease
8. QTcF >480 msec based on Fridericia's formula or other significant electrocardiogram abnormalities including second degree atrioventricular (AV) block Type II, or third degree AV block
9. Unable to swallow capsules or disease significantly affecting gastrointestinal function such as malabsorption syndrome, resection of the stomach or small bowel, symptomatic inflammatory bowel disease, or partial or complete bowel obstruction
10. Active infection including infections requiring oral or intravenous anti-microbials
11. Known human immunodeficiency virus (HIV), or active hepatitis B or hepatitis C infection (detected positive by polymerase chain reaction [PCR]).
12. Has received allogenic hematopoietic stem cell transplantation prior to enrollment
13. Any life-threatening illness, medical condition or organ system dysfunction which, in the investigator's opinion, could compromise the participants's safety, or put the study at risk
14. Requires ongoing treatment with any medication which is a strong cytochrome P450, family 3, subfamily A (CYP3A) inhibitor or strong CYP3A inducer
15. Known or clinically suspected Richter's transformation at the time of study entry
16. History of stroke or intracranial hemorrhage within 6 months prior to enrollment

NOTE: Other protocol defined Inclusion/Exclusion criteria may apply.

Sexes Eligible for the Study:

All

Ages *

[ICMJE](#)

18 Years and older (Adult, Older Adult)

Accepts Healthy Volunteers *§

[ICMJE](#)

No

Location Countries

[ICMJE](#)

China

Removed Location Countries

Administrative Information

NCT Number

[ICMJE](#)

NCT03206918

Other Study ID Numbers [*]

[ICMJE](#)

BGB-3111-205

CTR20160890(Registry Identifier)

Has Data Monitoring Committee

Yes

U.S. FDA-regulated Product *§

Studies a U.S. FDA-regulated Drug Product

No

Studies a U.S. FDA-regulated Device Product

No

IPD Sharing Statement

[ICMJE](#)

Plan to Share IPD:

Yes

Current Responsible Party *	
BeiGene	
Original Responsible Party *	
Same as current	
Current Study Sponsor *	ICMJE
BeiGene	
Original Study Sponsor *	ICMJE
Same as current	
Collaborators	ICMJE
Not provided	
Investigators	ICMJE
Principal Investigator: Study Director BeiGene	
PRS Account	
BeiGene	

Symbol Legend

- *** Required
- *§** Required if Study Start Date is on or after January 18, 2017
- [*]** Conditionally required
- No Symbol Unmarked fields are optional. If no information is provided, fields will be labeled as "not provided"
- ICMJE** Data element required by the [International Committee of Medical Journal Editors](https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html) (<https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html>) and the [World Health](#)

[Organization ICTRP](https://www.who.int/clinical-trials-registry-platform) (<https://www.who.int/clinical-trials-registry-platform>).



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ClinicalTrials.gov ID ⓘ NCT03206918

Sponsor ⓘ BeiGene

Information provided by ⓘ BeiGene (Responsible Party)

Last Update Posted ⓘ 2021-10-04

Results Posted Tab

Results Overview

Conditions ⓘ

Relapsed or Refractory Chronic Lymphocytic Leukemia

Relapsed or Refractory Small Lymphocytic Lymphoma

Intervention/Treatment ⓘ

- Drug: Zanubrutinib

Other Study ID Numbers ⓘ

- BGB-3111-205
- CTR20160890 (Registry Identifier) (REGISTRY: ChinaDrugTrials.org)

Study Design



Allocation ⓘ: N/A

Interventional Model ⓘ: Single Group Assignment

Masking ⓘ: None (Open Label)

Primary Purpose ⓘ: Treatment

Results Point of Contact

Name/Title: Study Director

Organization: BeiGene

Phone: +1-877-828-5568

Email: clinicaltrials@beigene.com

Enrollment (Actual) ⓘ

91

Study Type ⓘ

Interventional

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

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2017-06-29

First Posted ⓘ

2017-07-02

Results Reporting Dates

Results First Submitted ⓘ

2020-08-10

Results First Posted ⓘ

2020-09-25

Study Record Updates

Last Update Posted ⓘ

2021-10-04

Last Verified ⓘ

2021-09

Participant Flow

 ⓘ**Recruitment Details**

91 participants were enrolled at 11 sites in China. The first participant was dosed on 09 March 2017. Database lock date for the primary outcome measure was 14 December 2018. Final database lock date was 16 October 2020.

Pre-assignment Details

[Not Specified]

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.

Period Title: **Overall Study**

Started	91
Completed	0
Not Completed	91

Reason Not Completed

Death	11
Withdrawal by Subject	5

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.
Study terminated by sponsor	12
Lost to Follow-up	3
Transferred to extension study BGB-3111-LTE1 (NCT04170283)	60

Baseline Characteristics

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.
Overall Number of Baseline Participants	91
Baseline Analysis Population Description	Safety Analysis Set: All participants who received any dose of study drug.

[Expand all](#) / [Collapse all](#)

Age, Continuous

Mean (Standard Deviation) | Unit of measure: years

Number Analyzed	91 participants
	60.9 (9.73)

Age, Customized

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	91 participants
<65	60 65.9%
≥65	31 34.1%

Sex: Female, Male

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	91 participants
Female	39 42.9%
Male	52 57.1%

Race/Ethnicity, Customized

Measure Type: Number | Unit of measure: participants

Number Analyzed	91 participants
Chinese	91
Other	0

Outcome Measures

1. Overall Response Rate (ORR) by Independent Review Committee (IRC)

Type: Primary | Time Frame: Up to 1 year and 4 months

Description	ORR is defined as the number of participants who achieve a best response of CR or, CRi, Nodular Partial Response, PR, and PR with Lymphocytosis as assessed by IRC per the modified IWCLL Guidelines in participants with CLL and the Revised Criteria for Response for Malignant Lymphoma in participants with SLL.	
Time Frame	Up to 1 year and 4 months	
Analysis Population Description	Modified Safety Analysis Set: All participants in the safety analysis set who had confirmed Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL)	
Arm/Group Title	Zanubrutinib	
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to 3.5 years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.	
Overall Number of Participants Analyzed	91	
Measure Type: Count of Participants Unit of Measure: Participants	80	87.9%

Statistical Analysis 1

Statistical Analysis Overview

Comparison Group Selection	Zanubrutinib
Comments	[Not Specified]
Type of Statistical Test	Superiority

Comments	[Not Specified]
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Statistical Test of Hypothesis

P-Value	<0.0001
Comments	[Not Specified]
Method	Exact Binomial Test
Comments	The null hypothesis is ORR = 32%

Method of Estimation

Estimation Parameter	2-side Clopper-Pearson
Estimated Value	87.9
Confidence Interval	(2-Sided) 95% 79.40 to 93.81
Estimation Comments	[Not Specified]

2. Progression-free Survival (PFS): Percentage of Participants

Progression/Death Event Free

Type: Secondary | Time Frame: 6, 12, 24, and 36 months

Description	PFS is defined as the time from treatment initiation to first documentation of progression by International workshop on chronic lymphocytic leukemia (IWCLL) criteria/revised criteria for response for malignant lymphoma or death, whichever is earlier.
Time Frame	6, 12, 24, and 36 months
Analysis Population Description	The Safety Analysis Set included all participants who received ≥ 1 doses of study drug. All efficacy analyses were based on the Safety Analysis Set

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to 3.5 years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.
Overall Number of Participants Analyzed	91
6 months *Median (95% Confidence Interval) Unit of Measure: Percentage of participants	93.3 (85.72 to 96.94)
12 months *	88.7 (80.04 to 93.77)
24 months *	80.5 (70.52 to 87.42)
36 months *	68.1 (56.56 to 77.24)
* Median (95% Confidence Interval) Unit of Measure: Percentage of participants	

3. Duration of Response (DOR): Event Free Rate - Percentage of Participants Who Remained Event Free

Type: Secondary | Time Frame: 6, 12, 24, and 36 months

Description	DOR is defined as the time from the date that response criteria are first met to the date that progressive disease (PD) is objectively documented or death, whichever occurs first
Time Frame	6, 12, 24, and 36 months

Analysis Population Description	The Safety Analysis Set included all participants who received ≥ 1 doses of study drug. Duration of response was summarized for responders (with Best Overall Response of partial response with lymphocytosis (PR-L) or above) only
Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to 3.5 years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.
Overall Number of Participants Analyzed	80
6 Months *Median (95% Confidence Interval) Unit of Measure: Percentage of participants	97.5 (90.37 to 99.37)
12 Months *	92.5 (83.96 to 96.54)
24 Months *	83.4 (73.20 to 90.04)
36 Months *	69.9 (57.02 to 79.55)
* Median (95% Confidence Interval) Unit of Measure: Percentage of participants	

4. Time to Response (TTR)

Type: Secondary | Time Frame: Up to 3.5 years

Description	TTR is defined as the time from treatment initiation to first signs of response
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Time Frame	Up to 3.5 years
Analysis Population Description	The Safety Analysis Set included all participants who received ≥ 1 doses of study drug. Time to response was summarized for responders (those who achieved a best overall response of at least PR-L) only
Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to 3.5 years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.
Overall Number of Participants Analyzed	80
Median (Full Range) Unit of Measure: Months	2.79 (2.6 to 16.8)

5. Overall Response Rate as Determined by the Investigator

Type: Secondary | Time Frame: up to 3.5 years

Description	Overall response was defined as achieving a best overall response of CR, CRi, nodular partial response (nPR), PR, or partial response with lymphocytosis (PR-L).
Time Frame	up to 3.5 years
Analysis Population Description	The Safety Analysis Set included all participants who received ≥ 1 doses of study drug.

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to 3.5 years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.
Overall Number of Participants Analyzed	91
Median (95% Confidence Interval) Unit of Measure: Percentage of participants	92.3 (84.79 to 96.85)

6. Number of Participants Experiencing Adverse Events (AEs)

Type: Secondary | Time Frame: Up to 3.5 years

Description	An adverse event (AE) was defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. All AEs were monitored per the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE version [v] 4.03 2010). A treatment emergent adverse event (TEAE) is defined as an adverse event that has an onset date or a worsening in severity from baseline (pretreatment) on or after the date of first dose of study drug up to 30 days following study drug discontinuation or initiation of new anticancer therapy, whichever occurs first.
Time Frame	Up to 3.5 years
Analysis Population Description	The Safety Analysis Set included all participants who received ≥ 1 doses of study drug.

Arm/Group Title	Zanubrutinib	
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to 3.5 years or until progressive disease, unacceptable toxicity, death, withdrawal of consent, or study termination by the sponsor.	
Overall Number of Participants Analyzed	91	
At Least 1 TEAE *Measure Type: Count of Participants Unit of Measure: Participants	91	100.0%
Grade 3 or higher TEAE *	76	83.5%
Serious TEAEs *	47	51.6%
TEAE leading to death *	6	6.6%
TEAE leading to treatment discontinuation *	14	15.4%
TEAE leading to treatment modification *	42	46.2%
TEAE leading to treatment interruption *	42	46.2%
TEAE leading to dose reduction *	8	8.8%
Treatment-related TEAE *		
* Measure Type: Count of Participants Unit of Measure:	g Description	

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years

All-Cause Mortality

Arm/Group Title	Zanubrutinib
	Affected / at Risk (%)
Total	11/91 (12.09%)

Serious Adverse Events

Arm/Group Title	Zanubrutinib
	Affected / at Risk (%)
Total	47/91 (51.65%)

Blood and lymphatic system disorders

Anaemia ^{†1}	1/91 (1.10%)
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Cardiac disorders

Cardiac failure ^{†1}	1/91 (1.10%)
Cardiopulmonary failure ^{†1}	1/91 (1.10%)
Myocardial ischaemia ^{†1}	1/91 (1.10%)

Endocrine disorders

Goitre ^{†2}	1/91 (1.10%)
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Gastrointestinal disorders

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
Intestinal obstruction ^{†1}	1/91 (1.10%)
Haemorrhoids ^{†2}	1/91 (1.10%)
Intestinal polyp ^{†3}	1/91 (1.10%)

General disorders

Multiple organ dysfunction syndrome ^{†1}	1/91 (1.10%)
Death ^{†2}	1/91 (1.10%)

Hepatobiliary disorders

Cholecystitis ^{†1}	1/91 (1.10%)
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Infections and infestations

Anorectal infection ^{†1}	1/91 (1.10%)
Bronchitis ^{†1}	3/91 (3.30%)
Dermatitis infected ^{†1}	1/91 (1.10%)
Gastroenteritis ^{†1}	2/91 (2.20%)
Hepatitis B ^{†1}	3/91 (3.30%)
Lung infection ^{†1}	7/91 (7.69%)
Pneumonia ^{†1}	22/91 (24.18%)
Pneumonia fungal ^{†1}	1/91 (1.10%)
Skin infection ^{†1}	2/91 (2.20%)

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
Splenic infection ^{†1}	1/91 (1.10%)
Upper respiratory tract infection ^{†1}	4/91 (4.40%)
Appendicitis ^{†2}	1/91 (1.10%)
Cryptococcosis ^{†2}	1/91 (1.10%)
Enteritis infectious ^{†2}	1/91 (1.10%)
Infectious pleural effusion ^{†2}	1/91 (1.10%)

Injury, poisoning and procedural complications

Hand fracture ^{†1}	1/91 (1.10%)
Brain herniation ^{†2}	1/91 (1.10%)
Periprosthetic fracture ^{†3}	1/91 (1.10%)

Investigations

Neutrophil count decreased ^{†2}	1/91 (1.10%)
Platelet count decreased ^{†2}	1/91 (1.10%)
Osteoarthropathy ^{†2}	1/91 (1.10%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Breast cancer ^{†1}	1/91 (1.10%)
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Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
Colon cancer ^{†1}	1/91 (1.10%)
Adenocarcinoma gastric ^{†3}	2/91 (2.20%)
Rectal cancer ^{†2}	1/91 (1.10%)

Nervous system disorders

Haemorrhage intracranial ^{†1}	1/91 (1.10%)
Headache ^{†1}	2/91 (2.20%)
Post herpetic neuralgia ^{†1}	1/91 (1.10%)
Cerebrovascular insufficiency ^{†2}	1/91 (1.10%)

Renal and urinary disorders

Hydronephrosis ^{†2}	1/91 (1.10%)
Ureterolithiasis ^{†2}	1/91 (1.10%)

Reproductive system and breast disorders

Benign prostatic hyperplasia ^{†2}	1/91 (1.10%)
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Respiratory, thoracic and mediastinal disorders

Bronchiectasis ^{†1}	1/91 (1.10%)
Respiratory failure ^{†1}	1/91 (1.10%)

Skin and subcutaneous tissue disorders

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years

Rash maculo-papular ^{† 1}	1/91 (1.10%)
[†] Indicates events were collected by systematic assessment ¹ Term from vocabulary, MedDRA 20.0 ² Term from vocabulary, MedDRA (23.0) ³ Term from vocabulary, MedDRA (20.0)	

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	3%
Arm/Group Title	Zanubrutinib
	Affected / at Risk (%)
Total	91/91 (100.00%)

Blood and lymphatic system disorders

Anaemia ^{† 1}	32/91 (35.16%)
Thrombocytopenia ^{† 1}	12/91 (13.19%)
Neutropenia ^{† 2}	4/91 (4.40%)

Cardiac disorders

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
Sinus bradycardia ^{†2}	3/91 (3.30%)

Gastrointestinal disorders

Abdominal distension ^{†1}	7/91 (7.69%)
Abdominal pain upper ^{†1}	8/91 (8.79%)
Constipation ^{†1}	9/91 (9.89%)
Diarrhoea ^{†1}	20/91 (21.98%)
Toothache ^{†1}	8/91 (8.79%)
Vomiting ^{†1}	8/91 (8.79%)
Gastritis ^{†2}	5/91 (5.49%)
Dyspepsia ^{†2}	4/91 (4.40%)
Periodontal disease ^{†2}	4/91 (4.40%)
Abdominal pain ^{†2}	3/91 (3.30%)
Gastrooesophageal reflux disease ^{†2}	3/91 (3.30%)
Mouth ulceration ^{†2}	3/91 (3.30%)
Nausea ^{†2}	3/91 (3.30%)

General disorders

Influenza like illness ^{†1}	5/91 (5.49%)
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Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
Pyrexia ^{†1}	12/91 (13.19%)
Oedema peripheral ^{†2}	3/91 (3.30%)
Fatigue ^{†2}	3/91 (3.30%)

Hepatobiliary disorders

Hyperbilirubinaemia ^{†2}	6/91 (6.59%)
Hepatic function abnormal ^{†2}	4/91 (4.40%)

Infections and infestations

Bronchitis ^{†1}	8/91 (8.79%)
Paronychia ^{†1}	5/91 (5.49%)
Pharyngitis ^{†1}	9/91 (9.89%)
Skin infection ^{†1}	11/91 (12.09%)
Upper respiratory tract infection ^{†1}	50/91 (54.95%)
Urinary tract infection ^{†1}	18/91 (19.78%)
Pneumonia ^{†2}	24/91 (26.37%)
Herpes zoster ^{†3}	7/91 (7.69%)
Gastroenteritis ^{†3}	5/91 (5.49%)
Gingivitis ^{†3}	5/91 (5.49%)

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
Paronychia ^{†3}	5/91 (5.49%)
Periodontitis ^{†3}	5/91 (5.49%)
Sinusitis ^{†3}	5/91 (5.49%)
Asymptomatic bacteriuria ^{†3}	4/91 (4.40%)
Oral herpes ^{†3}	4/91 (4.40%)
Hepatitis B reactivation ^{†2}	3/91 (3.30%)
Rash pustular ^{†2}	3/91 (3.30%)
Tonsillitis ^{†2}	3/91 (3.30%)

Injury, poisoning and procedural complications

Ligament sprain ^{†3}	3/91 (3.30%)
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Investigations

Alanine aminotransferase increased ^{†1}	16/91 (17.58%)
Aspartate aminotransferase increased ^{†1}	14/91 (15.38%)
Bacterial test positive ^{†1}	6/91 (6.59%)
Blood alkaline phosphatase	7/91 (7.69%)

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
increased ^{† 1}	
Blood bilirubin increased ^{† 1}	15/91 (16.48%)
Blood fibrinogen decreased ^{† 1}	6/91 (6.59%)
Blood lactate dehydrogenase increased ^{† 1}	5/91 (5.49%)
Blood urine present ^{† 1}	12/91 (13.19%)
Carbon dioxide increased ^{† 1}	23/91 (25.27%)
Electrocardiogram QT prolonged ^{† 1}	8/91 (8.79%)
Neutrophil count decreased ^{† 1}	70/91 (76.92%)
Neutrophil percentage decreased ^{† 1}	8/91 (8.79%)
Platelet count decreased ^{† 1}	39/91 (42.86%)
Red blood cells urine positive ^{† 1}	8/91 (8.79%)
Urobilinogen urine increased ^{† 1}	16/91 (17.58%)
White blood cell count decreased ^{† 1}	23/91 (25.27%)

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
Gamma-glutamyltransferase increased ^{†3}	8/91 (8.79%)
Low density lipoprotein decreased ^{†3}	8/91 (8.79%)
Lymphocyte count decreased ^{†3}	8/91 (8.79%)
Blood creatinine increased ^{†3}	7/91 (7.69%)
Bacterial test positive ^{†3}	6/91 (6.59%)
Hepatitis B core antibody positive ^{†3}	6/91 (6.59%)
High density lipoprotein decreased ^{†2}	6/91 (6.59%)
Weight decreased ^{†2}	6/91 (6.59%)
Blood glucose increased ^{†3}	4/91 (4.40%)
Globulins decreased ^{†3}	4/91 (4.40%)
Haemoglobin decreased ^{†2}	4/91 (4.40%)
High density lipoprotein	4/91 (4.40%)

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
increased ^{†2}	
White blood cells urine positive ^{†3}	4/91 (4.40%)
Blood immunoglobulin A decreased ^{†2}	3/91 (3.30%)
Carbon dioxide decreased ^{†2}	3/91 (3.30%)
Urine leukocyte esterase positive ^{†2}	3/91 (3.30%)
White blood cell count increased ^{†3}	3/91 (3.30%)

Metabolism and nutrition disorders

Hyperglycaemia ^{†1}	26/91 (28.57%)
Hyperuricaemia ^{†1}	18/91 (19.78%)
Hypoalbuminaemia ^{†1}	12/91 (13.19%)
Hypocalcaemia ^{†1}	13/91 (14.29%)
Hypokalaemia ^{†1}	28/91 (30.77%)
Hyponatraemia ^{†1}	10/91 (10.99%)
Hypertriglyceridaemia ^{†3}	7/91 (7.69%)
Hyperlipidaemia ^{†3}	6/91 (6.59%)
Hypercholesterolaemi	5/91 (5.49%)

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
a ^{†2}	
Hypercalcaemia ^{†2}	4/91 (4.40%)
Hypophosphataemia ^{†2}	4/91 (4.40%)

Musculoskeletal and connective tissue disorders

Back pain ^{†2}	4/91 (4.40%)
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Nervous system disorders

Dizziness ^{†1}	7/91 (7.69%)
Headache ^{†2}	6/91 (6.59%)

Renal and urinary disorders

Haematuria ^{†1}	40/91 (43.96%)
Proteinuria ^{†1}	15/91 (16.48%)

Reproductive system and breast disorders

Benign prostatic hyperplasia ^{†2}	4/91 (4.40%)
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Respiratory, thoracic and mediastinal disorders

Cough ^{†1}	27/91 (29.67%)
Epistaxis ^{†1}	5/91 (5.49%)
Oropharyngeal pain ^{†2}	6/91 (6.59%)
Nasal obstruction ^{†2}	4/91 (4.40%)

Arm/Group Title	Zanubrutinib
Arm/Group Description	160 mg administered orally (two - 80 mg white opaque capsules) twice a day (BID) for up to three years
Tonsillar hypertrophy ^{† 2}	4/91 (4.40%)

Skin and subcutaneous tissue disorders

Haemorrhage subcutaneous ^{† 1}	7/91 (7.69%)
Purpura ^{† 1}	31/91 (34.07%)
Rash ^{† 1}	17/91 (18.68%)
Rash maculo-papular ^{† 1}	5/91 (5.49%)
Dermatitis allergic ^{† 2}	3/91 (3.30%)
Ecchymosis ^{† 2}	3/91 (3.30%)
Pruritus ^{† 2}	3/91 (3.30%)
Skin haemorrhage ^{† 2}	3/91 (3.30%)

Vascular disorders

Hypertension ^{† 1}	10/91 (10.99%)
[†] Indicates events were collected by systematic assessment ¹ Term from vocabulary, MedDRA 20.0 ² Term from vocabulary, MedDRA (23.0) ³ Term from vocabulary, MedDRA (20.0)	

Limitations and Caveats

[Not Specified]

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

BeiGene

Investigators ⓘ

- Principal Investigator: Study Director, BeiGene

Publications

Study Results

These publications are provided voluntarily by the person who enters information about the study and are about the study results.

- [Xu W, Yang S, Zhou K, Pan L, Li Z, Zhou J, Gao S, Zhou D, Hu J, Feng R, Huang H, Ji M, Guo H, Huang J, Novotny W, Feng S, Li J. Treatment of relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma with the BTK inhibitor zanubrutinib: phase 2, single-arm, multicenter study. J Hematol Oncol. 2020 May 11;13\(1\):48. doi: 10.1186/s13045-020-00884-4.](https://pubmed.ncbi.nlm.nih.gov/32393328/) (https://pubmed.ncbi.nlm.nih.gov/32393328).

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- [Xu W, Yang S, Tam CS, Seymour JF, Zhou K, Opat S, Qiu L, Sun M, Wang T, Trotman J, Pan L, Gao S, Zhou J, Zhou D, Zhu J, Song Y, Hu J, Feng R, Huang H, Su D, Shi M, Li J. Zanubrutinib Monotherapy for Naive and Relapsed/Refractory Chronic Lymphocytic](https://pubmed.ncbi.nlm.nih.gov/32393328/) (https://pubmed.ncbi.nlm.nih.gov/32393328).

More Information

Record History

Certain Agreements ⓘ

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed

BeiGene has 18 months from the end of the study at all sites to publish overall study results. After the 1st multi-site publication or the expiration of publication period, Investigators are free to publish/present the results of the study. Investigators must submit all draft publications/presentations to us for review 60 days prior to the planned publication/presentation date. BeiGene may request deletion of its confidential information & may request a further delay to protect its IP rights.



The U.S. government does not review or approve the safety and science of all studies listed on this website.

Read our full [disclaimer](https://clinicaltrials.gov/about-site/disclaimer) (<https://clinicaltrials.gov/about-site/disclaimer>) for details.

COMPLETED ⓘ

Efficacy and Safety of Zanubrutinib in Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

ClinicalTrials.gov ID ⓘ NCT03206918

Sponsor ⓘ BeiGene

Information provided by ⓘ BeiGene (Responsible Party)

Last Update Posted ⓘ 2021-10-04

Record History Tab

Study Record Versions

- This table shows all the versions of this study record arranged in order by submitted date.
 - To view one version of the study record, click the submitted date.
 - To compare two versions, select them using the check boxes and click "Compare" at the bottom of the list.

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	1	2017-06-29	None (earliest version on record)

Feedback

	Version	Date submitted (YYYY-MM-DD)	Changes
☐	2	2018-03-14	- Recruitment Status - Study Status - Study Design
☐	3	2019-05-16	- Study Status - Oversight - Eligibility - Contacts/Locations
☐	4	2019-07-17	- Study Status - Study Identification
☐	6	2019-11-01	Study Status
☐	7	2020-03-04	- Study Status - Study Description - Outcome Measures - Eligibility - Arms and Interventions - IPDSharing Results Submission Events (2) 2020-08-10: Returned after QC review: 2020-08-20 2020-08-25: (Canceled on 2020-08-25)
☐	8	2020-09-04	- Study Status - Study Identification - Conditions

	Version	Date submitted (YYYY-MM-DD)	Changes
			• Eligibility • References • Participant Flow • Baseline Characteristics • Outcome Measures • Adverse Events • More Information • Document Section • Study Description • Contacts/Locations
☐	9	2021-03-03	• Recruitment Status • Study Status
☐	10	2021-08-30	• Study Status • Outcome Measures • Participant Flow • Study Identification • Study Description • Eligibility • Contacts/Locations • Baseline Characteristics • Adverse Events
☐	11	2021-09-29	• Study Status • Outcome Measures • Participant Flow