A Global Study Testing the New Drug Olverembatinib combined with chemotherapy for Patients with Newly Diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (POLARIS-1)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	224
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2024-511496-14-00 (CTIS)

Cod. Protocolo
HQP1351AG301

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

Enfermedad investigada
Newly Diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL)

Título Científico
A Global Multicenter, Open Label, Randomized Phase 3 Registrational Study of Olverembatinib Combined with Chemotherapy Versus Investigators Choice of TKI Combined with Chemotherapy in Patients with Newly Diagnosed

Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL) (POLARIS-1)

Justificación

No aportado

Objetivo Principal

Part 1: To assess the efficacy of olverembatinib plus chemotherapy in newly diagnosed Ph+ ALL patients.
Part 2: To assess the efficacy of olverembatinib plus chemotherapy versus investigators choice of TKI plus chemotherapy in patients with newly diagnosed Ph+ ALL. The primary endpoint is minimal residual disease (MRD)-negative complete response (CR) rate at the end of induction.

Variables de Evaluación Primaria

MRD-negative CR rate at the end of induction (EOI): MRD-negativity is defined as BCR-ABL/ABL1 0.01% measured centrally by reverse transcription qPCR. CR is defined as meeting the following criteria: No circulating blasts; No extramedullary disease (i.e., no lymphadenopathy, splenomegaly, skin/gum infiltration, testicular mass or CNS involvement);
Normal maturation of all cellular components in the BM and less than 5% blasts in the bone marrow;
absolute neutrophil count (ANC) 1.0 × 109/L
platelet counts 100 × 109/L
no relapse within 4 weeks

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 1:To assess the pharmacokinetic (PK) profile of olverembatinib plus chemotherapy in patients with newly diagnosed Ph+ ALL.
To assess the safety of olverembatinib plus chemotherapy in patients with newly diagnosed Ph+ ALL.
Part 2: To assess the efficacy of olverembatinib plus chemotherapy versus investigators choice of TKI plus chemotherapy in patients with newly diagnosed Ph+ ALL. The key secondary efficacy endpoint is event free survival (EFS).
To further assess the efficacy of olverembatinib plus chemotherapy versus investigators choice of TKI plus chemotherapy through various parameters.
To compare the safety of olverembatinib plus chemotherapy with investigators choice of TKI plus chemotherapy
To characterize the population PK of olverembatinib in combination with chemotherapy in patients with Ph+ ALL.
To evaluate Patient-Reported Outcome (PRO) measures of olverembatinib plus chemotherapy with investigators choice of TKI plus chemotherapy based on Functional Assessment of Cancer Therapy-Leukemia (FACT-Leu).
To evaluate Health Economics Outcomes Research (HEOR) measures of olverembatinib plus chemotherapy with investigators choice of TKI plus chemotherapy based on Europol 5 Dimension (EQ-5D).

Variables de Evaluación Secundaria

Eventfree survival (EFS): EFS is the key secondary endpoint. EFS is defined as the time from study randomization to the date of treatment failure (ITF), relapse from CR, or death from any cause, whichever comes first. ITF is defined as failure to achieve CR during induction period (i.e., considering CRi responses treatment failures). Overall response rate (ORR): ORR is defined as complete response (CR), CR with partial hematologic recovery (CRh) and CR with incomplete hematologic recovery (CRi). (1) CRh is defined as hematologic complete remission with partial hematologic recovery and meeting all criteria for CR except platelet count and ANC (ANC > 0.5 × 109/L and platelet counts > 50 × 109/L) CRi is defined as hematologic complete remission with incomplete hematologic recovery and meeting all criteria for CR except platelet count or ANC (platelet counts < 100 × 109/L and ANC 1.0 × 109/L, or platelet counts 100 × 109/L and ANC < 1.0 × 109/L) Duration of MRD-negative CR: The interval from the date when MRD-negative CR criteria are first met upon evaluation to the date of molecular relapse from MRD-negativity, or relapse after CR, or to the date of leukemia-related death. Duration of CR, CRh or CRi: The interval from the date when CR, CRh, or CRi criteria are first met upon evaluation to the earliest date of relapse after CR, CRh or CRi. Time to MRD-negative CR: The interval from the date of randomization to the date when MRD-negative CR first met upon evaluation Time to CR, CRh or CRi: The interval from the date of randomization to the date when CR, CRh or CRi criteria are first met upon evaluation Time to treatment failure: The time to discontinuation of randomized study treatment (excluding HSCT performed when MRD-negativity is maintained) for patients due to safety concerns and/or the loss of efficacy benefit Progressionfree survival (PFS): PFS is defined as the date of randomization to the first documented occurrence of the following events: Progressive disease: An increase of at least 25% in the absolute number of circulating or bone marrow blasts or development of extramedullary disease Disease relapse: Reappearance of blasts in the blood or bone marrow (>5%) or in any extramedullary site after a CR/CRh/CRi Death due to any cause OS: The interval from the date of randomization to the date of death due to any cause (to the last contact date if the patient is still alive).

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

18 years old. Meet 2016 WHO classification and diagnostic criteria for Philadelphia chromosome- or BCR/ABL1-positive Ph+ ALL. Patients must be newly diagnosed with Ph+ ALL and haven't received systemic anti-leukaemia therapy previously, except for hydroxycarbamide treatment, vincristine treatment no more than once, and steroids therapy for no more than 28 days. Life expectancy of 3 months. Eastern Cooperative Oncology Group (ECOG) performance status of 2. Adequate organ function as indicated below: Hepatic function: Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) 2.5 × Upper Limit of Normal (ULN), serum total bilirubin 1.5 × ULN (and for patients with Gilberts syndrome serum total bilirubin 3.0 x ULN); Renal function: Serum creatinine 1.5 × ULN; or 24 h creatinine clearance (CrCL) must be 50 mL/min (Cockcroft-Gault formula) when serum creatinine is > 1.5 × ULN; Coagulation: International normalized ratio (INR), activated partial thromboplastin time (APTT), and prothrombin time (PT) all 1.5 × ULN; Cardiac function index: Left ventricular ejection fraction (LVEF) > 50%; Troponin I or T ULN; QT interval corrected using the Fridericia's formula (QTcF) on electrocardiogram (ECG): QTcF 450 ms in males or 470 ms in females. Males and females of childbearing potential (only postmenopausal women who have not menstruated for at least 12 months or are surgically sterilized can be considered infertile) and their partners voluntarily take effective contraceptive measures throughout the treatment and until at least 4 months after the last dose of the study drug. Male patients are not allowed to donate sperm. Female patients of childbearing potential have negative serum pregnancy test results within 7 days prior to the first dose Patients must be able to understand and voluntarily sign a written informed consent form that has been approved by the Ethics Committee (EC) and voluntarily complete study procedures and follow-up examinations

Criterios de Exclusión

Prior history of chronic myelocytic leukemia and diagnosis of chronic myelocytic leukemia in lymphoid blast phase (BP) Any disease or medical condition that is unstable or might affect the patients safety or study compliance, such as uncontrolled hypertension, uncontrolled diabetes mellitus, active hemorrhage (within 3 months), severe respiratory system disorder (e.g., chronic obstructive pulmonary disease, severe asthma, etc.), significant renal, nervous, endocrine, metabolic, immune, hepatic, digestive diseases, and mental diseases, etc. Use of drugs that are known to possibly cause prolonged ECG QT Active fungal/bacterial/viral infection that requires systemic treatment, including but not limited to human immunodeficiency virus (HIV), active viral hepatitis B and hepatitis C, known active COVID-19 (those who have received COVID-19 vaccine or other attenuated live vaccine more than 28 days before enrollment are acceptable). Diseases seriously affect oral administration and absorption of drugs or those who have active peptic ulcer Contraindications to glucocorticoids and unsuitable for participating in the study, at the discretion of the investigator Hemorrhagic disorder unrelated to the tumor: such as congenital hemorrhagic disorder (e.g., angiohaemophilia von Willebrand disease), acquired hemorrhagic disorder diagnosed within 1 year (e.g., acquired factor VIII inhibitor), etc. A major surgery within 14 days prior to the first dose of the study drug (except for minor surgeries such as bone marrow biopsy and deep vein catheterization) or those who havent fully recovered from previous surgeries, at the discretion of the investigator. Hypersensitivity to ingredients, excipients or analogues of drugs used in the study Females who are pregnant, breastfeeding, or planning to become pregnant during the study or within 4 months of Olverembatinib after the last dose Other malignancies within 2 years prior to enrollment, with the exception of: adequately treated cervical carcinoma in situ or breast carcinoma in situ; completely excised skin basal cell carcinoma or localized squamous cell carcinoma of the skin. It is necessary to discuss with the Sponsor for patients with a history of localized malignancy that has been cured by excision (or other methods) which will not affect safety and efficacy evaluation of the study, at the discretion of the investigator. Clinical manifestations of central nervous system (CNS) leukemia or ALL extramedullary infiltration, except lymphadenopathy or hepatosplenomegaly Any symptom or disease that may compromise patients' safety or interfere with the efficacy and safety assessment of the study drug, or any other situation or condition unsuitable for participating in the study. In special circumstances, a decision will be made after the investigator discusses with the Sponsor Previous or current clinical CNS diseases, e.g., epilepsy, epileptic seizure of children or adults, paresis, alogia, apoplexy, severe brain injury, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or mental aberration Autoimmune disorders that may involve CNS. Use of anticoagulants and/or antiplatelet drugs at therapeutic doses, but those using low-dose anticoagulants for keeping the central line patent are acceptable. Use of a drug for other concomitant diseases which interacts with the study drug (e.g., strong CYP2C9 inducers or inhibitors and moderate to strong CYP3A4 inducers or inhibitors) within 7 days or 5 half-lives prior to the first dose (whichever is shorter). Presence of any of the following heart injuries at screening: a. New York Heart Association (NYHA) Class III to IV; b. Uncontrolled angina, congestive cardiac failure or myocardial infarction within 6 months prior to the first dose; c. Second-degree type II, third-degree atrioventricular (AV) block or PR interval > 250 ms, etc.; d. Various factors that have a potential to increase the risk of prolonged QTcF or arrhythmia, such as cardiac failure, hypopotassaemia, congenital long QT syndrome, and a family history of sudden death of unknown cause before the age of 40 years in a first-degree relative; Any venous thromboembolism within 6 months before randomization, including but not limited to deep vein thrombosis (DVT) or lung embolism Use of prohibited drugs within 7 days or 5 half-lives prior to the first dose (whichever is shorter);

Calendario

(Última actualización: 10/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
02/07/2025	14/05/2026	15/05/2026	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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yzhai@asentage.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm HM Hospitales

Avda. Montepríncipe, 25 28660 Boadilla del Monte

secretariaceic@mail.hmhospitales.com

917089900

Centros

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

Activo (19/05/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Activo (07/07/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (03/06/2026)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

Activo (10/07/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Activo (18/05/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (01/07/2026)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Activo (14/05/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (03/07/2026)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-

Principios Activos: N/A

Experimental

PONATINIB
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

METHOTREXATE
CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

-

Principios Activos: N/A

Experimental

METHOTREXATE
CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

-

Principios Activos: N/A

Experimental

PREDNISOLONE
SOLUBLE TABLET
ORAL

-

Principios Activos: N/A

Experimental

DASATINIB
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL

-

Principios Activos: N/A

Experimental

DEXAMETHASONE
SOLUTION FOR INJECTION
INTRAVENOUS ADMINISTRATION

-

Principios Activos: N/A

Experimental

IMATINIB MESILATE
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-
Principios Activos: N/A

Experimental

DEXAMETHASONE
SOLUTION FOR INJECTION
INTRAVENOUS ADMINISTRATION

-
Principios Activos: N/A

Experimental

METHOTREXATE
SOLUTION FOR INJECTION
INTRATHECAL USE

-
Principios Activos: N/A

Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-
Principios Activos: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-
Principios Activos: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRATHECAL USE

-
Principios Activos: N/A
Experimental

-
Principios Activos: N/A
Experimental

DEXAMETHASONE
TABLET
ORAL

-
Principios Activos: N/A
Experimental

PREDNISOLONE
SOLUBLE TABLET
ORAL

-
Principios Activos: N/A
Experimental

METHOTREXATE
SOLUTION FOR INJECTION
INTRATHECAL USE

-
Principios Activos: N/A
Experimental

DEXAMETHASONE
TABLET
ORAL

-
Principios Activos: N/A
Experimental

DASATINIB
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRATHECAL USE

-
Principios Activos: N/A
Experimental

Olverembatinib
TABLET
ORAL

-

Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

A Global Study Testing the New Drug Olverembatinib combined with chemotherapy for Patients with Newly Diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (POLARIS-1)

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	224
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2024-511496-14-00 (CTIS)

Protocol Code
HQP1351AG301

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

Investigated Disease
Newly Diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL)

Scientific Title
A Global Multicenter, Open Label, Randomized Phase 3 Registrational Study of Olverembatinib Combined with Chemotherapy Versus Investigators Choice of TKI Combined with Chemotherapy in Patients with Newly Diagnosed

Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL) (POLARIS-1)

Rationale

Not provided

Main Objective

Part 1: To assess the efficacy of olverembatinib plus chemotherapy in newly diagnosed Ph+ ALL patients.
Part 2: To assess the efficacy of olverembatinib plus chemotherapy versus investigators choice of TKI plus chemotherapy in patients with newly diagnosed Ph+ ALL. The primary endpoint is minimal residual disease (MRD)-negative complete response (CR) rate at the end of induction.

Primary Endpoints

MRD-negative CR rate at the end of induction (EOI): MRD-negativity is defined as BCR-ABL/ABL1 0.01% measured centrally by reverse transcription qPCR. CR is defined as meeting the following criteria: No circulating blasts; No extramedullary disease (i.e., no lymphadenopathy, splenomegaly, skin/gum infiltration, testicular mass or CNS involvement);
Normal maturation of all cellular components in the BM and less than 5% blasts in the bone marrow;
absolute neutrophil count (ANC) 1.0 × 109/L
platelet counts 100 × 109/L
no relapse within 4 weeks

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 1:To assess the pharmacokinetic (PK) profile of olverembatinib plus chemotherapy in patients with newly diagnosed Ph+ ALL.
To assess the safety of olverembatinib plus chemotherapy in patients with newly diagnosed Ph+ ALL.
Part 2: To assess the efficacy of olverembatinib plus chemotherapy versus investigators choice of TKI plus chemotherapy in patients with newly diagnosed Ph+ ALL. The key secondary efficacy endpoint is event free survival (EFS).
To further assess the efficacy of olverembatinib plus chemotherapy versus investigators choice of TKI plus chemotherapy through various parameters.
To compare the safety of olverembatinib plus chemotherapy with investigators choice of TKI plus chemotherapy
To characterize the population PK of olverembatinib in combination with chemotherapy in patients with Ph+ ALL.
To evaluate Patient-Reported Outcome (PRO) measures of olverembatinib plus chemotherapy with investigators choice of TKI plus chemotherapy based on Functional Assessment of Cancer Therapy-Leukemia (FACT-Leu).
To evaluate Health Economics Outcomes Research (HEOR) measures of olverembatinib plus chemotherapy with investigators choice of TKI plus chemotherapy based on Europol 5 Dimension (EQ-5D).

Secondary Endpoints

Eventfree survival (EFS): EFS is the key secondary endpoint. EFS is defined as the time from study randomization to the date of treatment failure (ITF), relapse from CR, or death from any cause, whichever comes first. ITF is defined as failure to achieve CR during induction period (i.e., considering CRi responses treatment failures). Overall response rate (ORR): ORR is defined as complete response (CR), CR with partial hematologic recovery (CRh) and CR with incomplete hematologic recovery (CRi). (1) CRh is defined as hematologic complete remission with partial hematologic recovery and meeting all criteria for CR except platelet count and ANC (ANC > 0.5 × 109/L and platelet counts > 50 × 109/L) CRi is defined as hematologic complete remission with incomplete hematologic recovery and meeting all criteria for CR except platelet count or ANC (platelet counts < 100 × 109/L and ANC 1.0 × 109/L, or platelet counts 100 × 109/L and ANC < 1.0 × 109/L) Duration of MRD-negative CR: The interval from the date when MRD-negative CR criteria are first met upon evaluation to the date of molecular relapse from MRD-negativity, or relapse after CR, or to the date of leukemia-related death. Duration of CR, CRh or CRi: The interval from the date when CR, CRh, or CRi criteria are first met upon evaluation to the earliest date of relapse after CR, CRh or CRi. Time to MRD-negative CR: The interval from the date of randomization to the date when MRD-negative CR first met upon evaluation Time to CR, CRh or CRi: The interval from the date of randomization to the date when CR, CRh or CRi criteria are first met upon evaluation Time to treatment failure: The time to discontinuation of randomized study treatment (excluding HSCT performed when MRD-negativity is maintained) for patients due to safety concerns and/or the loss of efficacy benefit Progressionfree survival (PFS): PFS is defined as the date of randomization to the first documented occurrence of the following events: Progressive disease: An increase of at least 25% in the absolute number of circulating or bone marrow blasts or development of extramedullary disease Disease relapse: Reappearance of blasts in the blood or bone marrow (>5%) or in any extramedullary site after a CR/CRh/CRi Death due to any cause OS: The interval from the date of randomization to the date of death due to any cause (to the last contact date if the patient is still alive).

Temporary moments of secondary assessment

Not provided

Inclusion criteria

18 years old. Meet 2016 WHO classification and diagnostic criteria for Philadelphia chromosome- or BCR/ABL1-positive Ph+ ALL. Patients must be newly diagnosed with Ph+ ALL and haven't received systemic anti-leukaemia therapy previously, except for hydroxycarbamide treatment, vincristine treatment no more than once, and steroids therapy for no more than 28 days. Life expectancy of 3 months. Eastern Cooperative Oncology Group (ECOG) performance status of 2. Adequate organ function as indicated below: Hepatic function: Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) 2.5 × Upper Limit of Normal (ULN), serum total bilirubin 1.5 × ULN (and for patients with Gilberts syndrome serum total bilirubin 3.0 x ULN); Renal function: Serum creatinine 1.5 × ULN; or 24 h creatinine clearance (CrCL) must be 50 mL/min (Cockcroft-Gault formula) when serum creatinine is > 1.5 × ULN; Coagulation: International normalized ratio (INR), activated partial thromboplastin time (APTT), and prothrombin time (PT) all 1.5 × ULN; Cardiac function index: Left ventricular ejection fraction (LVEF) > 50%; Troponin I or T ULN; QT interval corrected using the Fridericia's formula (QTcF) on electrocardiogram (ECG): QTcF 450 ms in males or 470 ms in females. Males and females of childbearing potential (only postmenopausal women who have not menstruated for at least 12 months or are surgically sterilized can be considered infertile) and their partners voluntarily take effective contraceptive measures throughout the treatment and until at least 4 months after the last dose of the study drug. Male patients are not allowed to donate sperm. Female patients of childbearing potential have negative serum pregnancy test results within 7 days prior to the first dose Patients must be able to understand and voluntarily sign a written informed consent form that has been approved by the Ethics Committee (EC) and voluntarily complete study procedures and follow-up examinations

Exclusion criteria

Prior history of chronic myelocytic leukemia and diagnosis of chronic myelocytic leukemia in lymphoid blast phase (BP) Any disease or medical condition that is unstable or might affect the patients safety or study compliance, such as uncontrolled hypertension, uncontrolled diabetes mellitus, active hemorrhage (within 3 months), severe respiratory system disorder (e.g., chronic obstructive pulmonary disease, severe asthma, etc.), significant renal, nervous, endocrine, metabolic, immune, hepatic, digestive diseases, and mental diseases, etc. Use of drugs that are known to possibly cause prolonged ECG QT Active fungal/bacterial/viral infection that requires systemic treatment, including but not limited to human immunodeficiency virus (HIV), active viral hepatitis B and hepatitis C, known active COVID-19 (those who have received COVID-19 vaccine or other attenuated live vaccine more than 28 days before enrollment are acceptable). Diseases seriously affect oral administration and absorption of drugs or those who have active peptic ulcer Contraindications to glucocorticoids and unsuitable for participating in the study, at the discretion of the investigator Hemorrhagic disorder unrelated to the tumor: such as congenital hemorrhagic disorder (e.g., angiohaemophilia von Willebrand disease), acquired hemorrhagic disorder diagnosed within 1 year (e.g., acquired factor VIII inhibitor), etc. A major surgery within 14 days prior to the first dose of the study drug (except for minor surgeries such as bone marrow biopsy and deep vein catheterization) or those who havent fully recovered from previous surgeries, at the discretion of the investigator. Hypersensitivity to ingredients, excipients or analogues of drugs used in the study Females who are pregnant, breastfeeding, or planning to become pregnant during the study or within 4 months of Olverembatinib after the last dose Other malignancies within 2 years prior to enrollment, with the exception of: adequately treated cervical carcinoma in situ or breast carcinoma in situ; completely excised skin basal cell carcinoma or localized squamous cell carcinoma of the skin. It is necessary to discuss with the Sponsor for patients with a history of localized malignancy that has been cured by excision (or other methods) which will not affect safety and efficacy evaluation of the study, at the discretion of the investigator. Clinical manifestations of central nervous system (CNS) leukemia or ALL extramedullary infiltration, except lymphadenopathy or hepatosplenomegaly Any symptom or disease that may compromise patients' safety or interfere with the efficacy and safety assessment of the study drug, or any other situation or condition unsuitable for participating in the study. In special circumstances, a decision will be made after the investigator discusses with the Sponsor Previous or current clinical CNS diseases, e.g., epilepsy, epileptic seizure of children or adults, paresis, alogia, apoplexy, severe brain injury, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome, or mental aberration Autoimmune disorders that may involve CNS. Use of anticoagulants and/or antiplatelet drugs at therapeutic doses, but those using low-dose anticoagulants for keeping the central line patent are acceptable. Use of a drug for other concomitant diseases which interacts with the study drug (e.g., strong CYP2C9 inducers or inhibitors and moderate to strong CYP3A4 inducers or inhibitors) within 7 days or 5 half-lives prior to the first dose (whichever is shorter). Presence of any of the following heart injuries at screening: a. New York Heart Association (NYHA) Class III to IV; b. Uncontrolled angina, congestive cardiac failure or myocardial infarction within 6 months prior to the first dose; c. Second-degree type II, third-degree atrioventricular (AV) block or PR interval > 250 ms, etc.; d. Various factors that have a potential to increase the risk of prolonged QTcF or arrhythmia, such as cardiac failure, hypopotassaemia, congenital long QT syndrome, and a family history of sudden death of unknown cause before the age of 40 years in a first-degree relative; Any venous thromboembolism within 6 months before randomization, including but not limited to deep vein thrombosis (DVT) or lung embolism Use of prohibited drugs within 7 days or 5 half-lives prior to the first dose (whichever is shorter);

Calendar

(Last Update: 10/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
02/07/2025	14/05/2026	15/05/2026	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

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

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

Hospital Germans Trias I Pujol

Badalona

BARCELONA

Hematology

Active (19/05/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Active (07/07/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (03/06/2026)

Hospital Universitario De La Princesa

Madrid

MADRID

Hematology

Active (10/07/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Active (18/05/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Active (01/07/2026)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Active (14/05/2026)

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Active (03/07/2026)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-

Active Principles: N/A

Experimental

PONATINIB
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

METHOTREXATE
CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

-

Active Principles: N/A

Experimental

METHOTREXATE
CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

-

Active Principles: N/A

Experimental

PREDNISOLONE
SOLUBLE TABLET
ORAL

-

Active Principles: N/A

Experimental

DASATINIB
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL

-

Active Principles: N/A

Experimental

DEXAMETHASONE
SOLUTION FOR INJECTION
INTRAVENOUS ADMINISTRATION

-

Active Principles: N/A

Experimental

IMATINIB MESILATE
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-

Active Principles: N/A

Experimental

DEXAMETHASONE
SOLUTION FOR INJECTION
INTRAVENOUS ADMINISTRATION

-

Active Principles: N/A

Experimental

METHOTREXATE
SOLUTION FOR INJECTION
INTRATHECAL USE

-

Active Principles: N/A

Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-

Active Principles: N/A

Experimental

VINCRISTINE SULFATE
SOLUTION FOR INJECTION/INFUSION
IV INFUSION

-

Active Principles: N/A

Experimental

DEXAMETHASONE
TABLET
ORAL

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRATHECAL USE

-
Active Principles: N/A
Experimental

-
Active Principles: N/A
Experimental

DEXAMETHASONE
TABLET
ORAL

-
Active Principles: N/A
Experimental

PREDNISOLONE
SOLUBLE TABLET
ORAL

-
Active Principles: N/A
Experimental

METHOTREXATE
SOLUTION FOR INJECTION
INTRATHECAL USE

-
Active Principles: N/A
Experimental

DEXAMETHASONE
TABLET
ORAL

-
Active Principles: N/A
Experimental

DASATINIB
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Experimental

CYTARABINE
SOLUTION FOR INJECTION/INFUSION
INTRATHECAL USE

-
Active Principles: N/A
Experimental

Olverembatinib
TABLET
ORAL

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Active Principles: N/A

Orphan **Experimental**

No results