A phase III placebo-controlled efficacy and safety study of mocravimod as an adjunctive and maintenance treatment in AML patients undergoing allo-HCT (MO-TRANS Study)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Interrumpido	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	229
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
2024-512752-38-00 (CTIS)

Cod. Protocolo
PKRPC001

Transicionado 2021-002864-36

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Adjunctive and maintenance treatment to HCT

Título Científico
A prospective randomized, double-blind, placebo-controlled, multi-center phase III study to evaluate the efficacy and safety of mocravimod as an adjunctive and maintenance treatment in adult in acute myeloid leukemia (AML) patients undergoing allogeneic hematopoietic cell transplantation (HCT)

Justificación

No aportado

Objetivo Principal

1. To demonstrate the superior efficacy of mocravimod 3 mg to that of placebo in the TAC GvHD prophylaxis stratum
2. To demonstrate the superior efficacy of mocravimod 1 mg to that of placebo in the TAC GvHD prophylaxis stratum

Variables de Evaluación Primaria

Relapse-free survival (RFS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1. To demonstrate mocravimods 3 mg superior efficacy on overall survival (OS) to that of placebo in the TAC GvHD prophylaxis stratum.
2. To demonstrate mocravimods 1 mg superior efficacy on overall survival (OS) to that of placebo in the TAC GvHD prophylaxis stratum
3. To assess mocravimods effect on the occurrence of GvHD in comparison to placebo

Variables de Evaluación Secundaria

Overall Survival (OS) - mocravimod's effect on OS to that to placebo
RFS at EOS (End-of-study) - to assess the sustained efficacy of moc in comparison to placebo
Survival free from Grade III/IV aGvHD at 12 mo & time to acute GvHD
Survival free from moderate /severe cGvHD at EOS & time to cGvHD
GRFS (GvHD-free, Relapse-free survival at 12 mo and at EOS)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subjects with a diagnosis of AML (excluding acute promyelocytic leukemia) according to the World Health

Organization (WHO) 2022 classification of AML and related precursor neoplasms, including therapy AML with myelodysplasia related gene mutations. Subjects with European LeukemiaNet (ELN) high risk or intermediate risk or AML in CR1, or AML of any risk in CR2. (Complete remission with incomplete count recovery [CRi] is also allowable). - Complete remission is defined as: < 5% marrow blasts by morphologic examination and no circulating peripheral blasts; absence of extramedullary disease; absolute neutrophil count 1.0x109/L (1000/L); platelet count 100x109/L (100 000/L) - CRi is defined as meeting all complete remission criteria except for residual absolute neutropenia < 1000/L and/or thrombocytopenia <100 000/L Planned use of a related or unrelated donor or with no more than 1 antigen mismatch or planned use of a haploidentical donor Life expectancy 6 months at screening. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 Male or female, age 18 years and 75 years.

Criterios de Exclusión

Planned use of CsA, anti-thymocyte globulin (ATG), alemtuzumab, abatacept for GvHD prophylaxis. Subjects having received prior allogeneic HCT or recipients of a solid organ transplant. Immunosuppressive drugs for concomitant disease. Subjects must be able to be off prednisone (> 10 mg/day) or other immunosuppressive medications for at least 3 days prior to the start of treatment of the study. Physiologic replacement dosing of hydrocortisone is permissible. Require treatments for cardiac dysfunction Subjects with acute promyelocytic leukemia. Blast crisis of chronic myeloid leukemia Cardiac dysfunction Pulmonary dysfunction. Significant liver disease or liver injury or known history of alcohol abuse, chronic liver or biliary disease. Hepatic dysfunction as defined by aspartate aminotransferase (AST) and/or alanine aminotransferase (ALT) > 2.5 x upper limit of normal (ULN); or total bilirubin > 1.5 x ULN Renal dysfunction with creatinine clearance < 45 mL/min by the Cockcroft-Gault formula. History of stroke or intracranial hemorrhage within 1 year prior to screening. Active clinically significant infection (viral, bacterial, or fungal) that requires ongoing antimicrobial therapy and in the judgment of the investigator represents a risk to proceeding with HCT. Planned use of serotherapy during conditioning, including ATG and alemtuzumab. Planned ex vivo major graft manipulation, including T-cell depletion or CD34+ selection.

Calendario

(Última actualización: 04/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
12/07/2022	22/09/2022	13/01/2023	30/08/2024	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
30/08/2024	No aportado	No aportado	No aportado	No aportado

Promotor

Priothera S.A.S. France

57 Avenue Du General De Gaulle

Contact Person

Karen von Graevenitz

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Activo (01/02/2023)

Complejo Hospitalario Universitario De Gran Canaria Dr. Negrin

Palmas de Gran Canaria, Las

LAS PALMAS

Hematología

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

El Hospital Universitario De Gran Canaria Dr. Negrin

Las Palmas De Gran Canaria

LAS PALMAS

Hematology Department

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology Department

Activo (16/02/2023)

Hospital Universitari Vall d'Hebrón

Barcelona

BARCELONA

Oncohematology

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

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology Department

Activo (27/09/2022)

Hospital Universitario de Salamanca

Salamanca

SALAMANCA

Hematology

Cerrado (18/10/2024)

Hospital Universitario La Princesa

Madrid

MADRID

Hematology

Activo (25/01/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Hematología

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology Department

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

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

Hematology Department

Activo (22/09/2022)

Hospital Universitario Virgen de las Nieves

Granada

GRANADA

Hematology

Activo (15/12/2022)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Hematología

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology Department

Activo (26/01/2023)

Hospital Universitario 12

Madrid

MADRID

Hematology

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

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology Department

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology Department

Cerrado (28/05/2025)

Institut Catala D'oncologia

Badalona

BARCELONA

Hematología

Activo (10/03/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematología

Medicamentos

Mocravimod (KRP203)
CAPSULES
ORAL USE

-

Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

A phase III placebo-controlled efficacy and safety study of mocravimod as an adjunctive and maintenance treatment in AML patients undergoing allo-HCT (MO-TRANS Study)

State	**Type of participants**	**Age Ranges**
Halted	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	229
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
2024-512752-38-00 (CTIS)

Protocol Code
PKRPC001

Transitioned 2021-002864-36

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
Adjunctive and maintenance treatment to HCT

Scientific Title
A prospective randomized, double-blind, placebo-controlled, multi-center phase III study to evaluate the efficacy and safety of mocravimod as an adjunctive and maintenance treatment in adult in acute myeloid leukemia (AML) patients undergoing allogeneic hematopoietic cell transplantation (HCT)

Rationale

Not provided

Main Objective

1. To demonstrate the superior efficacy of mocravimod 3 mg to that of placebo in the TAC GvHD prophylaxis stratum
2. To demonstrate the superior efficacy of mocravimod 1 mg to that of placebo in the TAC GvHD prophylaxis stratum

Primary Endpoints

Relapse-free survival (RFS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

1. To demonstrate mocravimods 3 mg superior efficacy on overall survival (OS) to that of placebo in the TAC GvHD prophylaxis stratum.
2. To demonstrate mocravimods 1 mg superior efficacy on overall survival (OS) to that of placebo in the TAC GvHD prophylaxis stratum
3. To assess mocravimods effect on the occurrence of GvHD in comparison to placebo

Secondary Endpoints

Overall Survival (OS) - mocravimod's effect on OS to that to placebo
RFS at EOS (End-of-study) - to assess the sustained efficacy of moc in comparison to placebo
Survival free from Grade III/IV aGvHD at 12 mo & time to acute GvHD
Survival free from moderate /severe cGvHD at EOS & time to cGvHD
GRFS (GvHD-free, Relapse-free survival at 12 mo and at EOS)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subjects with a diagnosis of AML (excluding acute promyelocytic leukemia) according to the World Health

Organization (WHO) 2022 classification of AML and related precursor neoplasms, including therapy AML with myelodysplasia related gene mutations. Subjects with European LeukemiaNet (ELN) high risk or intermediate risk or AML in CR1, or AML of any risk in CR2. (Complete remission with incomplete count recovery [CRi] is also allowable). - Complete remission is defined as: < 5% marrow blasts by morphologic examination and no circulating peripheral blasts; absence of extramedullary disease; absolute neutrophil count 1.0x109/L (1000/L); platelet count 100x109/L (100 000/L) - CRi is defined as meeting all complete remission criteria except for residual absolute neutropenia < 1000/L and/or thrombocytopenia <100 000/L Planned use of a related or unrelated donor or with no more than 1 antigen mismatch or planned use of a haploidentical donor Life expectancy 6 months at screening. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 Male or female, age 18 years and 75 years.

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Calendar

(Last Update: 04/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
12/07/2022	22/09/2022	13/01/2023	30/08/2024	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
30/08/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

Priothera S.A.S. France

57 Avenue Du General De Gaulle

Contact Person

Karen von Graevenitz

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Monetary support: N/A

Sponsor type: Commercial

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917792613

Sites

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LAS PALMAS

Hematología

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

El Hospital Universitario De Gran Canaria Dr. Negrin

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LAS PALMAS

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Hospital Universitario De Salamanca

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Hospital Universitario de Salamanca

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SALAMANCA

Hematology

Closed (18/10/2024)

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Active (15/12/2022)

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València

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Hematología

Active (10/03/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematología

Medication

Mocravimod (KRP203)

CAPSULES

ORAL USE

-

Active Principles: N/A

Orphan **Experimental**

No results