A Study Evaluating the Efficacy and Safety of Pirtobrutinib in Participants With Relapsed or Refractory Chronic Lymphocytic Leukemia/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 II	101
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, dosis	NO

Información

Identificador
2024-515689-15-01 (CTIS)

Cod. Protocolo
J2N-MC-JZNX

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

Enfermedad investigada
Chronic Lymphocytic Leukemia
Small Lymphocytic Lymphoma

Título Científico
J2N-MC-JZNX: A Phase 2, Open-label, Randomized Study Evaluating the Efficacy and Safety of 3 Doses of Pirtobrutinib in Participants with Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Who Previously Received Treatment with a Covalent Bruton Tyrosine Kinase Inhibitor

Justificación

No aportado

Objetivo Principal

To compare the overall response rate of Pirtobrutinib 200 mg to 120 mg, and Pirtobrutinib 200 mg to 60 mg

Variables de Evaluación Primaria

Overall Response Rate

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

No aportado

Variables de Evaluación Secundaria

No aportado

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Have confirmed diagnosis of CLL/SLL as defined by these iwCLL 2018 criteria.
Have received prior CLL/SLL treatment.
Have received at least 1, but not more than 3 lines of prior treatment for CLL/SLL.
Have received a covalent BTK inhibitor.
Have a requirement for therapy consistent with iwCLL 2018 criteria for initiation of therapy.
Capable of swallowing oral study medication.
Have an Eastern Cooperative Oncology Group Performance Status (ECOG) score of 0 to 2.

Criterios de Exclusión

Have received prior treatment with a BTK degrader and a noncovalent BTK inhibitor. Have a history of greater than or equal to (>=) Grade 3 bleeding due to treatment with a BTK inhibitor. Have known or suspected Richters transformation. Have known or suspected history of central nervous system involvement by CLL/SLL. Previous or concurrent cancer distinct from CLL/SLL within 3 years before randomization. Exceptions may occur with documented sponsor approval. Examples include: nonmelanoma skin cancer or lentigo maligna melanoma cervical carcinoma in situ localized prostate cancer undergoing active surveillance, and localized (for example, lymph node negative) breast cancer with no evidence of active disease present for more than 3 years. Individual may be receiving adjuvant hormonal therapy

Calendario

(Última actualización: 03/04/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/02/2025	06/03/2025	12/03/2025	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

Eli Lilly & Co. United States

1 Lilly Corporate Center

Contact Person

Lilly Clinical Trials information desk

00353214232400

EU_lilly_clinical_trials@lilly.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Fundación Instituto Valenciano de Oncología

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ceim@fivo.org

961104674

Centros

No iniciado (--/--/----)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

No iniciado (--/--/----)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (11/03/2025)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (13/03/2025)

Hospital Costa Del Sol

Marbella

MÁLAGA

Hematology

Activo (09/04/2025)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncology

No iniciado (--/--/----)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Activo (15/03/2025)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Activo (19/03/2026)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

No iniciado (--/--/----)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (08/03/2026)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

No iniciado (--/--/----)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Activo (13/03/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Medical Oncology

Activo (07/03/2026)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Cerrado (24/05/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hemathology and hemotherapy

Activo (07/05/2025)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology

Activo (07/05/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (21/03/2025)

MD Anderson Cancer Center

Madrid

MADRID

Hematology

Activo (08/03/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

Pirtobrutinib
TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

PRD10892569
TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

PRD10916187
TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

Sin resultados

A Study Evaluating the Efficacy and Safety of Pirtobrutinib in Participants With Relapsed or Refractory Chronic Lymphocytic Leukemia/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 II	101
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, dose	NO

Information

Identifier
2024-515689-15-01 (CTIS)

Protocol Code
J2N-MC-JZNX

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

Investigated Disease
Chronic Lymphocytic Leukemia
Small Lymphocytic Lymphoma

Scientific Title
J2N-MC-JZNX: A Phase 2, Open-label, Randomized Study Evaluating the Efficacy and Safety of 3 Doses of Pirtobrutinib in Participants with Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) Who Previously Received Treatment with a Covalent Bruton Tyrosine Kinase Inhibitor

Rationale

Not provided

Main Objective

To compare the overall response rate of Pirtobrutinib 200 mg to 120 mg, and Pirtobrutinib 200 mg to 60 mg

Primary Endpoints

Overall Response Rate

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Have confirmed diagnosis of CLL/SLL as defined by these iwCLL 2018 criteria.
Have received prior CLL/SLL treatment.
Have received at least 1, but not more than 3 lines of prior treatment for CLL/SLL.
Have received a covalent BTK inhibitor.
Have a requirement for therapy consistent with iwCLL 2018 criteria for initiation of therapy.
Capable of swallowing oral study medication.
Have an Eastern Cooperative Oncology Group Performance Status (ECOG) score of 0 to 2.

Exclusion criteria

Have received prior treatment with a BTK degrader and a noncovalent BTK inhibitor. Have a history of greater than or equal to (>=) Grade 3 bleeding due to treatment with a BTK inhibitor. Have known or suspected Richters transformation. Have known or suspected history of central nervous system involvement by CLL/SLL. Previous or concurrent cancer distinct from CLL/SLL within 3 years before randomization. Exceptions may occur with documented sponsor approval. Examples include: nonmelanoma skin cancer or lentigo maligna melanoma cervical carcinoma in situ localized prostate cancer undergoing active surveillance, and localized (for example, lymph node negative) breast cancer with no evidence of active disease present for more than 3 years. Individual may be receiving adjuvant hormonal therapy

Calendar

(Last Update: 03/04/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/02/2025	06/03/2025	12/03/2025	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

Eli Lilly & Co. United States

1 Lilly Corporate Center

Contact Person

Lilly Clinical Trials information desk

00353214232400

EU_lilly_clinical_trials@lilly.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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961104674

Sites

not initialized (--/--/----)

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Pamplona

NAVARRA

Hematology

not initialized (--/--/----)

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Active (08/03/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

Pirtobrutinib
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

PRD10892569
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

PRD10916187
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

No results