Estudio para investigar la eficacia y seguridad de sonrotoclax más zanubrutinib en comparación con placebo más zanubrutinib en pacientes adultos con linfoma de células del manto recidivante/resistente al tratamiento.

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	160
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento	NO

Información

Identificador
2024-515593-27-00 (CTIS)

Cod. Protocolo
BGB-11417-302

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

Enfermedad investigada
linfoma de células del manto (LCM) recidivante/refractario (R/R)

Título Científico
Estudio de fase III multicéntrico, aleatorizado y doble ciego de sonrotoclax más zanubrutinib comparado con placebo más zanubrutinib en pacientes con linfoma de células del manto recidivante/refractario.

Justificación

No aportado

Objetivo Principal

Demostrar la superioridad de sonrotoclax más zanubrutinib frente a placebo más zanubrutinib medida por la supervivencia sin progresión (SSP) determinada por un comité de revisión independiente ciego (BIRC).

Variables de Evaluación Primaria

Supervivencia sin progresión (SSP), evaluada por un comité de revisión independiente ciego (BIRC), definida como el tiempo desde la aleatorización hasta la fecha de progresión o muerte, lo que ocurra primero

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Comparar la eficacia de sonrotoclax más zanubrutinib con la eficacia de placebo más zanubrutinib utilizando como medida la supervivencia global (SG).
Evaluar la eficacia, medida según lo siguiente: 1) Supervivencia sin progresión (SSP) determinada por el investigador. 2) Tasa de respuesta global (TRG), determinada por el comité de revisión independiente ciego (BIRC) y por la evaluación del investigador, según los criterios de Lugano 2014. 3) Tasa de respuesta completa (TRC), determinada por el BIRC y por el investigador. 4) Duración de la respuesta (DDR), determinada por el BIRC y por el investigador. 5) Tiempo hasta la primera respuesta, determinado por el BIRC y el investigador.
Evaluar la enfermedad y los síntomas del tratamiento notificados por el paciente.
Evaluar la seguridad y la tolerabilidad

Variables de Evaluación Secundaria

Overall survival (OS), defined as the time from randomization to the date of death from any cause.
Progression-free survival (PFS) as determined by investigator.
Overall response rate (ORR) as determined by BIRC and by investigator per the Lugano 2014 criteria. ORR is defined as the proportion of patients who achieved a best overall response of partial response or complete response (CR).
Duration of response (DOR) as determined by BIRC and by investigator. It is defined as the time from the first qualifying response to the date of progression or death, whichever occurs first.
Complete response rate (CRR), as determined by BIRC and by investigator. It is defined as the proportion of patients who achieved a best overall response of CR.
Time to first response as determined by BIRC and by investigator. It is defined as time from randomization to first response.
Time to initiation of new anticancer therapy.

Patient-reported symptom burden and physical condition/fatigue as measured by the European Organisation of Research and Treatment of Cancer-Quality of Life Questionnaire Non-Hodgkin Lymphoma High Grade Module 29 (EORTC-QLQ-NHL-HG29) questionnaire, and global health status (GHS) and physical function as measured by the European Organisation of Research and Treatment of Cancer-Quality of Life Questionnaire Core 30 (EORTC-QLQ-C30).
Incidence and severity of treatment-emergent adverse events (TEAE)s graded according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) v5.0

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Diagnóstico histológicamente confirmado de LCM basado en la clasificación de neoplasias hematolinfoides de la Organización Mundial de la Salud de 2022 (WHOHAEM5), o basado en la Clasificación Internacional de Consenso (ICC) Recibió de 1 a 5 líneas previas de terapia sistémica, incluida una inmunoterapia o quimioinmunoterapia basada en anticuerpos monoclonales (mAb) anti-CD20 y que requiere tratamiento en opinión del investigador Enfermedad recidivante o resistente al tratamiento después de la última línea de terapia Enfermedad medible definida como ¿1 lesión ganglionar de >1,5 cm de diámetro más largo, o ¿1 lesión extraganglionar de >1 cm de diámetro más largo Escala de valoración del Grupo Oncológico Cooperativo del Este (ECOG) de 0 a 2 Función orgánica adecuad

Criterios de Exclusión

Terapia previa con inhibidor de linfoma de linfocitos B-2
Terapia previa con inhibidor de la tirosina quinasa de Bruton (BTKi) covalente o no covalente, a menos que el participante sea intolerante al BTKi covalente o no covalente que no sea zanubrutinib
Autotrasplante de células madre previo o terapia de células T con receptor de antígeno quimérico dentro de los 3 meses anteriores a la primera dosis del fármaco del estudio
Trasplante alogénico de células madre previo dentro de los 6 meses de anteriores a la primera dosis del fármaco del estudio
Afectación conocida del sistema nervioso central debido a un linfoma
Enfermedad cardiovascular clínicamente significativa
Antecedentes de accidente cerebrovascular o hemorragia intracraneal dentro de los 6 meses anteriores a la primera dosis del fármaco del estudi

Calendario

(Última actualización: 19/10/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
21/04/2025	13/05/2025	23/05/2025	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 Medical Officer

+18778285568

clinicaltrials@beonemed.com

Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (13/05/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Cerrado (12/10/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Activo (14/05/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (16/07/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medicamentos

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

BGB-11417
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

Zanubrutinib
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

Sin resultados

A Study to Investigate the Efficacy and Safety of Sonrotoclax Plus Zanubrutinib Compared With Placebo Plus Zanubrutinib in Adult Patients With Relapsed/Refractory Mantle Cell Lymphoma

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	160
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment	NO

Information

Identifier
2024-515593-27-00 (CTIS)

Protocol Code
BGB-11417-302

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

Investigated Disease
relapsed or refractory mantle cell lymphoma (R/R MCL)

Scientific Title
A Phase 3 Randomized Double-Blind Multicenter Study of Sonrotoclax Plus Zanubrutinib Versus Placebo Plus Zanubrutinib in Patients With Relapsed/Refractory Mantle Cell Lymphoma

Rationale

Not provided

Main Objective

To demonstrate superiority of sonrotoclax plus zanubrutinib over placebo plus zanubrutinib as measured by progression-free survival (PFS) determined by a blinded independent review committee (BIRC).

Primary Endpoints

Progression-free survival (PFS), as assessed by blinded independent review committee (BIRC), defined as the time from randomization to the date of progression or death, whichever occurs first.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the efficacy of sonrotoclax plus zanubrutinib with that of placebo plus zanubrutinib as measured by overall survival (OS).
To evaluate efficacy, as measured by the following: 1) Progression-free survival (PFS) determined by investigator. 2) Overall response rate (ORR), as determined by blinded independent review committee (BIRC) and by investigator assessment, per Lugano 2014 criteria. 3) Complete response rate (CRR), as determined by BIRC and by investigator. 4) Duration of response (DOR), as determined by BIRC and by investigator. 5) Time to first response, as determined by BIRC and by investigator.
To evaluate patient-reported disease and treatment symptoms.
To evaluate safety and tolerability.

Secondary Endpoints

Overall survival (OS), defined as the time from randomization to the date of death from any cause.
Progression-free survival (PFS) as determined by investigator.
Overall response rate (ORR) as determined by BIRC and by investigator per the Lugano 2014 criteria. ORR is defined as the proportion of patients who achieved a best overall response of partial response or complete response (CR).
Duration of response (DOR) as determined by BIRC and by investigator. It is defined as the time from the first qualifying response to the date of progression or death, whichever occurs first.
Complete response rate (CRR), as determined by BIRC and by investigator. It is defined as the proportion of patients who achieved a best overall response of CR.
Time to first response as determined by BIRC and by investigator. It is defined as time from randomization to first response.
Time to initiation of new anticancer therapy.

Patient-reported symptom burden and physical condition/fatigue as measured by the European Organisation of Research and Treatment of Cancer-Quality of Life Questionnaire Non-Hodgkin Lymphoma High Grade Module 29 (EORTC-QLQ-NHL-HG29) questionnaire, and global health status (GHS) and physical function as measured by the European Organisation of Research and Treatment of Cancer-Quality of Life Questionnaire Core 30 (EORTC-QLQ-C30).
Incidence and severity of treatment-emergent adverse events (TEAE)s graded according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) v5.0

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Histologically confirmed diagnosis of MCL based on the World Health Organization 2022 classification of Haematolymphoid Tumors (WHOHAEM5), or based on International Consensus Classification (ICC) Received 1 to 5 prior lines of systemic therapy including an anti-CD20 monoclonal antibody (mAb)-based immunotherapy or chemoimmunotherapy and requiring treatment in the opinion of the investigator Relapsed or refractory disease after the last line of therapy Measurable disease defined as 1 nodal lesion that is > 1.5 cm in longest diameter, or 1 extranodal lesion that is > 1 cm in longest diameter Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 to 2 Adequate organ function

Exclusion criteria

Prior therapy with B-cell lymphoma-2 inhibitor
Prior therapy with covalent or non-covalent Bruton tyrosine kinase inhibitor (BTKi) unless the participant was intolerant of non-zanubrutinib covalent or non-covalent BTKi
Prior autologous stem cell transplantation or chimeric antigen receptor T-cell therapy within 3 months before first dose of study drug
Prior allogeneic stem cell transplant within 6 months of the first dose of the study drug
Known central nervous system involvement by lymphoma
Clinically significant cardiovascular disease
History of stroke or intracranial hemorrhage within 6 months before first dose of study drug

Calendar

(Last Update: 19/10/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
21/04/2025	13/05/2025	23/05/2025	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 Medical Officer

+18778285568

clinicaltrials@beonemed.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (13/05/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Closed (12/10/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Active (14/05/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Active (16/07/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medication

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

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FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

BGB-11417
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

Zanubrutinib
CAPSULE
ORAL

-
Active Principles: N/A
Experimental

No results