A Phase 3 Study Comparing Pirtobrutinib to Ibrutinib in CLL/SLL

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	Sujetos incapaces de otorgar consentimiento	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	362
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-507699-38-00 (CTIS)

Cod. Protocolo
LOXO-BTK-20030

Transicionado 2021-003206-41

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

Enfermedad investigada
Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Título Científico
A Phase 3 Open-Label, Randomized Study of Pirtobrutinib (LOXO-305) versus Ibrutinib in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BRUIN-CLL-314)

Justificación

No aportado

Objetivo Principal

Part 1:
To evaluate overall response rate (ORR) of pirtobrutinib (Arm A) compared to ibrutinib (Arm B) Part 2:
To evaluate ORR of pirtobrutinib in patients with del(17p) who are treatment naïve

Variables de Evaluación Primaria

Part 1 and Part 2: Primary endpoint: Overall response rate (ORR) as assessed by independent review committee (IRC) per iwCLL 2018 criteria. ORR is defined as the proportion of patients who achieve a BOR of CR, CRi, nPR, or PR at or before the initiation of subsequent anticancer therapy.

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

Confirmed diagnosis of CLL/SLL requiring therapy per iwCLL 2018 criteria.
Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2.
Adequate organ function Platelets greater than or equal to ()50 x 10/liter (L) or 30 x 10/L in participants with documented bone marrow involvement considered to impair hematopoiesis, Hemoglobin 8 grams/deciliter (g/dL) or 6 g/dL in participants with documented bone marrow involvement considered to impair hematopoiesis Absolute neutrophil count 0.75 x 10/L or 0.50 × 10/L in participants with documented bone marrow involvement considered to

impair hematopoiesis Kidney function: Estimated creatinine clearance 30 milliliters per minute (mL/min).
Part 1 - Known 17p deletion status (wildtype or deleted). Part 2 Must have deletion of 17p as determined by FISH testing performed in a CLIA, ISO/IEC, CAP, or other similarly certified laboratory as per local guidelines, including, but not limited to, IVDR compliance as applicable.

Criterios de Exclusión

Known or suspected Richter's transformation to diffuse large B-cell lymphoma (DLBCL), prolymphocytic leukemia, or Hodgkin's lymphoma at any time preceding enrollment. Clinically significant active malabsorption syndrome or other condition likely to affect GI absorption of the oral-administered study treatments. Ongoing inflammatory bowel disease. Part 1: Prior exposure to BTK inhibitor (covalent or noncovalent). Part 2: Prior therapy for CLL Concurrent use of investigational agent or anticancer therapy except hormonal therapy. Participants requiring therapeutic anticoagulation with warfarin or another Vitamin K antagonist. Use of > 20 mg prednisone daily or equivalent dose of steroid at the time of first dose of study drug. Vaccination with a live vaccine within 28 days prior to randomization. Participants receiving chronic therapy with a strong cytochrome P450 (CYP)3A inhibitor (except posaconazole and voriconazole) which cannot be stopped within 3-5 half lives of the CYP3A inhibitor therapy prior to start of study drug treatment. Participants with known hypersensitivity, including anaphylaxis, to any component or excipient of pirtobrutinib or ibrutinib. Known or suspected central nervous system (CNS) involvement. A significant history of renal, neurologic, psychiatric, endocrine, metabolic or immunologic disease. Active uncontrolled auto-immune cytopenia (e.g., autoimmune hemolytic anemia [AIHA], idiopathic thrombocytopenic purpura [ITP]). Significant cardiovascular disease including ejection fraction < 40% and any grade ongoing atrial fibrillation or atrial flutter. Hepatitis B or hepatitis C testing indicating active/ongoing infection, based on Screening laboratory tests. Active cytomegalovirus (CMV) infection. Active uncontrolled systemic bacterial, viral, or fungal infection. Known human immunodeficiency virus (HIV) infection, regardless of cluster of differentiation 4 (CD4) count.

Calendario

(Última actualización: 27/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
08/08/2022	07/10/2022	07/10/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
17/06/2024	No aportado	No aportado	No aportado	No aportado

Promotor

Loxo Oncology Inc. United States

281 Tresser Boulevard Floor 9th

Contact Person

Lilly Clinical Trials information desk

+353214232400

EU_lilly_clinical_trials@lilly.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Provincial de Sevilla

Avenida Doctor Fedriani 3 41009 Sevilla

administracion.eecc.hvm.sspa@juntadeandalucia.es

955043127

Centros

Activo (16/12/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Madrid

MADRID

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

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (14/11/2022)

COMPLEJO HOSPITALARIO A (ANTIGUO HOSPITAL DE NAVARRA)*

Pamplona/Iruña

NAVARRA

Activo (25/09/2023)

Complejo Hospitalario Universitario De Gran Canaria Dr. Negrin

Palmas de Gran Canaria, Las

LAS PALMAS

Activo (08/11/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (10/11/2022)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

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

Hospital Costa Del Sol

Marbella

MÁLAGA

Hematology

Activo (16/01/2023)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (30/01/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

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

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Activo (10/10/2022)

HOSPITAL UNIVERSITARIO INFANTA LEONOR

Madrid

MADRID

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

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Activo (28/10/2022)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

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

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (21/10/2022)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Activo (19/12/2022)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

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

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Activo (29/09/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Activo (16/09/2022)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

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

Institut Catala D´oncologia

Girona

GERONA

Hematology

Activo (18/01/2023)

Institut Catala D'oncologia

Girona

GERONA

Activo (21/11/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Activo (24/02/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

IBRUTINIB
CAPSULE, HARD
ORAL USE

-
Principios Activos: N/A

Experimental

PIRTOBRUTINIB
TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

PIRTOBRUTINIB
TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Sin resultados

A Phase 3 Study Comparing Pirtobrutinib to Ibrutinib in CLL/SLL

State	Type of participants	Age Ranges
End of recruitment	Incapable subjects of giving consent	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	362
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-507699-38-00 (CTIS)

Protocol Code
LOXO-BTK-20030

Transitioned 2021-003206-41

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

Investigated Disease
Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma

Scientific Title
A Phase 3 Open-Label, Randomized Study of Pirtobrutinib (LOXO-305) versus Ibrutinib in Patients with Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (BRUIN-CLL-314)

Rationale

Not provided

Main Objective

Part 1:
To evaluate overall response rate (ORR) of pirtobrutinib (Arm A) compared to ibrutinib (Arm B) Part 2:
To evaluate ORR of pirtobrutinib in patients with del(17p) who are treatment naïve

Primary Endpoints

Part 1 and Part 2: Primary endpoint: Overall response rate (ORR) as assessed by independent review committee (IRC) per iwCLL 2018 criteria. ORR is defined as the proportion of patients who achieve a BOR of CR, CRi, nPR, or PR at or before the initiation of subsequent anticancer therapy.

Temporary moments of secondary assessment

Not provided

Secondary Objective

Not provided

Secondary Endpoints

Not provided

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Confirmed diagnosis of CLL/SLL requiring therapy per iwCLL 2018 criteria.
Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2.
Adequate organ function Platelets greater than or equal to ()50 x 10/liter (L) or 30 x 10/L in participants with documented bone marrow involvement considered to impair hematopoiesis, Hemoglobin 8 grams/deciliter (g/dL) or 6 g/dL in participants with documented bone marrow involvement considered to impair hematopoiesis Absolute neutrophil count 0.75 x 10/L or 0.50 × 10/L in participants with documented bone marrow involvement considered to

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Calendar

(Last Update: 27/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
08/08/2022	07/10/2022	07/10/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
17/06/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

Loxo Oncology Inc. United States

281 Tresser Boulevard Floor 9th

Contact Person

Lilly Clinical Trials information desk

+353214232400

EU_lilly_clinical_trials@lilly.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Provincial de Sevilla

Avenida Doctor Fedriani 3 41009 Sevilla

administracion.eecc.hvm.sspa@juntadeandalucia.es

955043127

Sites

Active (16/12/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Madrid

MADRID

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

Clinica Universidad De Navarra

Madrid

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

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Hematology

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MÁLAGA

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Badalona

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SEVILLA

Hematology

Medication

IBRUTINIB
CAPSULE, HARD
ORAL USE

-
Active Principles: N/A

Experimental

PIRTOBRUTINIB
TABLET
ORAL USE

-
Active Principles: N/A

Experimental

PIRTOBRUTINIB
TABLET
ORAL USE

-
Active Principles: N/A

Experimental

No results