Asciminib treatment optimization in 3rd line CML-CP

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	95
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2024-511381-36-00 (CTIS)

Cod. Protocolo
CABL001A2302

Transicionado 2020-006057-21

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

Enfermedad investigada
Chronic Myelogenous Leukemia in chronic phase (CML-CP)

Título Científico
A phase IIIb, multi-center, open-label, treatment optimization study of oral asciminib in patients with Chronic Myelogenous Leukemia in chronic phase (CMLCP) previously treated with 2 or more tyrosine kinase inhibitors

Justificación

No aportado

Objetivo Principal

To estimate the molecular response rate (MMR) of all the patients at week 48 with CML-CP following two or more prior TKI treatments and with no evidence of MMR at baseline.

Variables de Evaluación Primaria

MMR at 48 weeks

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the safety and tolerability of asciminib in patients with CML-CP following 2 or more prior TKI treatments
To assess the rate of MMR in patients without MMR at baseline and at alternative time points at weeks 12, 24, 36, 72, 96 and 144
To assess the rate of MMR at week 48 for patients with MMR at baseline
To assess the time to MMR
To assess the rate of early responses of BCR-ABL1 10% and 1% at weeks 12, 24, 36 and 48
To assess the rate of deep molecular responses (MR4 and MR4.5) at weeks 12, 24, 36, 48, 72, 96 and 144
To assess cytogenetic response (% Ph+ metaphases) at weeks 48 and EOT.
To characterize the impact of additional cytogenetic abnormalities on efficacy
To assess cumulative molecular responses by all-time points
To assess duration of MMR
To assess sustained deep molecular responses as prerequisite for Treatment Free Remission (TFR)
To assess rate of progressions (PFS)
To assess overall survival (OS)
To assess time to treatment failure (TTF)
To evaluate patient reported outcomes and quality of life by using MDASI-CML

Variables de Evaluación Secundaria

Type, frequency and severity of adverse events, changes in laboratory values that fall outside the pre-determined ranges and clinically notable ECG and other safety data (vital signs, physical examination). MMR rate at weeks 12, 24, 36, 72, 96 and 144. MMR rate at week 48 for patients with MMR at baseline. Time from the date of randomization to the date of first documented MMR Rate of BCR-ABL1 10% and 1% at weeks 12, 24, 36 and 48 Rate of MR4 and MR4.5 at weeks 12, 24, 36, 48, 72, 96 and 144. Rate of complete cytogenetic response (CCyR) at weeks 48 and EOT. Additional chromosomal abnormalities and occurrence of high-risk ACAs Rate of BCR-ABL1 10%, BCR-ABL1

1%, MMR, MR4 and MR4.5 by all-time points. Duration of MMR. Duration of MR4 without loss of MMR. Time from randomization to death. Time from randomization to treatment failure defined as BCR-ABL1 > 1%. Change in symptom burden and interference from baseline over time according to the MDASI-CML PRO instrument. Time from randomization to the earliest occurrence of documented disease progression to AP/BC or death

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Signed informed consent must be obtained prior to participation in the study
Male or female patients with a diagnosis of CML-CP 18 years of age
Treatment with a minimum of 2 or more prior TKIs (i.e. imatinib, nilotinib, dasatinib, bosutinib, radotinib or ponatinib)
Warning or failure (adapted from the 2020 ELN Recommendations) or intolerance to the most recent TKI therapy at the time of screening
Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0, 1, or 2
Adequate end organ function (as per central laboratory tests)

Criterios de Exclusión

Known presence of the BCR-ABL1 T315I mutation at any time prior to study entry
Known second chronic phase of CML after previous progression to AP/BC
Previous treatment with a hematopoietic stem-cell transplantation
Patient planning to undergo allogeneic hematopoietic stem cell transplantation
Uncontrolled cardiac repolarization abnormality
Severe and/or uncontrolled concurrent medical disease that in the opinion of the investigator could cause unacceptable safety risks or compromise compliance with the protocol
History of acute pancreatitis within 1 year of study entry or past medical history of chronic pancreatitis
History of ongoing active acute or chronic liver disease

Calendario

(Última actualización: 11/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
02/11/2021	18/01/2022	18/01/2022	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	08/05/2023

Promotor

Novartis Pharma AG Switzerland

Lichtstrasse 35

Contact Person

Novartis Pharma Arzneimittel GmbH

+499112730

legal.representative@novartis.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Centros

Cerrado (05/08/2023)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE SANTIAGO

Santiago de Compostela

CORUÑA

Cerrado (05/08/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Cerrado (05/08/2023)

HOSPITAL UNIVERSITARIO BASURTO

Bilbao

VIZCAYA/BIZKAIA

Cerrado (05/08/2023)

HOSPITAL UNIVERSITARIO NUESTRA SEÑORA DE LA CANDELARIA

Santa Cruz de Tenerife

STA. CRUZ DE TENERIFE

Cerrado (05/08/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medicamentos

ASCIMINIB HYDROCHLORIDE
FILM-COATED TABLET
ORAL USE

-

Principios Activos: N/A

Huérfano **Experimental**

ASCIMINIB
FILM-COATED TABLET
ORAL USE

-

Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

Asciminib treatment optimization in 3rd line CML-CP

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	95
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2024-511381-36-00 (CTIS)

Protocol Code
CABL001A2302

Transitioned 2020-006057-21

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

Investigated Disease
Chronic Myelogenous Leukemia in chronic phase (CML-CP)

Scientific Title
A phase IIIb, multi-center, open-label, treatment optimization study of oral asciminib in patients with Chronic Myelogenous Leukemia in chronic phase (CMLCP) previously treated with 2 or more tyrosine kinase inhibitors

Rationale

Not provided

Main Objective

To estimate the molecular response rate (MMR) of all the patients at week 48 with CML-CP following two or more prior TKI treatments and with no evidence of MMR at baseline.

Primary Endpoints

MMR at 48 weeks

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the safety and tolerability of asciminib in patients with CML-CP following 2 or more prior TKI treatments
To assess the rate of MMR in patients without MMR at baseline and at alternative time points at weeks 12, 24, 36, 72, 96 and 144
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Secondary Endpoints

Type, frequency and severity of adverse events, changes in laboratory values that fall outside the pre-determined ranges and clinically notable ECG and other safety data (vital signs, physical examination). MMR rate at weeks 12, 24, 36, 72, 96 and 144. MMR rate at week 48 for patients with MMR at baseline. Time from the date of randomization to the date of first documented MMR Rate of BCR-ABL1 10% and 1% at weeks 12, 24, 36 and 48 Rate of MR4 and MR4.5 at weeks 12, 24, 36, 48, 72, 96 and 144. Rate of complete cytogenetic response (CCyR) at weeks 48 and EOT. Additional chromosomal abnormalities and occurrence of high-risk ACAs Rate of BCR-ABL1 10%, BCR-ABL1

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Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Calendar

(Last Update: 11/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
02/11/2021	18/01/2022	18/01/2022	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	08/05/2023

Sponsor

Novartis Pharma AG Switzerland

Lichtstrasse 35

Contact Person

Novartis Pharma Arzneimittel GmbH

+499112730

legal.representative@novartis.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Sites

Closed (05/08/2023)

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Closed (05/08/2023)

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Madrid

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Medication

ASCIMINIB HYDROCHLORIDE
FILM-COATED TABLET
ORAL USE

-

Active Principles: N/A

Orphan Experimental

ASCIMINIB
FILM-COATED TABLET
ORAL USE

-

Active Principles: N/A

Orphan Experimental

No results