A Study to Evaluate the Safety and Efficacy of BGB-16673 Compared to Pirtobrutinib in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma.

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	325
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2025-522860-34-00 (CTIS)

Cod. Protocolo
BGB-16673-304

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

Enfermedad investigada
Chronic lymphocytic leukemia (CLL)
Small lymphocytic lymphoma (SLL)

Título Científico
A Phase 3, Open-Label, Randomized Study to Evaluate the Safety and Efficacy of BGB-16673 Compared to Pirtobrutinib in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of BGB-16673 compared to pirtobrutinib as measured by progression-free survival (PFS) determined by independent review committee (IRC)

Variables de Evaluación Primaria

PFS, defined as time from the date of randomization to the date of first disease progression or death, whichever occurs first, as determined by IRC using modified 2018 International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria for patients with chronic lymphocytic leukemia (CLL) and Lugano classification for patients with small lymphocytic lymphoma (SLL)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of BGB-16673 compared to pirtobrutinib, as measured by overall survival (OS)
To further evaluate the efficacy of BGB-16673 compared to pirtobrutinib, as measured by additional efficacy endpoints
To evaluate the safety of BGB-16673 versus pirtobrutinib
To evaluate patient-reported disease and treatment-specific symptoms and functioning in patients receiving BGB-16673 versus pirtobrutinib

Variables de Evaluación Secundaria

OS, defined as time from the date of randomization to the date of death due to any cause
PFS determined by investigator assessment
Overall response rate (partial response [PR] or better) determined by IRC and by investigator assessment, per modified 2018 iwCLL criteria for patients with CLL and Lugano classification for patients with SLL
Rate of PR with lymphocytosis or higher determined by IRC and by investigator assessment
Duration of response determined by IRC and by investigator assessment
Time to next anti-CLL/SLL treatment (TTNT)
Incidence and severity of treatment-emergent adverse events (TEAEs), serious TEAEs, and laboratory abnormalities graded according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) v5.0
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 (EORTC) quality of life questionnaire IL409 (an itemized version of EORTC quality of life questionnaire core 30 [QLQ-C30] and its CLL module CLL17)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Confirmed diagnosis of CLL or SLL, requiring treatment, based on 2018 iwCLL criteria. Previously received treatment for CLL/SLL with a covalent Bruton tyrosine kinase inhibitor (cBTKi). Patients should have disease relapsed after or refractory to at least 1 line of therapy including a cBTKi. Patients with SLL must have measurable disease by computed tomography/magnetic resonance imaging, defined as 1 lymph node > 1.5 cm in longest diameter and measurable in 2 perpendicular diameters.

Criterios de Exclusión

Known prolymphocytic leukemia or history of, or currently suspected, Richters transformation.
Current or history of central nervous system involvement including the brain, spinal cord, leptomeninges, and cerebrospinal fluid (as documented by imaging, cytology, or biopsy) by CLL/SLL.
History of ischemic stroke or intracranial hemorrhage within 6 months before first dose of study drug.
Prior exposure to any Bruton tyrosine kinase (BTK) protein degraders or non covalent BTKi (ncBTKi). Patients who discontinue cBTKi due solely to toxicity are not eligible
History of known bleeding disorder such as hemophilia A, hemophilia B, von Willebrand disease, or history of spontaneous bleeding requiring blood transfusion or other medical intervention.

Calendario

(Última actualización: 19/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
21/11/2025	16/12/2025	16/12/2025	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 AG Switzerland

Aeschengraben 27

Contact Person

BeOne Medicines Clinical Support

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clinicaltrials@beonemed.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Activo (09/12/2025)

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Hematology

Activo (10/12/2025)

Hospital Universitario De Burgos

Burgos

BURGOS

Hematology and Hematherapy

Activo (09/12/2025)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Activo (11/12/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (24/12/2025)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology

Activo (04/12/2025)

University Hospital Son Espases

Palma

BALEARES

Hematology and Hematherapy

Activo (04/12/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology and Hematherapy

Medicamentos

BGB-16673
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

BGB-16673
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Jaypirca 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Sin resultados

A Study to Evaluate the Safety and Efficacy of BGB-16673 Compared to Pirtobrutinib in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma.

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	325
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2025-522860-34-00 (CTIS)

Protocol Code
BGB-16673-304

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

Investigated Disease
Chronic lymphocytic leukemia (CLL)
Small lymphocytic lymphoma (SLL)

Scientific Title
A Phase 3, Open-Label, Randomized Study to Evaluate the Safety and Efficacy of BGB-16673 Compared to Pirtobrutinib in Patients With Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma

Rationale

Not provided

Main Objective

To evaluate the efficacy of BGB-16673 compared to pirtobrutinib as measured by progression-free survival (PFS) determined by independent review committee (IRC)

Primary Endpoints

PFS, defined as time from the date of randomization to the date of first disease progression or death, whichever occurs first, as determined by IRC using modified 2018 International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria for patients with chronic lymphocytic leukemia (CLL) and Lugano classification for patients with small lymphocytic lymphoma (SLL)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of BGB-16673 compared to pirtobrutinib, as measured by overall survival (OS)
To further evaluate the efficacy of BGB-16673 compared to pirtobrutinib, as measured by additional efficacy endpoints
To evaluate the safety of BGB-16673 versus pirtobrutinib
To evaluate patient-reported disease and treatment-specific symptoms and functioning in patients receiving BGB-16673 versus pirtobrutinib

Secondary Endpoints

OS, defined as time from the date of randomization to the date of death due to any cause
PFS determined by investigator assessment
Overall response rate (partial response [PR] or better) determined by IRC and by investigator assessment, per modified 2018 iwCLL criteria for patients with CLL and Lugano classification for patients with SLL
Rate of PR with lymphocytosis or higher determined by IRC and by investigator assessment
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Temporary moments of secondary assessment

Not provided

Inclusion criteria

Confirmed diagnosis of CLL or SLL, requiring treatment, based on 2018 iwCLL criteria. Previously received treatment for CLL/SLL with a covalent Bruton tyrosine kinase inhibitor (cBTKi). Patients should have disease relapsed after or refractory to at least 1 line of therapy including a cBTKi. Patients with SLL must have measurable disease by computed tomography/magnetic resonance imaging, defined as 1 lymph node > 1.5 cm in longest diameter and measurable in 2 perpendicular diameters.

Exclusion criteria

Known prolymphocytic leukemia or history of, or currently suspected, Richters transformation.
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Calendar

(Last Update: 19/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
21/11/2025	16/12/2025	16/12/2025	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 AG Switzerland

Aeschengraben 27

Contact Person

BeOne Medicines Clinical Support

+18778285568

clinicaltrials@beonemed.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Provincial de Sevilla

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Sites

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Madrid

MADRID

Hematology

Active (11/12/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Active (24/12/2025)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology

Active (04/12/2025)

University Hospital Son Espases

Palma

BALEARES

Hematology and Hematherapy

Active (04/12/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology and Hematherapy

Medication

BGB-16673
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A

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Jaypirca 100 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A

Experimental

No results