A Phase 3 study to see the benefit and safety of Luspatercept in comparison with Epoetin Alfa to treat anaemia due to very low, low or intermediate risk Myelodysplastic Syndromes (MDS) in people who have not taken erythropoiesis-stimulating agents (ESA's) before and who require red blood cell transfusions.

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	162
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica	NO

Información

Identificador
2022-501485-22-00 (CTIS)

Cod. Protocolo
ACE-536-MDS-002

Transicionado 2017-003190-34

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

Enfermedad investigada
Myelodysplastic syndrome (MDS)

Título Científico

A Phase 3, Open -label, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low or Intermediate Risk Myelodysplastic Syndromes (MDS) in ESA Naïve Subjects Who Require Red Blood Cell Transfusions.

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of luspatercept on red blood cell transfusion independence (RBC-TI; for 12 weeks [84 days] with an associated concurrent mean hemoglobin increase 1.5 g/dL) compared with epoetin alfa for the treatment of anemia due to very low, low, or intermediate risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System -Revised IPSS-R) in erythropoiesis stimulating agent (ESA) naïve subjects who require RBC transfusions.

Variables de Evaluación Primaria

Proportion of subjects who are RBC transfusion-free for any 12-week period associated with a concurrent mean hemoglobin increase 1.5 g/dL compared to baseline

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess the safety and efficacy of luspatercept compared to epoetin alfa To assess health-related quality of life (HRQoL) and anemia outcome measures (ie, the European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire [EORTC QLQ-C30] and the Functional Assessment of Cancer Therapy - Anemia (FACT-An) questionnaire for subjects treated with luspatercept compared to epoetin alfa To evaluate pharmacokinetics for luspatercept in MDS subjects

Variables de Evaluación Secundaria

1. Proportion of subjects who are RBC transfusion-free from Week 1 through Week 24 2. Mean hemoglobin change over the 24-week period of Week 1 through Week 24 compared to baseline 3. Proportion of subjects achieving HI-E over any consecutive 56-day Period
4. Time from first dose to first onset of achieving HI-E 5. Proportion of subjects who are RBC transfusion-free over a consecutive 84-day period 6. Maximum duration of RBC transfusion independence for subjects who achieve RBC-TI 84 days
7. Time from first dose to first onset of transfusion independence 84 days 8. Time from first dose to first transfusion on treatment 9. Total number of RBC units transfused on treatment

10. Proportion of subjects who are RBC transfusion-free over a consecutive 56-day period 11. Proportion of subjects who are RBC transfusion-free for a consecutive 24-week period in the first 48 weeks from first dose 12. Evaluation of EORTC QLQ-C30 score and FACT-An
13. Type, frequency, severity of AEs and relationship of AEs to luspatercept/epoetin alfa 14. A Population PK model that describes the PK exposure data of luspatercept and associated variability. Exposure-response relationship for selected endpoints of efficacy and Safety
15. Frequency of antidrug antibodies and effects on efficacy, or safety, or PK 16. Number and percentage of subjects progressing to AML; time to AML Progression 17. Time from date of randomization to death due to any cause
18. Evaluation of biomarkers that may potentially impact luspatercept efficacy, predict response or relapse, help to better understand MOA and/or provide further prognostic classification of MDS subtypes. Molecular markers (eg, SF3B1) include evaluation of MDSassociated gene mutations and their impact on drug efficacy, clinical response or relapse, drug MOA and prognostication of MDS
19. Evaluation of healthcare resource use (eg, hospitalization) associated with investigational product (IP) during study 20. Description of QUALMS-P and Treatment Satisfaction

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Subject is 18 years of age the time of signing the informed consent form (ICF). 2. Subject must understand and voluntarily sign an ICF prior to any study-related assessments/procedures being conducted. 3. Subject is willing and able to adhere to the study visit schedule and other protocol requirements. 4. Subject has a documented diagnosis of MDS according to WHO 2016 classification that meets IPSS R classification of very low, low, or intermediate risk disease, and < 5% blasts in bone marrow. 5. Subject has an endogenous serum erythropoietin (sEPO) level of < 500 U/L. 6. Subject requires RBC transfusions, as documented by the following criteria: A transfusion requirement of 2 to 6 pRBCs units/8 weeks confirmed for a minimum of 8 weeks immediately preceding randomization. Hemoglobin levels at the time of or within 7 days prior to administration of a RBC transfusion must have been 9.0 g/dL (5.6 mmol/L) with symptoms of anemia (or 7 g/dL [4.3 mmol/L] in the absence of symptoms) in order for the transfusion to be counted towards meeting eligibility criteria. Red blood cell transfusions administered when Hgb levels were > 9.0 g/dL (or > 7 g/dL in the absence of symptoms) and/or RBC transfusions administered for elective surgery, infections or bleeding events will not qualify as a required transfusion for the purpose of meeting eligibility criteria or stratification. The hemoglobin level after the last RBC transfusion prior to randomization must be < 11.0 g/dL (6.8 mmol/L) (centrally or locally analyzed). 7. Subject has Eastern Cooperative Oncology Group (ECOG) score of 0, 1, or 2. 8. Females of childbearing potential (FCBP), defined as a sexually mature woman who: 1) has achieved menarche at some point, 2) not undergone a hysterectomy or bilateral oophorectomy or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy or amenorrhea due to other medical reasons does not rule out childbearing potential) for at least 24 consecutive months (ie, has had menses at any time in the preceding 24 consecutive months), must: Have two negative pregnancy tests as verified by the investigator prior to starting study therapy (unless the screening pregnancy test was done within 72 hours of W1D1). She must agree to ongoing pregnancy testing during the course of the study, and after end of study treatment. Either commit to true abstinence from heterosexual contact (which must be reviewed on a monthly basis and source documented), or agree to use, and be able to comply with, highly effective contraception without interruption, 5 weeks prior to starting investigational product, during the study therapy (including dose interruptions), and for 12 weeks after discontinuation of study therapy. 9. Male subjects must: Practice true abstinence (which must be reviewed prior to each IP administration or on a monthly basis [eg, in the event of dose delays]) or agree to use a condom (latex or non-latex, but not made out of natural [animal] membrane) during sexual contact with a pregnant female or a female of childbearing potential while participating in the study, during dose interruptions and for at least 12 weeks following investigational product discontinuation, even if he has undergone a successful vasectomy.

Criterios de Exclusión

1. Subject with the any of the following prior treatments: Erythropoiesis-stimulating agents (ESAs) Subjects may be randomized at the investigator's discretion contingent on the fact that the subject received no more than 2 doses of epoetin alfa (prior treatment with darbepoetin not acceptable for entry into the study). The last dose of epoetin alfa must be 8 weeks from the date of randomization. A blood sample to determine the endogenous sEPO level (central laboratory) for stratification must be taken within 5 days of randomization unless a prior screening sample analyzed by the central laboratory demonstrated an endogenous sEPO level 500 U/L Granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), within 8 weeks prior to randomization, unless given for treatment of febrile neutropenia Disease modifying agents (eg, immune-modulatory drug [IMiDs such as lenalidomide] Except if the subject received 1 week of treatment with a disease modifying agent 8 weeks from randomization, at the investigator's discretion. Hypomethylating agents Subjects may be randomized at the investigator's discretion contingent that the subject received no more than 2 doses of HMA. The last dose must be 8 weeks from the date of randomization. Luspatercept (ACE-536) or sotatercept (ACE-011) Immunosuppressive therapy for MDS Hematopoietic cell transplant 10. Subject with prior history of malignancies, other than MDS, unless the subject has been free of the disease for 5 years (see details in the Protocol). 11. Subject has history of active SARS-CoV-2 infection within 4 weeks prior to screening, unless the subject has adequately recovered from COVID symptoms and related complications as per investigator's discretion and following a discussion with the Medical Monitor. Use of a live COVID-19 vaccine is prohibited within 4 weeks prior to randomization. Further exclusion criteria are noted in the Protocol. 2. Subject with MDS associated with del(5q) cytogenetic abnormality or MDS unclassifiable (MDS-U) according to WHO 2016 classification. 3. Subject with myelodysplastic/myeloproliferative neoplasms (MDS/MPN) according to WHO 2016 classification (ie, Chronic myelomonocytic leukemia (CMML), Atypical chronic myeloid leukemia (aCML), BCR-ABL12, Juvenile myelomonocytic leukemia (JMML), MDS/MPN unclassifiable. 4. Subject with 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. 5. Subject with known clinically significant anemia due to iron, vitamin B12, or folate deficiencies, or autoimmune or hereditary hemolytic anemia, or hypothyroidism, or any type of known clinically significant bleeding or sequestration. Subject with drug induced anemia (eg, mycophenolate). Iron deficiency to be determined by serum ferritin < 100 µg/L and additional testing if clinically indicated (eg, calculated transferrin saturation [iron/total iron binding capacity 20%] or bone marrow aspirate stain for iron). 6. Subject with known history of diagnosis of AML. 7. Subject receiving any of the following treatment within 8 weeks prior to randomization: Anticancer cytotoxic chemotherapeutic agent or treatment Systemic corticosteroid, except for subjects on a stable or decreasing dose for 1 week prior to randomization for medical conditions other than MDS Iron-chelating agents, except for subjects on a stable or decreasing dose for at least 8 weeks prior to randomization Other RBC hematopoietic growth factors (eg, Interleukin-3) Androgens, unless to treat hypogonadism Hydroxyurea Oral retinoids (except for topical retinoids) Arsenic trioxide Interferon and interleukins Investigational drug or device, or approved therapy for investigational use (if 5 times the half-life of the previous investigational drug exceeds 8 weeks, then the time of exclusion should be extended up to 5 times the half-life of the investigational drug) 8. Subject with uncontrolled hypertension, defined as repeated elevations of systolic blood pressure (SBP) of 150 mmHg and/or diastolic blood pressure (DBP) 100 mmHg despite adequate treatment. 9. Subject with any of the following laboratory abnormalities: Absolute neutrophil count (ANC) < 500/L (0.5 x 10^9/L) Platelet count < 50,000/L (50 x 10^9/L) Estimated glomerular filtration rate (eGFR) < 40 mL/min/1.73 m2 (Appendix F) Serum aspartate aminotransferase/serum glutamic oxaloacetic transaminase (AST/SGOT) or alanine aminotransferase/serum glutamic pyruvic transaminase (ALT/SGPT) 3.0 x upper limit of normal (ULN) Total bilirubin 2.0 x ULN. Higher levels are acceptable if these can be attributed to active red blood cell precursor destruction within the bone marrow (ie, ineffective erythropoiesis) or in the presence of known history of Gilbert Syndrome.

Calendario

(Última actualización: 03/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
06/05/2019	21/05/2019	01/08/2019	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
23/08/2022	No aportado	No aportado	No aportado	No aportado

Promotor

Celgene Corp. United States

Route 206 And Province Line Road

Contact Person

GSM-CT

+3223527611

mg-gsm-ct@bms.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Centros

Activo (19/11/2020)

COMPLEJO ASISTENCIAL SON ESPASES (*)

Palma de Mallorca

BALEARES

Hematología

Cerrado (11/02/2025)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Hematology

Activo (11/06/2019)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE OURENSE

Ourense

OURENSE

Hematology

Cerrado (27/05/2026)

HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA

Valencia

VALENCIA

Hematology

Cerrado (22/02/2023)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN

Madrid

MADRID

Hematología

Cerrado (30/12/2022)

HOSPITAL GENERAL UNIVERSITARIO J.M. MORALES MESEGUER

Murcia

MURCIA

Hematología

Activo (21/05/2019)

HOSPITAL UNIVERSITARI I POLITÈCNIC LA FE

Valencia

VALENCIA

Hematology

Activo (27/08/2019)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Hematology

Activo (02/02/2021)

HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Oviedo

ASTURIAS

Hematology

Activo (29/10/2019)

HOSPITAL UNIVERSITARIO VIRGEN DE LAS NIEVES

Granada

GRANADA

Hematology

Cerrado (14/02/2023)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Hematología y Hemoterapia

Cerrado (17/02/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematología

Activo (29/10/2019)

HOSPITAL VIRGEN DE LA VICTORIA

Málaga

MÁLAGA

Hematology

Cerrado (18/05/2026)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematology

Medicamentos

EPREX 40,000 IU/mL solution for injection in pre-filled syringe.
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: B03XA01 - ERITROPOYETINA
Principios Activos: N/A

Experimental

EPREX 10,000 IU/mL solution for injection in pre-filled syringe.
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: B03XA01 - ERITROPOYETINA
Principios Activos: N/A

Experimental

EPREX 4,000 IU/mL solution for injection in pre-filled syringe.
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: B03XA01 - ERITROPOYETINA
Principios Activos: N/A

Experimental

Reblozyl 25 mg powder for solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS

Código ATC: B03XA06 - LUSPATERCEPT
Principios Activos: N/A

Huérfano Experimental

Reblozyl 75 mg powder for solution for injection
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

Código ATC: B03XA06 - LUSPATERCEPT
Principios Activos: N/A

Huérfano Experimental

Sin resultados

A Phase 3 study to see the benefit and safety of Luspatercept in comparison with Epoetin Alfa to treat anaemia due to very low, low or intermediate risk Myelodysplastic Syndromes (MDS) in people who have not taken erythropoiesis-stimulating agents (ESA's) before and who require red blood cell transfusions.

State	**Type of participants**	**Age Ranges**
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	162
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics	NO

Information

Identifier
2022-501485-22-00 (CTIS)

Protocol Code
ACE-536-MDS-002

Transitioned 2017-003190-34

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

Investigated Disease
Myelodysplastic syndrome (MDS)

Scientific Title

A Phase 3, Open -label, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low or Intermediate Risk Myelodysplastic Syndromes (MDS) in ESA Naïve Subjects Who Require Red Blood Cell Transfusions.

Rationale

Not provided

Main Objective

To evaluate the efficacy of luspatercept on red blood cell transfusion independence (RBC-TI; for 12 weeks [84 days] with an associated concurrent mean hemoglobin increase 1.5 g/dL) compared with epoetin alfa for the treatment of anemia due to very low, low, or intermediate risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System -Revised IPSS-R) in erythropoiesis stimulating agent (ESA) naïve subjects who require RBC transfusions.

Primary Endpoints

Proportion of subjects who are RBC transfusion-free for any 12-week period associated with a concurrent mean hemoglobin increase 1.5 g/dL compared to baseline

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess the safety and efficacy of luspatercept compared to epoetin alfa To assess health-related quality of life (HRQoL) and anemia outcome measures (ie, the European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire [EORTC QLQ-C30] and the Functional Assessment of Cancer Therapy - Anemia (FACT-An) questionnaire for subjects treated with luspatercept compared to epoetin alfa To evaluate pharmacokinetics for luspatercept in MDS subjects

Secondary Endpoints

1. Proportion of subjects who are RBC transfusion-free from Week 1 through Week 24 2. Mean hemoglobin change over the 24-week period of Week 1 through Week 24 compared to baseline 3. Proportion of subjects achieving HI-E over any consecutive 56-day Period
4. Time from first dose to first onset of achieving HI-E 5. Proportion of subjects who are RBC transfusion-free over a consecutive 84-day period 6. Maximum duration of RBC transfusion independence for subjects who achieve RBC-TI 84 days
7. Time from first dose to first onset of transfusion independence 84 days 8. Time from first dose to first transfusion on treatment 9. Total number of RBC units transfused on treatment

10. Proportion of subjects who are RBC transfusion-free over a consecutive 56-day period 11. Proportion of subjects who are RBC transfusion-free for a consecutive 24-week period in the first 48 weeks from first dose 12. Evaluation of EORTC QLQ-C30 score and FACT-An
13. Type, frequency, severity of AEs and relationship of AEs to luspatercept/epoetin alfa 14. A Population PK model that describes the PK exposure data of luspatercept and associated variability. Exposure-response relationship for selected endpoints of efficacy and Safety
15. Frequency of antidrug antibodies and effects on efficacy, or safety, or PK 16. Number and percentage of subjects progressing to AML; time to AML Progression 17. Time from date of randomization to death due to any cause
18. Evaluation of biomarkers that may potentially impact luspatercept efficacy, predict response or relapse, help to better understand MOA and/or provide further prognostic classification of MDS subtypes. Molecular markers (eg, SF3B1) include evaluation of MDSassociated gene mutations and their impact on drug efficacy, clinical response or relapse, drug MOA and prognostication of MDS
19. Evaluation of healthcare resource use (eg, hospitalization) associated with investigational product (IP) during study 20. Description of QUALMS-P and Treatment Satisfaction

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Subject is 18 years of age the time of signing the informed consent form (ICF). 2. Subject must understand and voluntarily sign an ICF prior to any study-related assessments/procedures being conducted. 3. Subject is willing and able to adhere to the study visit schedule and other protocol requirements. 4. Subject has a documented diagnosis of MDS according to WHO 2016 classification that meets IPSS R classification of very low, low, or intermediate risk disease, and < 5% blasts in bone marrow. 5. Subject has an endogenous serum erythropoietin (sEPO) level of < 500 U/L. 6. Subject requires RBC transfusions, as documented by the following criteria: A transfusion requirement of 2 to 6 pRBCs units/8 weeks confirmed for a minimum of 8 weeks immediately preceding randomization. Hemoglobin levels at the time of or within 7 days prior to administration of a RBC transfusion must have been 9.0 g/dL (5.6 mmol/L) with symptoms of anemia (or 7 g/dL [4.3 mmol/L] in the absence of symptoms) in order for the transfusion to be counted towards meeting eligibility criteria. Red blood cell transfusions administered when Hgb levels were > 9.0 g/dL (or > 7 g/dL in the absence of symptoms) and/or RBC transfusions administered for elective surgery, infections or bleeding events will not qualify as a required transfusion for the purpose of meeting eligibility criteria or stratification. The hemoglobin level after the last RBC transfusion prior to randomization must be < 11.0 g/dL (6.8 mmol/L) (centrally or locally analyzed). 7. Subject has Eastern Cooperative Oncology Group (ECOG) score of 0, 1, or 2. 8. Females of childbearing potential (FCBP), defined as a sexually mature woman who: 1) has achieved menarche at some point, 2) not undergone a hysterectomy or bilateral oophorectomy or 3) has not been naturally postmenopausal (amenorrhea following cancer therapy or amenorrhea due to other medical reasons does not rule out childbearing potential) for at least 24 consecutive months (ie, has had menses at any time in the preceding 24 consecutive months), must: Have two negative pregnancy tests as verified by the investigator prior to starting study therapy (unless the screening pregnancy test was done within 72 hours of W1D1). She must agree to ongoing pregnancy testing during the course of the study, and after end of study treatment. Either commit to true abstinence from heterosexual contact (which must be reviewed on a monthly basis and source documented), or agree to use, and be able to comply with, highly effective contraception without interruption, 5 weeks prior to starting investigational product, during the study therapy (including dose interruptions), and for 12 weeks after discontinuation of study therapy. 9. Male subjects must: Practice true abstinence (which must be reviewed prior to each IP administration or on a monthly basis [eg, in the event of dose delays]) or agree to use a condom (latex or non-latex, but not made out of natural [animal] membrane) during sexual contact with a pregnant female or a female of childbearing potential while participating in the study, during dose interruptions and for at least 12 weeks following investigational product discontinuation, even if he has undergone a successful vasectomy.

Exclusion criteria

1. Subject with the any of the following prior treatments: Erythropoiesis-stimulating agents (ESAs) Subjects may be randomized at the investigator's discretion contingent on the fact that the subject received no more than 2 doses of epoetin alfa (prior treatment with darbepoetin not acceptable for entry into the study). The last dose of epoetin alfa must be 8 weeks from the date of randomization. A blood sample to determine the endogenous sEPO level (central laboratory) for stratification must be taken within 5 days of randomization unless a prior screening sample analyzed by the central laboratory demonstrated an endogenous sEPO level 500 U/L Granulocyte colony-stimulating factor (G-CSF), granulocyte macrophage colony-stimulating factor (GM-CSF), within 8 weeks prior to randomization, unless given for treatment of febrile neutropenia Disease modifying agents (eg, immune-modulatory drug [IMiDs such as lenalidomide] Except if the subject received 1 week of treatment with a disease modifying agent 8 weeks from randomization, at the investigator's discretion. Hypomethylating agents Subjects may be randomized at the investigator's discretion contingent that the subject received no more than 2 doses of HMA. The last dose must be 8 weeks from the date of randomization. Luspatercept (ACE-536) or sotatercept (ACE-011) Immunosuppressive therapy for MDS Hematopoietic cell transplant 10. Subject with prior history of malignancies, other than MDS, unless the subject has been free of the disease for 5 years (see details in the Protocol). 11. Subject has history of active SARS-CoV-2 infection within 4 weeks prior to screening, unless the subject has adequately recovered from COVID symptoms and related complications as per investigator's discretion and following a discussion with the Medical Monitor. Use of a live COVID-19 vaccine is prohibited within 4 weeks prior to randomization. Further exclusion criteria are noted in the Protocol. 2. Subject with MDS associated with del(5q) cytogenetic abnormality or MDS unclassifiable (MDS-U) according to WHO 2016 classification. 3. Subject with myelodysplastic/myeloproliferative neoplasms (MDS/MPN) according to WHO 2016 classification (ie, Chronic myelomonocytic leukemia (CMML), Atypical chronic myeloid leukemia (aCML), BCR-ABL12, Juvenile myelomonocytic leukemia (JMML), MDS/MPN unclassifiable. 4. Subject with 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. 5. Subject with known clinically significant anemia due to iron, vitamin B12, or folate deficiencies, or autoimmune or hereditary hemolytic anemia, or hypothyroidism, or any type of known clinically significant bleeding or sequestration. Subject with drug induced anemia (eg, mycophenolate). Iron deficiency to be determined by serum ferritin < 100 µg/L and additional testing if clinically indicated (eg, calculated transferrin saturation [iron/total iron binding capacity 20%] or bone marrow aspirate stain for iron). 6. Subject with known history of diagnosis of AML. 7. Subject receiving any of the following treatment within 8 weeks prior to randomization: Anticancer cytotoxic chemotherapeutic agent or treatment Systemic corticosteroid, except for subjects on a stable or decreasing dose for 1 week prior to randomization for medical conditions other than MDS Iron-chelating agents, except for subjects on a stable or decreasing dose for at least 8 weeks prior to randomization Other RBC hematopoietic growth factors (eg, Interleukin-3) Androgens, unless to treat hypogonadism Hydroxyurea Oral retinoids (except for topical retinoids) Arsenic trioxide Interferon and interleukins Investigational drug or device, or approved therapy for investigational use (if 5 times the half-life of the previous investigational drug exceeds 8 weeks, then the time of exclusion should be extended up to 5 times the half-life of the investigational drug) 8. Subject with uncontrolled hypertension, defined as repeated elevations of systolic blood pressure (SBP) of 150 mmHg and/or diastolic blood pressure (DBP) 100 mmHg despite adequate treatment. 9. Subject with any of the following laboratory abnormalities: Absolute neutrophil count (ANC) < 500/L (0.5 x 10^9/L) Platelet count < 50,000/L (50 x 10^9/L) Estimated glomerular filtration rate (eGFR) < 40 mL/min/1.73 m2 (Appendix F) Serum aspartate aminotransferase/serum glutamic oxaloacetic transaminase (AST/SGOT) or alanine aminotransferase/serum glutamic pyruvic transaminase (ALT/SGPT) 3.0 x upper limit of normal (ULN) Total bilirubin 2.0 x ULN. Higher levels are acceptable if these can be attributed to active red blood cell precursor destruction within the bone marrow (ie, ineffective erythropoiesis) or in the presence of known history of Gilbert Syndrome.

Calendar

(Last Update: 03/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
06/05/2019	21/05/2019	01/08/2019	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
23/08/2022	Not aported	Not aported	Not aported	Not aported

Sponsor

Celgene Corp. United States

Route 206 And Province Line Road

Contact Person

GSM-CT

+3223527611

mg-gsm-ct@bms.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital General Universitario Gregorio Marañón

C/ Doctor Esquerdo, 46 28007 Madrid

ceim.hgugm@salud.madrid.org

915867007

Sites

Active (19/11/2020)

COMPLEJO ASISTENCIAL SON ESPASES (*)

Palma de Mallorca

BALEARES

Hematología

Closed (11/02/2025)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Hematology

Active (11/06/2019)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE OURENSE

Ourense

OURENSE

Hematology

Closed (27/05/2026)

HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA

Valencia

VALENCIA

Hematology

Closed (22/02/2023)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN

Madrid

MADRID

Hematología

Closed (30/12/2022)

HOSPITAL GENERAL UNIVERSITARIO J.M. MORALES MESEGUER

Murcia

MURCIA

Hematología

Active (21/05/2019)

HOSPITAL UNIVERSITARI I POLITÈCNIC LA FE

Valencia

VALENCIA

Hematology

Active (27/08/2019)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Hematology

Active (02/02/2021)

HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Oviedo

ASTURIAS

Hematology

Active (29/10/2019)

HOSPITAL UNIVERSITARIO VIRGEN DE LAS NIEVES

Granada

GRANADA

Hematology

Closed (14/02/2023)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Hematología y Hemoterapia

Closed (17/02/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematología

Active (29/10/2019)

HOSPITAL VIRGEN DE LA VICTORIA

Málaga

MÁLAGA

Hematology

Closed (18/05/2026)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematology

Medication

EPREX 40,000 IU/mL solution for injection in pre-filled syringe.

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

ATC code: B03XA01 - ERITROPOYETINA

Active Principles: N/A

Experimental

EPREX 10,000 IU/mL solution for injection in pre-filled syringe.

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

ATC code: B03XA01 - ERITROPOYETINA

Active Principles: N/A

Experimental

EPREX 4,000 IU/mL solution for injection in pre-filled syringe.

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

ATC code: B03XA01 - ERITROPOYETINA

Active Principles: N/A

Experimental

Reblozyl 25 mg powder for solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS

ATC code: B03XA06 - LUSPATERCEPT

Active Principles: N/A

Orphan

Experimental

Reblozyl 75 mg powder for solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

ATC code: B03XA06 - LUSPATERCEPT

Active Principles: N/A

Orphan

Experimental

No results