Ensayo clínico en fase I/II para evaluar la seguridad, tolerabilidad, farmacocinética y eficacia de TERN¿701 en participantes con leucemia mielógena crónica

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	116
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
2023-507677-18-00 (CTIS)

Cod. Protocolo
TERN701-1012

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

Enfermedad investigada
leucemia mielógena crónica

Título Científico
A Phase 1/2 Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of TERN-701 in Participants with Chronic Myeloid Leukemia

Justificación

No aportado

Objetivo Principal

1. Part 1 To evaluate the safety and tolerability of TERN-701 in participants with previously treated CP-CML 2. Part 2 To evaluate the efficacy of TERN-701 in participants with previously treated CP-CML

Variables de Evaluación Primaria

Part 1 Incidence of DLTs during the first cycle of treatment AE, SAEs, changes in vital signs, laboratory values, and ECG
Part 2 Hematologic and molecular response (BCR::ABL1 transcript level in peripheral blood assessed centrally) Best categorical shift in BCR::ABL1 transcript levels from baseline

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 1 To evaluate the pharmacokinetics of TERN-701 in participants with previously treated CP-CML To evaluate the efficacy of TERN-701 in participants with previously treated CP-CML
Part 2 To evaluate the safety and tolerability of TERN-701 in participants with previously treated CP-CML To evaluate the pharmacokinetics of TERN-701 in participants with previously treated CP-CML

Variables de Evaluación Secundaria

Part 1 Plasma concentration and derived PK parameters for TERN-701 Hematologic and molecular response (BCR::ABL1 transcript level in peripheral blood assessed centrally) Best categorical shift in BCR::ABL1 transcript levels from baseline
Part 2 AE, SAEs, changes in vital signs, laboratory values, and ECG Plasma concentration and derived PK parameters for TERN-701

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Male or female participants 18 years of age at the time of signing the informed consent or the legal age of adulthood in countries where the local law considers the legal adult age tobe > 18 years of age 2. Have an ECOG performance status score of 0 to 1 3. Have an established cytopathologically confirmed diagnosis of BCR::ABL1 positive CML in CP, and meet at least 1 of the following: For Part 1: Participants without the BCR::ABL1 T315Im who: o Received 2 or more tyrosine kinase inhibitors (TKIs) and have experienced treatment failure, suboptimal response, or treatment intolerance as determined by the investigator OR o Experienced treatment failure or suboptimal response (as determined by the investigator) to frontline therapy with dasatinib, nilotinib, or bosutinib and are ineligible for alternative TKIs per the investigators discretion Participants with BCR::ABL1 T315Im who received 1 or more TKIs and have experienced treatment failure, suboptimal response, or intolerance, as determined by the investigator.; pParticipants should have received prior treatment with ponatinib unless the participant is ineligible for or is not a candidate to receive ponatinib, in the opinion of the investigator For Part 2 (randomized dose expansion): Participants who have experienced treatment failure or suboptimal response (as determined by the investigator) to at least 1 but not more than 4 TKIs. Change of TKI due to intolerance without associated treatment failure or suboptimal response will not be counted towards the upper limit of 4 TKIs. 4.Adequate organ function, as assessed by the following screening laboratory values obtained locally: ANC 1500/mm3 Hemoglobin 8.0 g/dL Platelets 100,000/mm3 CrCl 50 mL/min Serum total bilirubin 1.5 × ULN (for participants with Gilberts syndrome, serum total bilirubin 3 × ULN) AST (SGOT) and ALT (SGPT) 2.5 × ULN For Part 2m (mutation cohort): Participants with BCR::ABL1 resistance mutation(s) including T315I, M244V, H396R, E355G, F359I/C/V, and I502L. Other mutations not listed, but present in the P-loop, active site, A-loop, and C-helix, may be considered for inclusion on a case-by-case basis. AND Have received 1 or more TKIs and have experienced treatment failure, suboptimal response, or intolerance, as determined by the investigator. Participants should have received prior treatment with ponatinib unless the participant is ineligible for or is not a candidate to receive ponatinib, in the opinion of the investigator

Criterios de Exclusión

1. Peripheral blasts 10%, peripheral basophils 20% and/or additional new clonal chromosomal abnormalities in Ph+ cells 10. Have a history of acute pancreatitis within 1 year of trial entry or chronic pancreatitis 11. Have acute or chronic liver disease (including hepatic encephalopathy, hepatorenal syndrome, or Child-Pugh class B hepatic cirrhosis) 12. Have known significant mental illness or other condition such as active alcohol or other substance abuse or addiction, or other psychosocial conditions, that, in the opinion of the investigator, predisposes the participant to high risk of noncompliance with the protocol; where required by local law, participants will be excluded who are under court protection, persons not affiliated with the local social security system and protected adults 13. Have any of the following cardiovascular conditions: Uncontrolled severe hypertension despite current therapy (blood pressure 150/90 mmHg on more than 1 occasion at least 24 hours apart) within the 28 days prior to the first dose of TERN-701 Symptomatic congestive heart failure, defined as Class II of the New York Heart Association functional classification Recent myocardial infarction (within 3 months) Clinically significant arrhythmias that would preclude participation, in the judgment of the investigator Known history of marked prolongation of QT/QTc interval that, in the judgment of the investigator, would preclude participation QTc interval> 470 ms for women and > 450 ms for men using Fridericias QT correction formula 14. Female participants who are pregnant or lactating 2. CML with atypical transcript (e13a3,e14a3, e8a2, e1a2 and/or e6a2) 3. Mutation Status Exclusions:For Part 1: The following known BCR:ABL1 myristoyl domain resistance mutations: A337V, P465S, V468F, I502L, G463D, G463S, C464W and mutation(s) in the SH2/SH3 contact sites or C lobe For Part 2 randomized dose expansion. The following known mutations in the BCR::ABL1 domain: T315I, M244V, E355D/G/A, A337V, A344V, M351T, P465S, V468F, I502L, G463D, G463S,F359C/V/I, F486S, C464W, mutation(s) in the C-terminal lobe, as well as those in the SH2 and/or SH3 contact sites along with any mutations in the DFG motif (D381, F382, G383) of the activation loop, which extends from the C-lobe 4. Systemic antineoplastic therapy (including prior TKIs, interferon-alfa, therapeutic antibodies, chemotherapy) or other experimental therapy within 7 days or 5 half-lives (whichever is longer) before the first dose of TERN-701; hydroxyurea, if used for leukocytosis, should be weaned off before the first dose of TERN-701 5. Unable to swallow oral medication 6. Have had major surgery within 4 weeks before the start of trial intervention 7. History of significant small bowel resection, gastric bypass, use of feeding tubes or other condition that may preclude adequate absorption of orally dosed trial intervention 8. Have completed previous anticancer therapy without resolution of all associated clinically significant toxicity (to Grade 2 or baseline) prior to TERN-701 administration 9. Prior or concurrent malignancy whose natural history or treatment has the potential to interfere with safety or efficacy assessments per the investigators discretion

Calendario

(Última actualización: 21/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
22/04/2024	17/05/2024	17/05/2024	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

Terns Inc. United States

126 East Lincoln Avenue

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (13/06/2024)

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Hematology

Activo (14/05/2024)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (10/09/2024)

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

Activo (23/05/2024)

Hospital Quironsalud Zaragoza

Zaragoza

ZARAGOZA

Hematology

Activo (06/06/2024)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (26/04/2024)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

Activo (07/05/2024)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Activo (09/05/2024)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

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

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology

Medicamentos

TERN-701
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

TERN-701
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

TERN-701
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

Sin resultados

A Phase 1/2 Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of TERN-701 in Participants with Chronic Myeloid Leukemia

State	Type of participants	Age Ranges
Recruiting	Not provided	Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	116
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
2023-507677-18-00 (CTIS)

Protocol Code
TERN701-1012

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

Investigated Disease
Chronic Myeloid Leukemia

Scientific Title
A Phase 1/2 Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of TERN-701 in Participants with Chronic Myeloid Leukemia

Rationale

Not provided

Main Objective

1. Part 1 To evaluate the safety and tolerability of TERN-701 in participants with previously treated CP-CML 2. Part 2 To evaluate the efficacy of TERN-701 in participants with previously treated CP-CML

Primary Endpoints

Part 1 Incidence of DLTs during the first cycle of treatment AE, SAEs, changes in vital signs, laboratory values, and ECG
Part 2 Hematologic and molecular response (BCR::ABL1 transcript level in peripheral blood assessed centrally) Best categorical shift in BCR::ABL1 transcript levels from baseline

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 1 To evaluate the pharmacokinetics of TERN-701 in participants with previously treated CP-CML To evaluate the efficacy of TERN-701 in participants with previously treated CP-CML
Part 2 To evaluate the safety and tolerability of TERN-701 in participants with previously treated CP-CML To evaluate the pharmacokinetics of TERN-701 in participants with previously treated CP-CML

Secondary Endpoints

Part 1 Plasma concentration and derived PK parameters for TERN-701 Hematologic and molecular response (BCR::ABL1 transcript level in peripheral blood assessed centrally) Best categorical shift in BCR::ABL1 transcript levels from baseline
Part 2 AE, SAEs, changes in vital signs, laboratory values, and ECG Plasma concentration and derived PK parameters for TERN-701

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Male or female participants 18 years of age at the time of signing the informed consent or the legal age of adulthood in countries where the local law considers the legal adult age tobe > 18 years of age 2. Have an ECOG performance status score of 0 to 1 3. Have an established cytopathologically confirmed diagnosis of BCR::ABL1 positive CML in CP, and meet at least 1 of the following: For Part 1: Participants without the BCR::ABL1 T315Im who: o Received 2 or more tyrosine kinase inhibitors (TKIs) and have experienced treatment failure, suboptimal response, or treatment intolerance as determined by the investigator OR o Experienced treatment failure or suboptimal response (as determined by the investigator) to frontline therapy with dasatinib, nilotinib, or bosutinib and are ineligible for alternative TKIs per the investigators discretion Participants with BCR::ABL1 T315Im who received 1 or more TKIs and have experienced treatment failure, suboptimal response, or intolerance, as determined by the investigator.; pParticipants should have received prior treatment with ponatinib unless the participant is ineligible for or is not a candidate to receive ponatinib, in the opinion of the investigator For Part 2 (randomized dose expansion): Participants who have experienced treatment failure or suboptimal response (as determined by the investigator) to at least 1 but not more than 4 TKIs. Change of TKI due to intolerance without associated treatment failure or suboptimal response will not be counted towards the upper limit of 4 TKIs. 4.Adequate organ function, as assessed by the following screening laboratory values obtained locally: ANC 1500/mm3 Hemoglobin 8.0 g/dL Platelets 100,000/mm3 CrCl 50 mL/min Serum total bilirubin 1.5 × ULN (for participants with Gilberts syndrome, serum total bilirubin 3 × ULN) AST (SGOT) and ALT (SGPT) 2.5 × ULN For Part 2m (mutation cohort): Participants with BCR::ABL1 resistance mutation(s) including T315I, M244V, H396R, E355G, F359I/C/V, and I502L. Other mutations not listed, but present in the P-loop, active site, A-loop, and C-helix, may be considered for inclusion on a case-by-case basis. AND Have received 1 or more TKIs and have experienced treatment failure, suboptimal response, or intolerance, as determined by the investigator. Participants should have received prior treatment with ponatinib unless the participant is ineligible for or is not a candidate to receive ponatinib, in the opinion of the investigator

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Calendar

(Last Update: 21/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
22/04/2024	17/05/2024	17/05/2024	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

Terns Inc. United States

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Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (13/06/2024)

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Hematology

Active (14/05/2024)

Hospital Clinic De Barcelona

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Active (10/09/2024)

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Badalona

BARCELONA

Hematology

Active (23/05/2024)

Hospital Quironsalud Zaragoza

Zaragoza

ZARAGOZA

Hematology

Active (06/06/2024)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (26/04/2024)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

Active (07/05/2024)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Active (09/05/2024)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

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

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology

Medication

TERN-701
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

TERN-701
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

TERN-701
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

No results