A Study of Oral Asciminib Versus Other TKIs in Adult Patients With Newly Diagnosed Ph+ CML-CP

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	246
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenética	NO

Información

Identificador
2023-508838-33-00 (CTIS)

Cod. Protocolo
CABL001J12301

Transicionado 2021-000678-27

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

Enfermedad investigada
Chronic Myeloid Leukemia

Título Científico
A phase III, multi-center, open-label, randomized study of oral asciminib versus Investigator selected TKI in patients with newly diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukemia in Chronic Phase

Justificación

No aportado

Objetivo Principal

To compare the efficacy of asciminib versus Investigator selected TKI with respect to the proportion of participants that are in Major Molecular Response (MMR) at Week 48.
To compare the efficacy of asciminib versus Investigator selected TKI, within the stratum of participants with imatinib as the pre-randomization selected TKI, with respect to the proportion of participants that are in MMR at Week 48.

Variables de Evaluación Primaria

Major Molecular Response (MMR) at Week 48 (Yes/No)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare the efficacy of asciminib versus Investigator selected TKI, with respect to the proportion of participants that are in MMR at Week 96.
To compare the efficacy of asciminib versus Investigator selected TKI, within the stratum of participants with imatinib as the pre-randomization selected TKI, with respect to the proportion of participants that are in MMR at Week 96.

Variables de Evaluación Secundaria

Major Molecular Response (MMR) at Week 96 (Yes/No)
Major Molecular response (MMR) at Week 96 (Yes/No)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Male or female participants 18 years of age. Participants with CML-CP within 3 months of diagnosis. Diagnosis of CML-CP (ELN 2020 criteria) with cytogenetic confirmation of the Philadelphia chromosome Documented chronic phase CML will meet all the below criteria (Hochhaus et al 2020): < 15% blasts in peripheral blood and bone marrow,

< 30% blasts plus promyelocytes in peripheral blood and bone marrow, < 20% basophils in the peripheral blood, Platelet (PLT) count 100 x 109/L (100,000/mm3), No evidence of extramedullary leukemic involvement, with the exception of hepatosplenomegaly. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. Adequate end organ function as defined by: Total bilirubin (TBL) < 3 x upper limit of normal (ULN); participants with Gilberts syndrome may only be included if TBL 3.0 x ULN or direct bilirubin 1.5 x ULN Creatinine clearance (CrCl) 30 mL/min as calculated using Cockcroft-Gault formula Serum lipase 1.5 x ULN. For serum lipase > ULN - 1.5 x ULN, value must be considered not clinically significant and not associated with risk factors for acute pancreatitis Participants must have the following laboratory values within normal limits or corrected to within normal limits with supplements prior to randomization: Potassium (potassium increase of up to 6.0 mmol/L is acceptable if associated with CrCl* 90 mL/min) Total calcium (corrected for serum albumin); (calcium increase of up to 12.5 mg/dl or 3.1 mmol/L is acceptable if associated with CrCl* 90 mL/min) Magnesium (magnesium increase of up to 3.0 mg/dL or 1.23 mmol/L if associated with CrCl* 90 mL/min) For participants with mild to moderate renal impairment (CrCl* 30 mL/min and <90 mL/min) - potassium, total calcium (corrected for serum albumin) and magnesium should be LLN or corrected to within normal limits with supplements prior to randomization. CrCl* as calculated using Cockcroft-Gault formula Signed informed consent must be obtained prior to any study related screening procedures being performed. Evidence of typical BCR-ABL1 transcript [e14a2 and/or e13a2] at the time of screening which is amenable to standardized Real time quantitative polymerase chain reaction (RQ-PCR) quantification.

Criterios de Exclusión

Previous treatment of CML with any other anticancer agents including chemotherapy and/or biologic agents or prior stem cell transplant, with the exception of hydroxyurea and/or anagrelide. Treatment with either imatinib, or nilotinib, or dasatinib or bosutinib for 2 weeks is allowed. No treatment with other tyrosine kinase inhibitors prior to randomization is permitted.
Known cytopathologically confirmed CNS infiltration (in absence of suspicion of CNS involvement, lumbar puncture not required).
Impaired cardiac function or cardiac repolarization abnormality including but not limited to any one of the following: History within 6 months prior to starting study treatment of myocardial infarction (MI), angina pectoris, coronary artery bypass graft (CABG). Clinically significant cardiac arrhythmias (e.g., ventricular tachycardia), complete left bundle branch block, high-grade AV block (e.g., bifascicular block, Mobitz type II and third degree AV block). QTc 450 ms (male participants), 460 ms (female participants) on the average of three serial baseline ECG (using the QTcF formula) as determined by central reading. If QTcF 450 ms and electrolytes are not within normal ranges, electrolytes should be corrected and then the participant re-screened for QTc. Long QT syndrome, family history of idiopathic sudden death or congenital long QT syndrome, or any of the following: Risk factors for Torsades de Pointes (TdP) including uncorrected hypokalemia or hypomagnesemia, history of cardiac failure, or history of clinically significant/symptomatic bradycardia. Concomitant medication(s) with a Known risk of Torsades de Pointes per //.crediblemeds.org/ that cannot be discontinued or replaced 7 days prior to starting study drug by safe alternative medication. Inability to determine the QTcF interval.
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 (e.g., uncontrolled diabetes, active or uncontrolled infection; uncontrolled arterial or pulmonary hypertension, uncontrolled clinically significant hyperlipidemia).
History of significant congenital or acquired bleeding disorder unrelated to cancer.
Major surgery within 4 weeks prior to study entry or who have not recovered from prior surgery.
History of other active malignancy within 3 years prior to study entry with the exception of previous or concomitant basal cell skin cancer and previous carcinoma in situ treated curatively.
History of acute pancreatitis within 1 year prior to randomization or medical history of chronic pancreatitis.
History of chronic liver disease leading to severe hepatic impairment, or ongoing acute liver disease.

Calendario

(Última actualización: 12/11/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
07/09/2021	06/10/2021	06/10/2021	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
20/12/2022	No aportado	No aportado	No aportado	No aportado

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 La Paz

Paseo de la Castellana, 261 28046 Madrid

ceic.hulp@salud.madrid.org

917277413

Centros

Activo (21/10/2021)

COMPLEJO HOSPITALARIO A (ANTIGUO HOSPITAL DE NAVARRA)*

Pamplona/Iruña

NAVARRA

Activo (21/01/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

#2041: Inther unit

Activo (06/10/2021)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Cerrado (05/04/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

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

Hospital Universitario De Navarra

Pamplona

NAVARRA

#2040: ensayos clínicos

Activo (05/11/2021)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

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

Hospital Universitario La Paz

Madrid

MADRID

#2044: Servicio Hematología

Cerrado (24/07/2025)

HOSPITAL UNIVERSITARIO VIRGEN DE LAS NIEVES

Granada

GRANADA

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

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

#2043: Consulta Hematología

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

#2042: Unidad de trasplante hematopoyético y terapia celular

Medicamentos

ASCIMINIB HYDROCHLORIDE
FILM-COATED TABLET
ORAL USE

-

Principios Activos: N/A

Huérfano

Experimental

DASATINIB
FILM COATED TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

DASATINIB
FILM COATED TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

NILOTINIB
CAPSULE, HARD
ORAL USE

-

Principios Activos: N/A

Experimental

BOSUTINIB
FILM-COATED TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

DASATINIB
FILM-COATED TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

IMATINIB
FILM COATED TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

IMATINIB
FILM-COATED TABLET
ORAL USE

-

Principios Activos: N/A

Experimental

DASATINIB
FILM COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

NILOTINIB
CAPSULE, HARD
ORAL USE

-
Principios Activos: N/A

Experimental

IMATINIB
CAPSULE, HARD
ORAL USE

-
Principios Activos: N/A

Experimental

BOSUTINIB
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

DASATINIB
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

DASATINIB
FILM COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Sin resultados

A Study of Oral Asciminib Versus Other TKIs in Adult Patients With Newly Diagnosed Ph+ CML-CP

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	246
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics, pharmacogenetics	NO

Information

Identifier
2023-508838-33-00 (CTIS)

Protocol Code
CABL001J12301

Transitioned 2021-000678-27

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

Investigated Disease
Chronic Myeloid Leukemia

Scientific Title
A phase III, multi-center, open-label, randomized study of oral asciminib versus Investigator selected TKI in patients with newly diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukemia in Chronic Phase

Rationale

Not provided

Main Objective

To compare the efficacy of asciminib versus Investigator selected TKI with respect to the proportion of participants that are in Major Molecular Response (MMR) at Week 48.
To compare the efficacy of asciminib versus Investigator selected TKI, within the stratum of participants with imatinib as the pre-randomization selected TKI, with respect to the proportion of participants that are in MMR at Week 48.

Primary Endpoints

Major Molecular Response (MMR) at Week 48 (Yes/No)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the efficacy of asciminib versus Investigator selected TKI, with respect to the proportion of participants that are in MMR at Week 96.
To compare the efficacy of asciminib versus Investigator selected TKI, within the stratum of participants with imatinib as the pre-randomization selected TKI, with respect to the proportion of participants that are in MMR at Week 96.

Secondary Endpoints

Major Molecular Response (MMR) at Week 96 (Yes/No)
Major Molecular response (MMR) at Week 96 (Yes/No)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Male or female participants 18 years of age. Participants with CML-CP within 3 months of diagnosis. Diagnosis of CML-CP (ELN 2020 criteria) with cytogenetic confirmation of the Philadelphia chromosome Documented chronic phase CML will meet all the below criteria (Hochhaus et al 2020): < 15% blasts in peripheral blood and bone marrow,

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Exclusion criteria

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History of acute pancreatitis within 1 year prior to randomization or medical history of chronic pancreatitis.
History of chronic liver disease leading to severe hepatic impairment, or ongoing acute liver disease.

Calendar

(Last Update: 12/11/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
07/09/2021	06/10/2021	06/10/2021	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
20/12/2022	Not aported	Not aported	Not aported	Not aported

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 La Paz

Paseo de la Castellana, 261 28046 Madrid

ceic.hulp@salud.madrid.org

917277413

Sites

Active (21/10/2021)

COMPLEJO HOSPITALARIO A (ANTIGUO HOSPITAL DE NAVARRA)*

Pamplona/Iruña

NAVARRA

Active (21/01/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

#2041: Inther unit

Active (06/10/2021)

HOSPITAL CLINICO UNIVERSITARIO VIRGEN DE LA ARRIXACA

Murcia

MURCIA

Closed (05/04/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

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

Hospital Universitario De Navarra

Pamplona

NAVARRA

#2040: ensayos clínicos

Active (05/11/2021)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

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

Hospital Universitario La Paz

Madrid

MADRID

#2044: Servicio Hematología

Closed (24/07/2025)

HOSPITAL UNIVERSITARIO VIRGEN DE LAS NIEVES

Granada

GRANADA

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

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

#2043: Consulta Hematología

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

#2042: Unidad de trasplante hematopoyético y terapia celular

Medication

ASCIMINIB HYDROCHLORIDE
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Orphan Experimental

DASATINIB
FILM COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

DASATINIB
FILM COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

NILOTINIB
CAPSULE, HARD
ORAL USE

-
Active Principles: N/A
Experimental

BOSUTINIB
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

DASATINIB
FILM-COATED TABLET
ORAL USE

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Active Principles: N/A
Experimental

IMATINIB
FILM COATED TABLET
ORAL USE

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Active Principles: N/A
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Active Principles: N/A
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DASATINIB
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Active Principles: N/A
Experimental

NILOTINIB
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ORAL USE

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Active Principles: N/A
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IMATINIB
CAPSULE, HARD
ORAL USE

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Active Principles: N/A
Experimental

BOSUTINIB
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

DASATINIB
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

DASATINIB
FILM COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

No results