A Phase 2, Open-Label, Ascending Dose Study of KER-050 for the Treatment of Anemia in Patients with Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	77
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador

2023-507469-24-00 (CTIS)

Cod. Protocolo

KER050-MD-201

Transicionado 2021-001838-19

Área terapéutica

Enfermedades [C] - Hematología [C15]|

Enfermedad investigada

Anemia in Patients with Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS).

Título Científico

A Phase 2, Open-Label, Ascending Dose Study of KER-050 for the Treatment of Anemia in Patients with Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS)

Justificación

No aportado

Objetivo Principal

Part 1: Dose Escalation
To evaluate the safety and tolerability of ascending doses of elritercept in participants with very low, low, or intermediate risk MDS in order to determine the dose(s) that will be evaluated in Part 2 of the study.
Part 2: Dose Confirmation
To confirm the safety and tolerability of the dose(s) selected in Part 1. Long-Term Extension To evaluate the long-term safety and tolerability of elritercept in participants with very low, low, or intermediate risk MDS in the Long term Extension (LTE).

Variables de Evaluación Primaria

Part 1 and Part 2: Safety and tolerability as determined by the incidence of treatment emergent adverse events(TEAEs) and serious adverse events (SAEs).
Long-term Extension: Safety and tolerability as determined by the incidence of TEAEs and SAEs over time

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Safety Objective: To evaluate the progression to higher risk MDS or acute myeloid leukemia (AML)
Efficacy Objective: To evaluate the efficacy of elritercept on anemia in participants with very low, low, or intermediate risk MDS, separately for ring sideroblast (RS)- positive and non-RS populations
Pharmacodynamic Objective: To evaluate the pharmacodynamic (PD) effects of elritercept on erythropoiesis in participants with very low, low, or intermediate risk MDS, separately for RS-positive and non-RS populations.

Variables de Evaluación Secundaria

Incidence of progression to higher risk MDS or AML per World Health Organization (WHO) 2016 criteria.
Proportion of low transfusion burden (LTB) and high transfusion burden (HTB) participants who achieve red blood cell (RBC) transfusion independence (TI) 8 weeks, overall and by RS status.
Proportion of participants who achieve modified 2006 International Working Group (IWG) Hematologic Improvement-Erythroid (HI E) response overall and by RS status (See Table 3 in Protocol KER050-MD-201 v 7.0).
Efficacy Endpoint: Proportion of participants who achieve overall erythroid response, defined as either HI-E or TI over any 8-week period, overall and by RS status
Efficacy Endpoint: Proportion of participants who achieve erythropoietic improvement overall and by RS status (See Table 3 in Protocol KER050-MD-201 v 7.0).
Efficacy Endpoint: Mean change from Baseline in Hgb by visit

Efficacy Endpoint: Time to HI-E response.
Efficacy Endpoint: Duration of HI-E response.
Efficacy Endpoint: Time to TI response.
Efficacy Endpoint: Time to TI response.
Efficacy Endpoint: Proportion of LTB and HTB participants who achieve TI 12 weeks, 16 weeks, 24 weeks, 48 weeks.
Proportion of LTB and HTB participants who achieve TI 12 weeks, 16 weeks, 24 weeks, 48 weeks.
Pharmacodynamic Endpoint: Change from baseline of red cell parameters, including reticulocyte count, mean corpuscular volume, mean corpuscular hemoglobin, and reticulocyte cell Hgb by visit.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Diagnosis of MDS (Parts 1 and 2) according to WHO classification that meets International Prognostic Scoring System-Revised (IPSS-R) classification of very low, low, or intermediate risk disease. < 5% blasts in bone marrow during the Pretreatment Period. Peripheral blood white blood cell (WBC) count < 13,000/L during the Pretreatment Period. Anemia defined as: A). In non-transfused participants, having received no RBC transfusions within 8 weeks, Hgb concentration 10.0 g/dL during the Pretreatment Period OR B).a. In LTB participants, having received 1 to 3 units of RBCs for Hgb 9.0 g/dL within 8 weeks of the Pretreatment Period OR C). In HTB participants, having received 4 units of RBCs for Hgb 9.0 g/dL within 8 weeks of the Pretreatment Period. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 (if related to anemia). Females of child-bearing potential and sexually active males must agree to use highly effective methods of contraception.

Criterios de Exclusión

Active infection requiring parenteral antibiotic therapy within 28 days prior to C1D1 or oral antibiotics within 14 days of C1D1. Prophylactic antibiotics and/or antifungals for neutropenia are allowed. Treatment history: Prior treatment with azacitidine, decitabine, lenalidomide, luspatercept, or sotatercept. Treatment history: Treatment with ESA within 8 weeks prior to C1D1 (or C5D1 for the Part 1 Extension). Treatment history for part 2: Prior treatment with luspatercept (Cohorts A, B, C, D, E, and F only) Treatment history: Prior or concurrent chronic treatment with granulocyte colony stimulating factor (G-CSF) orgranulocyte-macrophage colony stimulating factor (GM-CSF), for reasons other than the treatment of MDS. Platelet count > 450 x 10*9/L or < 30 x 10*9/L. Transferrin saturation < 15%. Ferritin < 50 g/L. Folate < 4.5 nmol/L (< 2.0 ng/mL). Vitamin B12 < 148 pmol/L (< 200 pg/mL). Estimated glomerular filtration rate (GFR) < 30 mL/min/1.73 m2 (as determined by the Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI]. Pregnant or lactating females. For Cohort G ONLY (for part 2): 1. Any luspatercept related AE Grade 3 that has not resolved to baseline or Grade 1 2. No history of allergy/anaphylaxis/hypersensitivity to luspatercept. 3. No prior treatment with imetelstat. Medical history: Diagnosis of MDS with deletion of chromosome 5q (Del5q). Medical history: Presence of uncontrolled heart disease or New York Heart Association Class III or IV heart failure. Medical history: Presence of uncontrolled hypertension (Grade >/= 2 high blood pressure). Diagnosis of secondary MDS (ie, MDS that is known to have arisen as the result of chemical injury or treatment with chemotherapy and/or radiation for other diseases). Medical history: Any malignancy other than MDS that has not been in remission and/or has required systemictherapy 1 year prior to C1D1 (or C5D1 for the Part 1 Extension). Medical history: History of solid organ or hematological transplantation Medical history: Body mass index >/= 40 kg/m2 during the pretreatment period.

Calendario

(Última actualización: 18/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
09/03/2022	25/04/2022	06/05/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
15/07/2024	No aportado	No aportado	No aportado	No aportado

Promotor

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Contact Person

Takeda

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Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Activo (26/10/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

Activo (27/07/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Activo (29/04/2022)

HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Oviedo

ASTURIAS

Activo (28/07/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Activo (23/09/2022)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Activo (29/09/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medicamentos

elritercept
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

Sin resultados

A Phase 2, Open-Label, Ascending Dose Study of KER-050 for the Treatment of Anemia in Patients with Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS)

State	**Type of participants**	**Age Ranges**
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	77
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2023-507469-24-00 (CTIS)

Protocol Code
KER050-MD-201

Transitioned 2021-001838-19

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

Investigated Disease
Anemia in Patients with Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS).

Scientific Title
A Phase 2, Open-Label, Ascending Dose Study of KER-050 for the Treatment of Anemia in Patients with Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS)

Rationale

Not provided

Main Objective

Part 1: Dose Escalation
To evaluate the safety and tolerability of ascending doses of elritercept in participants with very low, low, or intermediate risk MDS in order to determine the dose(s) that will be evaluated in Part 2 of the study.
Part 2: Dose Confirmation
To confirm the safety and tolerability of the dose(s) selected in Part 1. Long-Term Extension To evaluate the long-term safety and tolerability of elritercept in participants with very low, low, or intermediate risk MDS in the Long term Extension (LTE).

Primary Endpoints

Part 1 and Part 2: Safety and tolerability as determined by the incidence of treatment emergent adverse events(TEAEs) and serious adverse events (SAEs).
Long-term Extension: Safety and tolerability as determined by the incidence of TEAEs and SAEs over time

Temporary moments of secondary assessment

Not provided

Secondary Objective

Safety Objective: To evaluate the progression to higher risk MDS or acute myeloid leukemia (AML)
Efficacy Objective: To evaluate the efficacy of elritercept on anemia in participants with very low, low, or intermediate risk MDS, separately for ring sideroblast (RS)- positive and non-RS populations
Pharmacodynamic Objective: To evaluate the pharmacodynamic (PD) effects of elritercept on erythropoiesis in participants with very low, low, or intermediate risk MDS, separately for RS-positive and non-RS populations.

Secondary Endpoints

Incidence of progression to higher risk MDS or AML per World Health Organization (WHO) 2016 criteria.
Proportion of low transfusion burden (LTB) and high transfusion burden (HTB) participants who achieve red blood cell (RBC) transfusion independence (TI) 8 weeks, overall and by RS status.
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Efficacy Endpoint: Mean change from Baseline in Hgb by visit

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Efficacy Endpoint: Duration of HI-E response.
Efficacy Endpoint: Time to TI response.
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Efficacy Endpoint: Proportion of LTB and HTB participants who achieve TI 12 weeks, 16 weeks, 24 weeks, 48 weeks.
Proportion of LTB and HTB participants who achieve TI 12 weeks, 16 weeks, 24 weeks, 48 weeks.
Pharmacodynamic Endpoint: Change from baseline of red cell parameters, including reticulocyte count, mean corpuscular volume, mean corpuscular hemoglobin, and reticulocyte cell Hgb by visit.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Diagnosis of MDS (Parts 1 and 2) according to WHO classification that meets International Prognostic Scoring System-Revised (IPSS-R) classification of very low, low, or intermediate risk disease. < 5% blasts in bone marrow during the Pretreatment Period. Peripheral blood white blood cell (WBC) count < 13,000/L during the Pretreatment Period. Anemia defined as: A). In non-transfused participants, having received no RBC transfusions within 8 weeks, Hgb concentration 10.0 g/dL during the Pretreatment Period OR B).a. In LTB participants, having received 1 to 3 units of RBCs for Hgb 9.0 g/dL within 8 weeks of the Pretreatment Period OR C). In HTB participants, having received 4 units of RBCs for Hgb 9.0 g/dL within 8 weeks of the Pretreatment Period. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 (if related to anemia). Females of child-bearing potential and sexually active males must agree to use highly effective methods of contraception.

Exclusion criteria

Active infection requiring parenteral antibiotic therapy within 28 days prior to C1D1 or oral antibiotics within 14 days of C1D1. Prophylactic antibiotics and/or antifungals for neutropenia are allowed. Treatment history: Prior treatment with azacitidine, decitabine, lenalidomide, luspatercept, or sotatercept. Treatment history: Treatment with ESA within 8 weeks prior to C1D1 (or C5D1 for the Part 1 Extension). Treatment history for part 2: Prior treatment with luspatercept (Cohorts A, B, C, D, E, and F only) Treatment history: Prior or concurrent chronic treatment with granulocyte colony stimulating factor (G-CSF) orgranulocyte-macrophage colony stimulating factor (GM-CSF), for reasons other than the treatment of MDS. Platelet count > 450 x 10*9/L or < 30 x 10*9/L. Transferrin saturation < 15%. Ferritin < 50 g/L. Folate < 4.5 nmol/L (< 2.0 ng/mL). Vitamin B12 < 148 pmol/L (< 200 pg/mL). Estimated glomerular filtration rate (GFR) < 30 mL/min/1.73 m2 (as determined by the Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI]. Pregnant or lactating females. For Cohort G ONLY (for part 2): 1. Any luspatercept related AE Grade 3 that has not resolved to baseline or Grade 1 2. No history of allergy/anaphylaxis/hypersensitivity to luspatercept. 3. No prior treatment with imetelstat. Medical history: Diagnosis of MDS with deletion of chromosome 5q (Del5q). Medical history: Presence of uncontrolled heart disease or New York Heart Association Class III or IV heart failure. Medical history: Presence of uncontrolled hypertension (Grade >/= 2 high blood pressure). Diagnosis of secondary MDS (ie, MDS that is known to have arisen as the result of chemical injury or treatment with chemotherapy and/or radiation for other diseases). Medical history: Any malignancy other than MDS that has not been in remission and/or has required systemictherapy 1 year prior to C1D1 (or C5D1 for the Part 1 Extension). Medical history: History of solid organ or hematological transplantation Medical history: Body mass index >/= 40 kg/m2 during the pretreatment period.

Calendar

(Last Update: 18/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
09/03/2022	25/04/2022	06/05/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
15/07/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (26/10/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

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SEVILLA

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València

VALENCIA

Active (29/09/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medication

elritercept
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

No results