A Study to Investigate Sonrotoclax (BGB-11417) Plus Zanubrutinib (BGB 3111) Compared With Venetoclax Plus Acalabrutinib in Patients With Previously Untreated Chronic Lymphocytic Leukemia

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	314
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2025-524366-21-00 (CTIS)

Cod. Protocolo
BGB-11417-304

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
treatment-naive Chronic Lymphocytic Leukemia

Título Científico
A Phase 3, Open-Label, Randomized Study of Sonrotoclax (BGB-11417) plus Zanubrutinib (BGB-3111) Compared with Venetoclax plus Acalabrutinib in Patients with Previously Untreated Chronic Lymphocytic Leukemia

Justificación

No aportado

Objetivo Principal

To compare efficacy between Arm A (SZ) vs Arm B (AV), as measured by PFS determined by the Independent Review Committee (IRC) in all enrolled patients.

Variables de Evaluación Primaria

PFS, defined as time from the date of randomization to the date of disease progression as determined by IRC or death due to any cause, whichever occurs first.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare the rate of undetectable MRD at < 10-4 sensitivity (uMRD4) in both PB and BMA among patients enrolled to Arm A vs Arm B To compare PFS determined by IRC among high-risk patients enrolled to Arm A vs Arm B To compare overall survival (OS) among patients enrolled to Arm A vs Arm B To compare overall response rate (ORR) among patients enrolled to Arm A vs Arm B determined by IRC To compare the rate of undetectable MRD at < 10-5 sensitivity (uMRD5) in both PB and BMA among patients enrolled to Arm A vs Arm B Safety To further compare the outcomes of Arms A and Arm B To evaluate the patient-reported disease and treatment specific symptoms and functioning in patients receiving SZ compared with patients receiving AV; and compare changes in the key patient-reported outcomes (PRO) endpoints in patients receiving SZ vs AV

Variables de Evaluación Secundaria

uMRD4 rate defined as the proportion of patients that achieved uMRD4 measured in both PB and BMA at the PTFU1 Visit based on next-generation sequencing (NGS [clonoSEQ])
PFS as determined by IRC in high-risk patients that have unmutated IGHV and/or TP53 aberrations (del(17p) present and/or TP53 mutated)
OS, defined as time from the date of randomization to the date of death due to any cause
ORR defined as the proportion of patients with a CR, CRi, nodular partial response (nPR), or partial response (PR) per the IRC assessment
uMRD5 rate defined as the proportion of patients that achieved uMRD5 measured in both PB and BMA at the PTFU1 Visit based on NGS (clonoSEQ)
Adverse events (AEs), adverse events of clinical interest (AECIs), serious adverse events (SAEs), changes from baseline in clinical laboratory tests, physical examinations, and vital signs
PFS determined by investigator assessment
Overall CRR determined by IRC and by investigator assessment.

ORR determined by investigator assessment
Duration of response (DOR; determined by both IRC and investigator assessment) defined as the time from first qualifying response (CR, CRi, nPR, or PR) until disease progression or death
Time to next treatment (TTNT) defined as the time from randomization to the start of next treatment for CLL
Patient-reported symptoms of global health status (GHS), role functioning, and physical functioning, symptom burden, and physical condition/fatigue measured by European Organization for Research and Treatment of Cancer quality of life questionnaire EORTC IL-409

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Confirmed diagnosis of CLL that meets the iwCLL criteria: a. Clonal, either kappa or lambda light chain restricted, monoclonal B cells that are co-expressing CD5 surface antigen together with B-cell antigens CD19, CD20, and CD23. b. Clonal B-cells 5 x 109/L in peripheral blood at any timepoint since the initial diagnosis. c. Absence of t(11:14) in FISH 10. Female patients of childbearing potential must be willing to use a highly effective method of birth control and refrain from egg donation for the duration of the study and for the following, whichever comes last: 7 days after the last dose of sonrotoclax, 30 days after the last dose of zanubrutinib or venetoclax, 7 days after the last dose of acalabrutinib. Female patients must also have a negative serum pregnancy test result 7 days before enrollment and randomization, as well as a negative highly sensitive urine or serum pregnancy test result within 24 hours prior to Day 1 of Cycle 1 dosing. 11. Nonsterile male patients must be willing to use a highly effective method of birth control and must refrain from donating sperm for the duration of the study and for the following, whichever comes last: 7 days after the last dose of sonrotoclax, 30 days after the last dose of zanubrutinib or venetoclax, 7 days after the last dose of acalabrutinib A sterile male is defined as one for whom azoospermia has been previously demonstrated in a semen sample examination as definitive evidence of infertility. Males with known low sperm counts (consistent with subfertility) are not to be considered sterile for purposes of this study. 2. CLL requiring treatment as defined by 1 of the following criteria: a. Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia. Hemoglobin concentrations < 10 g/dL or platelet counts < 100 x 109 cells/L are generally regarded as indications for treatment. b. Massive (ie, 6 cm below the left costal margin), progressive, or symptomatic splenomegaly. c. Massive (ie, 10 cm in longest diameter [LDi]), progressive, or symptomatic lymphadenopathy. d. Progressive lymphocytosis with an increase of 50% over a 2-month period, or lymphocyte doubling time (LDT) < 6 months. NOTE: LDT can be obtained by linear regression extrapolation of absolute lymphocyte counts obtained at intervals of 2 weeks over an observation period of 2 to 3 months; patients with initial blood lymphocyte counts < 30 x 109 cells/L may require a longer observation period to determine the LDT. Factors contributing to lymphocytosis other than CLL (eg, infections and steroid administration) should be excluded. e. Symptomatic or functional extranodal involvement (eg, skin, kidney, lung, and spine). f. Disease-related symptoms as defined by any of the following: Unintentional weight loss 10% within the previous 6 months. Fevers 100.5°F or 38.0°C for 2 or more weeks without evidence of infection. Night sweats for 1 month without evidence of infection. Significant fatigue (ie, ECOG Performance Status score of 2 or worse; cannot work or unable to perform usual activities). NOTE: Patients with significant fatigue cannot have an ECOG score of 0. 3. ECOG Performance Status of 0, 1, or 2. 4. Measurable disease by CT/MRI. Measurable disease is defined as 1 lymph node 1.5 cm in LDi and measurable in 2 perpendicular diameters. 5. Adequate marrow function as defined by: a. Absolute neutrophil count 1.0 x 109 cells/L with an exception for patients with bone marrow involvement, in which case, the absolute neutrophil count must be 0.75 x 109 cells/L (without growth factor support within the past 14 days). b. Platelet counts 50 x 109 cells/L; in cases of thrombocytopenia clearly due to marrow involvement of CLL, platelet count should be 30 x 109 cells/L (without growth factor support or transfusion within the past 14 days). c. Hemoglobin > 75 g/L (may be posttransfusion). 6. Adequate liver function as indicated by AST and ALT 2.5 x the institutional ULN value; serum total bilirubin 2.0 x ULN (unless documented Gilbert syndrome when serum total bilirubin 3.0 x ULN and conjugated bilirubin 1.5 x ULN). 7. Adequate renal function defined as creatinine clearance

30 mL/min directly measured with a 24-hour urine collection or 30 mL/min calculated according to the BSA-adjusted CKD-EPI calculation 8. Life expectancy > 6 months. 9. Adult patient 18 years of age, inclusive, at the time of signing the ICF and be capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the ICF and in this protocol. Prisoners, individuals institutionalized by regulatory or court order, and persons who may be dependent on the sponsor or an investigator are excluded from the study.

Criterios de Exclusión

1. Previous systemic treatment for CLL. (Note: Up to 4 doses of anti-CD-20 antibody specifically for autoimmune cytopenia is allowed; the last dose should be given 6 months before screening). 10. Active fungal, bacterial, and/or viral infection requiring systemic therapy. History or known hypersensitivity to zanubrutinib, sonrotoclax, acalabrutinib, venetoclax, or any of its excipients (eg, trehalose), xanthine oxidase inhibitors, or rasburicase. 12. History of severe bleeding disorder, such as hemophilia A, hemophilia B, von Willebrand disease, or history of spontaneous bleeding requiring blood transfusion or other medical intervention. 13. Female patients who are pregnant or are breastfeeding. 14. Vaccination with a live vaccine within 28 days before enrollment and randomization 15. Patients with underlying medical conditions (including laboratory abnormalities) or alcohol or drug abuse or dependence that will be unfavorable for the administration of study treatment, precludes the patients safe participation in the study or will affect the explanation of drug toxicity or AEs, or will result in insufficient or impaired compliance with study conduct. 16. Positive HIV serology (HIVAb) status or serologic status reflecting active hepatitis B or C infection as follows: a. Presence of HBsAg. b. Patients with presence of HBcAb, in the absence of HBsAg, with detectable HBV DNA. NOTE: The limit of detection for HBV DNA must have a sensitivity of < 20 IU/mL; Patients with presence of HBcAb but undetectable HBV DNA who are willing to undergo HBV DNA monitoring every 4 weeks for HBV reactivation are eligible. c. Patients with presence of HCV antibody and HCV RNA detectable NOTE: The limit of detection for HCV RNA must have a sensitivity of < 15 IU/mL; Patients with presence of HCVAb and undetectable HCV RNA who are willing to undergo HCV RNA monitoring every 4 weeks for HCV reactivation are eligible. 17. Requires the use of warfarin, marcumar, phenprocoumon, or vitamin K antagonist. 18. Receiving treatment with any moderate or strong CYP3A4 inhibitor or strong CYP3A4 inducer (14 days or 5 half lives, whichever is shorter) before the first dose of study drug, or requiring ongoing treatment with a moderate or strong CYP3A inhibitor or a strong CYP3A inducer. 19. Consumed grapefruit, grapefruit products, Seville oranges (including marmalade containing Seville oranges), or star fruit within 3 days before the first dose of study treatment. 2. Known prolymphocytic leukemia or history of, or currently suspected, Richters transformation (biopsy based on clinical suspicion may be needed to rule out transformation). 20. Unable to swallow capsules or tablets or diseases significantly affecting GI function, such as malabsorption syndrome, resection of the stomach or small bowel, bariatric surgery procedures, symptomatic inflammatory bowel disease, or partial or complete bowel obstruction. 21. At time of enrollment, receiving systemic corticosteroids unless administered for adrenal replacement. 22. Major surgery within 4 weeks of the first dose of study treatment. 3. Known CNS involvement. 4. Patients with a history of confirmed progressive multifocal leukoencephalopathy. 5. Severe or debilitating pulmonary disease, defined as chronic supplementation of oxygen and/or respiratory failure requiring assisted ventilation. 6. Clinically significant cardiovascular disease including the following: a. Myocardial infarction within 6 months before screening. b. Unstable angina within 3 months before screening. c. New York Heart Association class III or IV congestive heart failure. d. History of clinically significant arrhythmias (eg, sustained ventricular tachycardia, ventricular fibrillation, or torsades de pointes). e. QTcF > 480 milliseconds based on Fridericias formula. NOTE: QTcF value may be calculated as the numerical average of up to 3 separate readings for eligibility. f. History of Mobitz II second-degree or third-degree heart block without a permanent pacemaker in place. g. Uncontrolled hypertension as indicated by a minimum of 2 consecutive blood pressure measurements showing systolic blood pressure > 170 mmHg and diastolic blood pressure > 105 mmHg at screening. 7. Uncontrolled autoimmune hemolytic anemia or immune thrombocytopenia requiring treatment. 8. History of prior malignancy, except for conditions as listed below and as long as patients have recovered from the acute side effects incurred because of previous therapy: a. Malignancies surgically treated with curative intent and with no known active disease present for 3 years before enrollment and randomization. b. Adequately treated nonmelanoma skin cancer or lentigo maligna without evidence of disease. c. Adequately treated cervical carcinoma in situ without evidence of disease. d. Localized prostate cancer with Gleason score 6. 9. Use of investigational agents within the last 4 weeks before screening.

Calendario

(Última actualización: 22/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
24/04/2026	18/05/2026	18/05/2026	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

BeOne Medicines I GmbH Switzerland

Aeschengraben 27

Contact Person

BeOne Medical Officer

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clinicaltrials@beonemed.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Activo (14/05/2026)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (14/05/2026)

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

Hematology

Activo (20/05/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematatology

Activo (18/05/2026)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medicamentos

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01EL02 - ACALABRUTINIB
Principios Activos: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

Zanubrutinib
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Venclyxto 50 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

Venclyxto 10 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01XX52 - VENETOCLAX
Principios Activos: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

Sin resultados

A Study to Investigate Sonrotoclax (BGB-11417) Plus Zanubrutinib (BGB 3111) Compared With Venetoclax Plus Acalabrutinib in Patients With Previously Untreated Chronic Lymphocytic Leukemia

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	314
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2025-524366-21-00 (CTIS)

Protocol Code
BGB-11417-304

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
treatment-naive Chronic Lymphocytic Leukemia

Scientific Title
A Phase 3, Open-Label, Randomized Study of Sonrotoclax (BGB-11417) plus Zanubrutinib (BGB-3111) Compared with Venetoclax plus Acalabrutinib in Patients with Previously Untreated Chronic Lymphocytic Leukemia

Rationale

Not provided

Main Objective

To compare efficacy between Arm A (SZ) vs Arm B (AV), as measured by PFS determined by the Independent Review Committee (IRC) in all enrolled patients.

Primary Endpoints

PFS, defined as time from the date of randomization to the date of disease progression as determined by IRC or death due to any cause, whichever occurs first.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the rate of undetectable MRD at < 10-4 sensitivity (uMRD4) in both PB and BMA among patients enrolled to Arm A vs Arm B To compare PFS determined by IRC among high-risk patients enrolled to Arm A vs Arm B To compare overall survival (OS) among patients enrolled to Arm A vs Arm B To compare overall response rate (ORR) among patients enrolled to Arm A vs Arm B determined by IRC To compare the rate of undetectable MRD at < 10-5 sensitivity (uMRD5) in both PB and BMA among patients enrolled to Arm A vs Arm B Safety To further compare the outcomes of Arms A and Arm B To evaluate the patient-reported disease and treatment specific symptoms and functioning in patients receiving SZ compared with patients receiving AV; and compare changes in the key patient-reported outcomes (PRO) endpoints in patients receiving SZ vs AV

Secondary Endpoints

uMRD4 rate defined as the proportion of patients that achieved uMRD4 measured in both PB and BMA at the PTFU1 Visit based on next-generation sequencing (NGS [clonoSEQ])
PFS as determined by IRC in high-risk patients that have unmutated IGHV and/or TP53 aberrations (del(17p) present and/or TP53 mutated)
OS, defined as time from the date of randomization to the date of death due to any cause
ORR defined as the proportion of patients with a CR, CRi, nodular partial response (nPR), or partial response (PR) per the IRC assessment
uMRD5 rate defined as the proportion of patients that achieved uMRD5 measured in both PB and BMA at the PTFU1 Visit based on NGS (clonoSEQ)
Adverse events (AEs), adverse events of clinical interest (AECIs), serious adverse events (SAEs), changes from baseline in clinical laboratory tests, physical examinations, and vital signs
PFS determined by investigator assessment
Overall CRR determined by IRC and by investigator assessment.

ORR determined by investigator assessment
Duration of response (DOR; determined by both IRC and investigator assessment) defined as the time from first qualifying response (CR, CRi, nPR, or PR) until disease progression or death
Time to next treatment (TTNT) defined as the time from randomization to the start of next treatment for CLL
Patient-reported symptoms of global health status (GHS), role functioning, and physical functioning, symptom burden, and physical condition/fatigue measured by European Organization for Research and Treatment of Cancer quality of life questionnaire EORTC IL-409

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Confirmed diagnosis of CLL that meets the iwCLL criteria: a. Clonal, either kappa or lambda light chain restricted, monoclonal B cells that are co-expressing CD5 surface antigen together with B-cell antigens CD19, CD20, and CD23. b. Clonal B-cells 5 x 109/L in peripheral blood at any timepoint since the initial diagnosis. c. Absence of t(11:14) in FISH 10. Female patients of childbearing potential must be willing to use a highly effective method of birth control and refrain from egg donation for the duration of the study and for the following, whichever comes last: 7 days after the last dose of sonrotoclax, 30 days after the last dose of zanubrutinib or venetoclax, 7 days after the last dose of acalabrutinib. Female patients must also have a negative serum pregnancy test result 7 days before enrollment and randomization, as well as a negative highly sensitive urine or serum pregnancy test result within 24 hours prior to Day 1 of Cycle 1 dosing. 11. Nonsterile male patients must be willing to use a highly effective method of birth control and must refrain from donating sperm for the duration of the study and for the following, whichever comes last: 7 days after the last dose of sonrotoclax, 30 days after the last dose of zanubrutinib or venetoclax, 7 days after the last dose of acalabrutinib A sterile male is defined as one for whom azoospermia has been previously demonstrated in a semen sample examination as definitive evidence of infertility. Males with known low sperm counts (consistent with subfertility) are not to be considered sterile for purposes of this study. 2. CLL requiring treatment as defined by 1 of the following criteria: a. Evidence of progressive marrow failure as manifested by the development of, or worsening of, anemia and/or thrombocytopenia. Hemoglobin concentrations < 10 g/dL or platelet counts < 100 x 109 cells/L are generally regarded as indications for treatment. b. Massive (ie, 6 cm below the left costal margin), progressive, or symptomatic splenomegaly. c. Massive (ie, 10 cm in longest diameter [LDi]), progressive, or symptomatic lymphadenopathy. d. Progressive lymphocytosis with an increase of 50% over a 2-month period, or lymphocyte doubling time (LDT) < 6 months. NOTE: LDT can be obtained by linear regression extrapolation of absolute lymphocyte counts obtained at intervals of 2 weeks over an observation period of 2 to 3 months; patients with initial blood lymphocyte counts < 30 x 109 cells/L may require a longer observation period to determine the LDT. Factors contributing to lymphocytosis other than CLL (eg, infections and steroid administration) should be excluded. e. Symptomatic or functional extranodal involvement (eg, skin, kidney, lung, and spine). f. Disease-related symptoms as defined by any of the following: Unintentional weight loss 10% within the previous 6 months. Fevers 100.5°F or 38.0°C for 2 or more weeks without evidence of infection. Night sweats for 1 month without evidence of infection. Significant fatigue (ie, ECOG Performance Status score of 2 or worse; cannot work or unable to perform usual activities). NOTE: Patients with significant fatigue cannot have an ECOG score of 0. 3. ECOG Performance Status of 0, 1, or 2. 4. Measurable disease by CT/MRI. Measurable disease is defined as 1 lymph node 1.5 cm in LDi and measurable in 2 perpendicular diameters. 5. Adequate marrow function as defined by: a. Absolute neutrophil count 1.0 x 109 cells/L with an exception for patients with bone marrow involvement, in which case, the absolute neutrophil count must be 0.75 x 109 cells/L (without growth factor support within the past 14 days). b. Platelet counts 50 x 109 cells/L; in cases of thrombocytopenia clearly due to marrow involvement of CLL, platelet count should be 30 x 109 cells/L (without growth factor support or transfusion within the past 14 days). c. Hemoglobin > 75 g/L (may be posttransfusion). 6. Adequate liver function as indicated by AST and ALT 2.5 x the institutional ULN value; serum total bilirubin 2.0 x ULN (unless documented Gilbert syndrome when serum total bilirubin 3.0 x ULN and conjugated bilirubin 1.5 x ULN). 7. Adequate renal function defined as creatinine clearance

30 mL/min directly measured with a 24-hour urine collection or 30 mL/min calculated according to the BSA-adjusted CKD-EPI calculation 8. Life expectancy > 6 months. 9. Adult patient 18 years of age, inclusive, at the time of signing the ICF and be capable of giving written informed consent, which includes compliance with the requirements and restrictions listed in the ICF and in this protocol. Prisoners, individuals institutionalized by regulatory or court order, and persons who may be dependent on the sponsor or an investigator are excluded from the study.

Exclusion criteria

1. Previous systemic treatment for CLL. (Note: Up to 4 doses of anti-CD-20 antibody specifically for autoimmune cytopenia is allowed; the last dose should be given 6 months before screening). 10. Active fungal, bacterial, and/or viral infection requiring systemic therapy. History or known hypersensitivity to zanubrutinib, sonrotoclax, acalabrutinib, venetoclax, or any of its excipients (eg, trehalose), xanthine oxidase inhibitors, or rasburicase. 12. History of severe bleeding disorder, such as hemophilia A, hemophilia B, von Willebrand disease, or history of spontaneous bleeding requiring blood transfusion or other medical intervention. 13. Female patients who are pregnant or are breastfeeding. 14. Vaccination with a live vaccine within 28 days before enrollment and randomization 15. Patients with underlying medical conditions (including laboratory abnormalities) or alcohol or drug abuse or dependence that will be unfavorable for the administration of study treatment, precludes the patients safe participation in the study or will affect the explanation of drug toxicity or AEs, or will result in insufficient or impaired compliance with study conduct. 16. Positive HIV serology (HIVAb) status or serologic status reflecting active hepatitis B or C infection as follows: a. Presence of HBsAg. b. Patients with presence of HBcAb, in the absence of HBsAg, with detectable HBV DNA. NOTE: The limit of detection for HBV DNA must have a sensitivity of < 20 IU/mL; Patients with presence of HBcAb but undetectable HBV DNA who are willing to undergo HBV DNA monitoring every 4 weeks for HBV reactivation are eligible. c. Patients with presence of HCV antibody and HCV RNA detectable NOTE: The limit of detection for HCV RNA must have a sensitivity of < 15 IU/mL; Patients with presence of HCVAb and undetectable HCV RNA who are willing to undergo HCV RNA monitoring every 4 weeks for HCV reactivation are eligible. 17. Requires the use of warfarin, marcumar, phenprocoumon, or vitamin K antagonist. 18. Receiving treatment with any moderate or strong CYP3A4 inhibitor or strong CYP3A4 inducer (14 days or 5 half lives, whichever is shorter) before the first dose of study drug, or requiring ongoing treatment with a moderate or strong CYP3A inhibitor or a strong CYP3A inducer. 19. Consumed grapefruit, grapefruit products, Seville oranges (including marmalade containing Seville oranges), or star fruit within 3 days before the first dose of study treatment. 2. Known prolymphocytic leukemia or history of, or currently suspected, Richters transformation (biopsy based on clinical suspicion may be needed to rule out transformation). 20. Unable to swallow capsules or tablets or diseases significantly affecting GI function, such as malabsorption syndrome, resection of the stomach or small bowel, bariatric surgery procedures, symptomatic inflammatory bowel disease, or partial or complete bowel obstruction. 21. At time of enrollment, receiving systemic corticosteroids unless administered for adrenal replacement. 22. Major surgery within 4 weeks of the first dose of study treatment. 3. Known CNS involvement. 4. Patients with a history of confirmed progressive multifocal leukoencephalopathy. 5. Severe or debilitating pulmonary disease, defined as chronic supplementation of oxygen and/or respiratory failure requiring assisted ventilation. 6. Clinically significant cardiovascular disease including the following: a. Myocardial infarction within 6 months before screening. b. Unstable angina within 3 months before screening. c. New York Heart Association class III or IV congestive heart failure. d. History of clinically significant arrhythmias (eg, sustained ventricular tachycardia, ventricular fibrillation, or torsades de pointes). e. QTcF > 480 milliseconds based on Fridericias formula. NOTE: QTcF value may be calculated as the numerical average of up to 3 separate readings for eligibility. f. History of Mobitz II second-degree or third-degree heart block without a permanent pacemaker in place. g. Uncontrolled hypertension as indicated by a minimum of 2 consecutive blood pressure measurements showing systolic blood pressure > 170 mmHg and diastolic blood pressure > 105 mmHg at screening. 7. Uncontrolled autoimmune hemolytic anemia or immune thrombocytopenia requiring treatment. 8. History of prior malignancy, except for conditions as listed below and as long as patients have recovered from the acute side effects incurred because of previous therapy: a. Malignancies surgically treated with curative intent and with no known active disease present for 3 years before enrollment and randomization. b. Adequately treated nonmelanoma skin cancer or lentigo maligna without evidence of disease. c. Adequately treated cervical carcinoma in situ without evidence of disease. d. Localized prostate cancer with Gleason score 6. 9. Use of investigational agents within the last 4 weeks before screening.

Calendar

(Last Update: 22/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
24/04/2026	18/05/2026	18/05/2026	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

BeOne Medicines I GmbH Switzerland

Aeschengraben 27

Contact Person

BeOne Medical Officer

+18778285568

clinicaltrials@beonemed.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (14/05/2026)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Active (14/05/2026)

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

Hematology

Active (20/05/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematatology

Active (18/05/2026)

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medication

Calquence 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01EL02 - ACALABRUTINIB
Active Principles: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A

Experimental

Zanubrutinib
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

Venclyxto 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

Experimental

Venclyxto 50 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

Experimental

Venclyxto 10 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01XX52 - VENETOCLAX
Active Principles: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A

Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

No results