A Worldwide Study Testing the New Drug Olverembatinib for Patients with Chronic Phase Chronic Myeloid Leukemia (POLARIS-2)

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	265
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacogenética	NO

Información

Identificador
2024-511495-32-00 (CTIS)

Cod. Protocolo
HQP1351CG301

Área terapéutica
·Enfermedades [C] - Hematología [C15]
·Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Chronic Phase Chronic Myeloid Leukemia

Título Científico
A Global Multicenter, Open Label, Randomized, Phase 3 Registrational Study of Olverembatinib (HQP1351) in Patients with Chronic Phase Chronic Myeloid Leukemia (POLARIS-2)

Justificación

No aportado

Objetivo Principal

Part A: To compare the major molecular response (MMR) rate at 24 weeks of olverembatinib versus bosutinib
Part B: To evaluate the MMR rate by 24 weeks of olverembatinib in CML-CP patients with T315I mutation

Variables de Evaluación Primaria

Part A: MMR rate at 24 weeks
Part B: MMR rate by 24 weeks

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part A: To compare the MMR rate at 96 weeks of olverembatinib versus bosutinib
Part A: To compare additional efficacy parameters of olverembatinib versus bosutinib
Part A:To compare the safety profile of olverembatinib versus bosutinib
Part A:To characterize the population pharmacokinetics (Pop PK) of olverembatinib in the CML-CP population
Part A:To evaluate health utility measures of olverembatinib vs. bosutinib based on EuroQol 5 Dimension (EQ-5D).
Part A:To evaluate patient-reported outcome (PRO) quality of life (QoL) measures of olverembatinib vs. bosutinib based on EORTC QLQ-C30.
Part B:To evaluate the MMR rate by 96 weeks of olverembatinib in CML-CP patients with T315I mutation
Part B:To evaluate additional efficacy parameters of olverembatinib in CML-CP patients with T315I mutation
Part B:To evaluate the safety profile of olverembatinib in CML-CP patients with T315I mutation
Part B:To characterize the population PK of olverembatinib in the CML-CP population with T315I mutation
Part B:To evaluate health utility measures of olverembatinib based on EuroQol 5 Dimension (EQ-5D)
Part B:To evaluate PRO QoL measures of olverembatinib based on EORTC QLQ-C30
Part A: To compare the impact of treatment on patients on work productivity and activity impairment from baseline to end of treatment (EOT) between treatment arms in all patients based on the Work Productivity and Activity Impairment General Health (WPAI-GH) questionnaire.
Part B: To evaluate the impact of treatment on patients on work productivity and activity impairment from baseline to EOT in all patients based on the WPAI-GH.

Variables de Evaluación Secundaria

Part A: MMR rate at 96 weeks
Part A: Cytogenetic response rate (complete, partial, major, minor, minimal, no response) at and by all scheduled data collection time points, including 24, 48 and 96 weeks

Part A: MMR, MR4, MR4.5 rate at all scheduled data collection time points (except 24 and 96 weeks which are already covered by primary and key secondary endpoints)
Part A: MMR, MR4, MR4.5 rate by all scheduled data collection time points including 24, 48 and 96 weeks
Part A: Time to MMR, MR4, MR4.5
Part A: Duration of MMR, MR4, MR4.5
Part A: Time to complete cytogenetic response (CCyR)
Part A: Duration of CCyR
Part A: Time to treatment failure
Part A: Progression free survival
Part A: OS
Part A: Type, frequency, and severity of adverse events
Part A:Changes in laboratory values that fall outside the normal ranges and clinically notable ECG and other safety data (vital signs, physical examination)
Part A:Trough plasma concentration; key PK parameters including apparent clearance, apparent volume of distribution and other appropriate parameters
Part A: Change in health utility from baseline over time according to EQ-5D-5L
Part A: Change in work productivity and activity impairment over time according to WPAI- GH
Part B: MMR rate by 96 weeks
Part B:Cytogenetic response rate (complete, partial, major, minor, minimal, no response) by all scheduled data collection time points, including 24, 48 and 96 weeks
Part B:MMR, MR4, MR4.5 rate by all scheduled data collection time points (except 24 and 96 weeks, which are already covered by primary and key secondary endpoints)
Part B:Time to MMR, MR4, MR4.5
Part B:Duration of MMR, MR4, MR4.5
Part B:Time to CCyR
Part B:Duration of CCyR
Part B: Time to treatment failure
Part B:Progression free survival
Part B:OS
Part B:Type, frequency, and severity of adverse events.
Part B:Changes in laboratory values that fall outside the normal ranges and clinically notable ECG and other safety data (vital signs, physical examination)
Part B:Trough plasma concentration; key PK parameters including apparent clearance, apparent volume of distribution and other appropriate parameters
Part B:Change in QoL from baseline over time according to EORTC QLQ-C30
Part B:Change in work productivity and activity impairment over time according to WPAI- GH
Part A: Change in Quality of Life (QoL) over time according to EORTC QLQ-C30
Part B: Change in health utility from baseline over time according to EQ-5D-5L

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Age 18 years old. Adequate organ functions as defined below: Creatinine clearance 30 mL/min as calculated using Cockcroft-Gault formula. Total bilirubin < 1.5 × ULN except for patients with Gilberts syndrome who may only be included if total bilirubin 3.0 × ULN or direct bilirubin 1.5× ULN. AST < 3 × ULN ALT < 3 × ULN Serum amylase 1.5 × ULN. For serum lipase 1.0 × ULN, value must be considered not clinically significant and not associated with risk factors for acute pancreatitis Alkaline phosphatase 2.5 × ULN Must have the following electrolyte values within normal limits or corrected to be within normal limits with supplements prior to first dose of study medication:

Potassium (potassium increase of up to 6.0 mmol/L is acceptable at study entry if associated with creatinine clearance within normal limits) Total calcium (corrected for serum albumin); (calcium increase of up to 12.5 mg/dl or 3.1 mmol/L is acceptable at study entry if associated with creatinine clearance within normal limits)Magnesium, except for magnesium increase > ULN 3.0 mg/dL; > ULN 1.23 mmol/L associated with creatinine clearance (calculated using Cockcroft-Gault formula) within normal limits Diagnosis of CML-CP according to CML NCCN Guidelines version 1.2024 Evidence of typical BCR::ABL1 transcript at the timing of screening which are amenable to standardized RQ-PCR quantification. Must meet all the following laboratory values at the screening visit: Peripheral blood myeloblasts < 15% Peripheral blood myeloblasts and promyelocytes combined < 30% Peripheral blood basophils < 20% 50 × 109/L (50,000/mm3) platelets Transient prior therapy related thrombocytopenia (<50,000/mm3 for 30 days prior to screening) is acceptable. No evidence of extramedullary infiltrates of leukemia cells, except for hepatomegaly or splenomegaly Part A: Prior treated with at least two approved TKIs, such as imatinib, nilotinib, dasatinib, radotinib, flumatinib, ponatinib, or asciminib Part B: Patients must meet all three of the following criteria at screening. Previously treated with at least one approved TKIs, such as imatinib, nilotinib, dasatinib, bosutinib, radotinib, flumatinib, ponatinib, or asciminib. Have T315I mutation at screening. There are no other effective and/or tolerable therapies available Failure (adapted from the 2025 ELN Guidelines; Apperley et al, 2025) or intolerance to the most recent TKI therapy at the time of screening. Failure is defined for CML-CP patients (CP at the time of initiation of last therapy) as follows. Patients must meet at least one of the following criteria. Three months after the initiation of therapy: BCR::ABL1 (IS) >10% and confirmed within 1-3 months. Six months after the initiation of therapy: BCR::ABL1 (IS) >10%. Twelve months after initiation of therapy: BCR::ABL1 (IS) >1% At any time after the initiation of therapy, if new BCR::ABL1 mutations that cause resistance to current treatment are developed (refer to the latest version of the NCCN or ELN guidelines), and BCR::ABL1 (IS) > 0.1%. At any time after the initiation of therapy, loss of response At any time after the initiation of therapy, new clonal chromosome abnormalities in Ph+ cells: high risk ACA in Ph+ cells, and BCR>>ABL1 (IS) >0.1% Intolerance is defined as below. Patients intolerant to the most recent TKI therapy must have BCR::ABL1 (IS) ratio more than 0.1% at screening. Non-hematological intolerance: patients with grade 3 or 4 toxicity while on therapy, or with persistent grade 2 toxicity, unresponsive to optimal management, including dose adjustments (unless dose reduction is not considered in the best interest of the patient if response is already suboptimal) Hematological intolerance: patients with grade 3 or 4 toxicity (ANC or platelets) while on therapy that is recurrent after dose reduction to the lowest doses recommended in label. ECOG performance status (PS) 2. Written informed consent obtained prior to any screening procedures.

Criterios de Exclusión

For Part A only: T315I or V299L mutation at any time prior to starting study treatment.
Plan to undergo allogeneic hematopoietic stem cell transplantation
Clinically significant, uncontrolled, or active cardiovascular disease, specifically including any of the following prior to starting study treatment: Any history of myocardial infarction (MI) within 6 months. Unstable angina within 3 months. Any history of cerebrovascular accident within 1 year. Transient ischemic attacks (TIA) within 3 months. Any history of peripheral vascular or visceral infarction within 6 months. Congestive heart failure (CHF) (New York Heart Association [NYHA] class III or IV) within 6 months. Left ventricular ejection fraction (LVEF) less than lower limit of normal, per local institutional standards, within 6 months History of clinically significant atrial arrhythmia (such as atrial fibrillation with increased risk of thrombosis) or any history of ventricular arrhythmia (determined by the treating physician). Venous thromboembolism, including deep venous thrombosis or pulmonary embolism, within 3 months prior to enrollment. Patients who have experienced a venous thromboembolic event should only be eligible if the condition is well controlled with optimal intervention (as determined by the treating physician). Continued prophylactic anticoagulation is acceptable. Patients with revascularization procedures, including cardiac bypass within the 6 months and stenting within the past 3 months. QTcF at screening 450 msec (male patients), 470 msec (female patients).
Presence of significant congenital or acquired bleeding disorder unrelated to CML
Another malignancy within 1 year prior to study entry. Patients with nonmelanoma skin cancer or carcinoma in situ of any type are not excluded if they have undergone complete resection and are considered disease-free at the time of study entry
Active infection that requires systemic drug therapy, including active human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection.
Impairment of gastrointestinal (GI) function or GI disease that may significantly alter absorption of study drugs (e.g.,

ulcerative disease, uncontrolled nausea, vomiting, diarrhea, malabsorption syndrome, small bowel resection, or gastric bypass surgery).
(EU only) For Part A only: patient with impairment of hepatic function, which is contraindicated in the bosutinib Summary of Product Characteristics.
Treatment with medications that meet one of the following criteria and cannot be discontinued at least 7 days prior to the first dose of olverembatinib or bosutinib. Moderate or strong inhibitors of CYP3A4 Moderate or strong inducers of CYP3A4
Previous treatment with or known / suspected hypersensitivity to olverembatinib or any of its excipients
For Part A only: Previous treatment with or known / suspected hypersensitivity to bosutinib or any of its excipients
Participation in an investigational study within 30 days prior to randomization or within 5 half-lives of the investigational product, whichever is shorter
Pregnant or nursing (lactating) women
Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using adequate methods of contraception during dosing and for 4 months after last dose of olverembatinib and certain period according to the locally approved prescribing information for bosutinib. (Refer to protocol section 9.2.12.1 subsection pregnancy protection)
Prior diagnosis of CML AP or BP
Previous treatment with hematopoietic stem-cell transplantation.

Calendario

(Última actualización: 17/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
20/01/2025	16/04/2025	01/09/2025	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

Ascentage Pharma Group Inc. United States

700 King Farm Boulevard

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm HM Hospitales

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917089900

Centros

Activo (20/05/2026)

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

Hematology

Activo (08/12/2025)

Fundacion Para La Investigacion Biomedica Del Hospital Universitario La Princesa

Madrid

MADRID

Hematology

Activo (30/05/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology Service

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

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

Hospital Universitario Del Vinalopo

Elche

ALICANTE

Hematoloy

Activo (02/10/2025)

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Hematology

Activo (08/10/2025)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Activo (06/10/2025)

Hospital Universitario La Paz

Madrid

MADRID

Hematology

Activo (26/01/2026)

Hospital Universitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

Activo (17/10/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (07/11/2025)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hematology

Activo (16/04/2025)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Hematology

Activo (16/04/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Activo (31/07/2025)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology Service

Activo (18/09/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology Service

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medicamentos

Bosulif 500 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

Código ATC: L01EA04 - BOSUTINIB
Principios Activos: N/A

Experimental

Bosulif 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

Código ATC: L01EA04 - BOSUTINIB
Principios Activos: N/A

Experimental

Olverembatinib
TABLET
ORAL

-
Principios Activos: N/A

Huérfano Experimental

Sin resultados

A Worldwide Study Testing the New Drug Olverembatinib for Patients with Chronic Phase Chronic Myeloid Leukemia (POLARIS-2)

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	265
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacogenetics	NO

Information

Identifier
2024-511495-32-00 (CTIS)

Protocol Code
HQP1351CG301

Therapeutic area
·Diseases [C] - Hemic and Lymphatic Diseases [C15]
·Diseases [C] - Cancer [C04]

Investigated Disease
Chronic Phase Chronic Myeloid Leukemia

Scientific Title
A Global Multicenter, Open Label, Randomized, Phase 3 Registrational Study of Olverembatinib (HQP1351) in Patients with Chronic Phase Chronic Myeloid Leukemia (POLARIS-2)

Rationale

Not provided

Main Objective

Part A: To compare the major molecular response (MMR) rate at 24 weeks of olverembatinib versus bosutinib
Part B: To evaluate the MMR rate by 24 weeks of olverembatinib in CML-CP patients with T315I mutation

Primary Endpoints

Part A: MMR rate at 24 weeks
Part B: MMR rate by 24 weeks

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part A: To compare the MMR rate at 96 weeks of olverembatinib versus bosutinib
Part A: To compare additional efficacy parameters of olverembatinib versus bosutinib
Part A:To compare the safety profile of olverembatinib versus bosutinib
Part A:To characterize the population pharmacokinetics (Pop PK) of olverembatinib in the CML-CP population
Part A:To evaluate health utility measures of olverembatinib vs. bosutinib based on EuroQol 5 Dimension (EQ-5D).
Part A:To evaluate patient-reported outcome (PRO) quality of life (QoL) measures of olverembatinib vs. bosutinib based on EORTC QLQ-C30.
Part B:To evaluate the MMR rate by 96 weeks of olverembatinib in CML-CP patients with T315I mutation
Part B:To evaluate additional efficacy parameters of olverembatinib in CML-CP patients with T315I mutation
Part B:To evaluate the safety profile of olverembatinib in CML-CP patients with T315I mutation
Part B:To characterize the population PK of olverembatinib in the CML-CP population with T315I mutation
Part B:To evaluate health utility measures of olverembatinib based on EuroQol 5 Dimension (EQ-5D)
Part B:To evaluate PRO QoL measures of olverembatinib based on EORTC QLQ-C30
Part A: To compare the impact of treatment on patients on work productivity and activity impairment from baseline to end of treatment (EOT) between treatment arms in all patients based on the Work Productivity and Activity Impairment General Health (WPAI-GH) questionnaire.
Part B: To evaluate the impact of treatment on patients on work productivity and activity impairment from baseline to EOT in all patients based on the WPAI-GH.

Secondary Endpoints

Part A: MMR rate at 96 weeks
Part A: Cytogenetic response rate (complete, partial, major, minor, minimal, no response) at and by all scheduled data collection time points, including 24, 48 and 96 weeks

Part A: MMR, MR4, MR4.5 rate at all scheduled data collection time points (except 24 and 96 weeks which are already covered by primary and key secondary endpoints)
Part A: MMR, MR4, MR4.5 rate by all scheduled data collection time points including 24, 48 and 96 weeks
Part A: Time to MMR, MR4, MR4.5
Part A: Duration of MMR, MR4, MR4.5
Part A: Time to complete cytogenetic response (CCyR)
Part A: Duration of CCyR
Part A: Time to treatment failure
Part A: Progression free survival
Part A: OS
Part A: Type, frequency, and severity of adverse events
Part A:Changes in laboratory values that fall outside the normal ranges and clinically notable ECG and other safety data (vital signs, physical examination)
Part A:Trough plasma concentration; key PK parameters including apparent clearance, apparent volume of distribution and other appropriate parameters
Part A: Change in health utility from baseline over time according to EQ-5D-5L
Part A: Change in work productivity and activity impairment over time according to WPAI- GH
Part B: MMR rate by 96 weeks
Part B:Cytogenetic response rate (complete, partial, major, minor, minimal, no response) by all scheduled data collection time points, including 24, 48 and 96 weeks
Part B:MMR, MR4, MR4.5 rate by all scheduled data collection time points (except 24 and 96 weeks, which are already covered by primary and key secondary endpoints)
Part B:Time to MMR, MR4, MR4.5
Part B:Duration of MMR, MR4, MR4.5
Part B:Time to CCyR
Part B:Duration of CCyR
Part B: Time to treatment failure
Part B:Progression free survival
Part B:OS
Part B:Type, frequency, and severity of adverse events.
Part B:Changes in laboratory values that fall outside the normal ranges and clinically notable ECG and other safety data (vital signs, physical examination)
Part B:Trough plasma concentration; key PK parameters including apparent clearance, apparent volume of distribution and other appropriate parameters
Part B:Change in QoL from baseline over time according to EORTC QLQ-C30
Part B:Change in work productivity and activity impairment over time according to WPAI- GH
Part A: Change in Quality of Life (QoL) over time according to EORTC QLQ-C30
Part B: Change in health utility from baseline over time according to EQ-5D-5L

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Age 18 years old. Adequate organ functions as defined below: Creatinine clearance 30 mL/min as calculated using Cockcroft-Gault formula. Total bilirubin < 1.5 × ULN except for patients with Gilberts syndrome who may only be included if total bilirubin 3.0 × ULN or direct bilirubin 1.5× ULN. AST < 3 × ULN ALT < 3 × ULN Serum amylase 1.5 × ULN. For serum lipase 1.0 × ULN, value must be considered not clinically significant and not associated with risk factors for acute pancreatitis Alkaline phosphatase 2.5 × ULN Must have the following electrolyte values within normal limits or corrected to be within normal limits with supplements prior to first dose of study medication:

Potassium (potassium increase of up to 6.0 mmol/L is acceptable at study entry if associated with creatinine clearance within normal limits) Total calcium (corrected for serum albumin); (calcium increase of up to 12.5 mg/dl or 3.1 mmol/L is acceptable at study entry if associated with creatinine clearance within normal limits)Magnesium, except for magnesium increase > ULN 3.0 mg/dL; > ULN 1.23 mmol/L associated with creatinine clearance (calculated using Cockcroft-Gault formula) within normal limits Diagnosis of CML-CP according to CML NCCN Guidelines version 1.2024 Evidence of typical BCR::ABL1 transcript at the timing of screening which are amenable to standardized RQ-PCR quantification. Must meet all the following laboratory values at the screening visit: Peripheral blood myeloblasts < 15% Peripheral blood myeloblasts and promyelocytes combined < 30% Peripheral blood basophils < 20% 50 × 109/L (50,000/mm3) platelets Transient prior therapy related thrombocytopenia (<50,000/mm3 for 30 days prior to screening) is acceptable. No evidence of extramedullary infiltrates of leukemia cells, except for hepatomegaly or splenomegaly Part A: Prior treated with at least two approved TKIs, such as imatinib, nilotinib, dasatinib, radotinib, flumatinib, ponatinib, or asciminib Part B: Patients must meet all three of the following criteria at screening. Previously treated with at least one approved TKIs, such as imatinib, nilotinib, dasatinib, bosutinib, radotinib, flumatinib, ponatinib, or asciminib. Have T315I mutation at screening. There are no other effective and/or tolerable therapies available Failure (adapted from the 2025 ELN Guidelines; Apperley et al, 2025) or intolerance to the most recent TKI therapy at the time of screening. Failure is defined for CML-CP patients (CP at the time of initiation of last therapy) as follows. Patients must meet at least one of the following criteria. Three months after the initiation of therapy: BCR::ABL1 (IS) >10% and confirmed within 1-3 months. Six months after the initiation of therapy: BCR::ABL1 (IS) >10%. Twelve months after initiation of therapy: BCR::ABL1 (IS) >1% At any time after the initiation of therapy, if new BCR::ABL1 mutations that cause resistance to current treatment are developed (refer to the latest version of the NCCN or ELN guidelines), and BCR::ABL1 (IS) > 0.1%. At any time after the initiation of therapy, loss of response At any time after the initiation of therapy, new clonal chromosome abnormalities in Ph+ cells: high risk ACA in Ph+ cells, and BCR>>ABL1 (IS) >0.1% Intolerance is defined as below. Patients intolerant to the most recent TKI therapy must have BCR::ABL1 (IS) ratio more than 0.1% at screening. Non-hematological intolerance: patients with grade 3 or 4 toxicity while on therapy, or with persistent grade 2 toxicity, unresponsive to optimal management, including dose adjustments (unless dose reduction is not considered in the best interest of the patient if response is already suboptimal) Hematological intolerance: patients with grade 3 or 4 toxicity (ANC or platelets) while on therapy that is recurrent after dose reduction to the lowest doses recommended in label. ECOG performance status (PS) 2. Written informed consent obtained prior to any screening procedures.

Exclusion criteria

For Part A only: T315I or V299L mutation at any time prior to starting study treatment.
Plan to undergo allogeneic hematopoietic stem cell transplantation
Clinically significant, uncontrolled, or active cardiovascular disease, specifically including any of the following prior to starting study treatment: Any history of myocardial infarction (MI) within 6 months. Unstable angina within 3 months. Any history of cerebrovascular accident within 1 year. Transient ischemic attacks (TIA) within 3 months. Any history of peripheral vascular or visceral infarction within 6 months. Congestive heart failure (CHF) (New York Heart Association [NYHA] class III or IV) within 6 months. Left ventricular ejection fraction (LVEF) less than lower limit of normal, per local institutional standards, within 6 months History of clinically significant atrial arrhythmia (such as atrial fibrillation with increased risk of thrombosis) or any history of ventricular arrhythmia (determined by the treating physician). Venous thromboembolism, including deep venous thrombosis or pulmonary embolism, within 3 months prior to enrollment. Patients who have experienced a venous thromboembolic event should only be eligible if the condition is well controlled with optimal intervention (as determined by the treating physician). Continued prophylactic anticoagulation is acceptable. Patients with revascularization procedures, including cardiac bypass within the 6 months and stenting within the past 3 months. QTcF at screening 450 msec (male patients), 470 msec (female patients).
Presence of significant congenital or acquired bleeding disorder unrelated to CML
Another malignancy within 1 year prior to study entry. Patients with nonmelanoma skin cancer or carcinoma in situ of any type are not excluded if they have undergone complete resection and are considered disease-free at the time of study entry
Active infection that requires systemic drug therapy, including active human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) infection.
Impairment of gastrointestinal (GI) function or GI disease that may significantly alter absorption of study drugs (e.g.,

ulcerative disease, uncontrolled nausea, vomiting, diarrhea, malabsorption syndrome, small bowel resection, or gastric bypass surgery).
(EU only) For Part A only: patient with impairment of hepatic function, which is contraindicated in the bosutinib Summary of Product Characteristics.
Treatment with medications that meet one of the following criteria and cannot be discontinued at least 7 days prior to the first dose of olverembatinib or bosutinib. Moderate or strong inhibitors of CYP3A4 Moderate or strong inducers of CYP3A4
Previous treatment with or known / suspected hypersensitivity to olverembatinib or any of its excipients
For Part A only: Previous treatment with or known / suspected hypersensitivity to bosutinib or any of its excipients
Participation in an investigational study within 30 days prior to randomization or within 5 half-lives of the investigational product, whichever is shorter
Pregnant or nursing (lactating) women
Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using adequate methods of contraception during dosing and for 4 months after last dose of olverembatinib and certain period according to the locally approved prescribing information for bosutinib. (Refer to protocol section 9.2.12.1 subsection pregnancy protection)
Prior diagnosis of CML AP or BP
Previous treatment with hematopoietic stem-cell transplantation.

Calendar

(Last Update: 17/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
20/01/2025	16/04/2025	01/09/2025	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

Ascentage Pharma Group Inc. United States

700 King Farm Boulevard

Contact Person

Yifan Zhai, M.D., Ph.D.

+12405056608

yzhai@asentage.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm HM Hospitales

Avda. Montepríncipe, 25 28660 Boadilla del Monte

secretariaceic@mail.hmhospitales.com

917089900

Sites

Active (20/05/2026)

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

Hematology

Active (08/12/2025)

Fundacion Para La Investigacion Biomedica Del Hospital Universitario La Princesa

Madrid

MADRID

Hematology

Active (30/05/2025)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology Service

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

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

Hospital Universitario Del Vinalopo

Elche

ALICANTE

Hematoloy

Active (02/10/2025)

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Hematology

Active (08/10/2025)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Active (06/10/2025)

Hospital Universitario La Paz

Madrid

MADRID

Hematology

Active (26/01/2026)

Hospital Universitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

Active (17/10/2025)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Active (07/11/2025)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Hematology

Active (16/04/2025)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Hematology

Active (16/04/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Active (31/07/2025)

Institut Catala D´oncologia

Badalona

BARCELONA

Hematology Service

Active (18/09/2025)

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology Service

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Medication

Bosulif 500 mg film-coated tablets
FILM-COATED TABLET
ORAL USE

ATC code: L01EA04 - BOSUTINIB
Active Principles: N/A

Experimental

Bosulif 100 mg film-coated tablets
FILM-COATED TABLET
ORAL

ATC code: L01EA04 - BOSUTINIB
Active Principles: N/A

Experimental

Olverembatinib
TABLET
ORAL

-

Active Principles: N/A

Orphan Experimental

No results