A phase 3B, open-label, single-arm, rollover study to evaluate long-term safety of Luspatercept in subjects who have participated in other Luspatercept (ACE-536) clinical trials.

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	154
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Unicéntrico nacional	seguridad	NO

Información

Identificador
2022-502498-40-00 (CTIS)

Cod. Protocolo
ACE-536-LTFU-001

Transicionado 2018-002915-93

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

Enfermedad investigada
myelodysplastic syndrome (MDS); beta ()-thalassemia (THAL); myelofibrosis (MF)

Título Científico
A Phase 3b, open-label, single-arm, rollover study to evaluate long-term safety in subjects who have participated in other luspatercept (ACE-536, also known as BMS 986346) clinical trials.

Justificación

No aportado

Objetivo Principal

To evaluate the long-term safety (including progression to acute myeloid leukemia (AML) and/or other malignancies/pre-malignancies) of luspatercept in subjects who have participated in other luspatercept clinical trials.

Variables de Evaluación Primaria

Adverse events (AEs)
Progression to high/very high-risk myelodysplastic syndrome (MDS)
Progression to Acute myeloid leukemia (AML) (MDS and myelofibrosis [MF] only)
Development of other malignancies/premalignancies

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To follow subjects for overall survival. To evaluate treatment emergent EMH (extramedullary hematopoiesis) masses.

Variables de Evaluación Secundaria

Overall survival
Treatment-emergent EMH masses

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subjects must meet all the following criteria to be enrolled in this study: 1) Subject is 18 years at the time of signing the informed consent form (ICF).
2) Subject is willing and able to adhere to the study visit schedule and other protocol requirements.

3) Subject has been participating in a luspatercept trial and continues to fulfill all the requirements of the parent protocol and the subject has been either: a) Assigned to luspatercept treatment, continues to receive clinical benefit in the opinion of the investigator and should continue to receive luspatercept treatment, OR b) Assigned to placebo arm in the parent protocol (at the time of unblinding or in follow-up) and should cross over to luspatercept treatment, OR c) Assigned to the Follow-up Phase of the parent protocol, previously treated with luspatercept or placebo in the parent protocol who shall continue into Long-term Posttreatment Follow-up Phase in the rollover study until the follow-up commitments are met (unless requirements are met as per parent protocol to cross over to luspatercept treatment).
4) Subject understands and voluntarily signs an informed consent document prior to any studyrelated assessments or procedures being conducted.
5) Subject demonstrates compliance, as assessed by the investigator, with the parent study protocol requirements.
6) Applies to on treatment subjects only- females of childbearing potential (FCBP) defined as a sexually mature woman who: 1) has achieved menarche at some point, 2) has 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) and must: a) Have two negative pregnancy tests as verified by the investigator prior to starting study therapy. A medically supervised serum pregnancy test (conducted locally) is to be obtained and verified negative in all female subjects of childbearing potential at enrollment (for details refer to Section 6.1.7). She must agree to ongoing pregnancy testing during the course of the study, and after end of study therapy. This applies even if the subject practices true abstinence* from heterosexual contact. b) 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, 35 days prior to starting investigational product (IP), during the study therapy (including dose interruptions), and for 84 days after discontinuation of study therapy.
7) Applies to on treatment subjects only- Male subjects must: a) Agree to use a condom 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 84 days following investigational product discontinuation even if he has undergone a successful vasectomy.

Criterios de Exclusión

1) Applies to on treatment subjects only- Concomitant use of any medications/procedures that are prohibited in the parent luspatercept protocol.
2) Subject has met one or more criteria for study discontinuation as stipulated in the parent luspatercept protocol.
3) Applies to on treatment subjects only- More than 26 days between last luspatercept dose in the parent protocol and first dose into ACE-536-LTFU-001 protocol unless dose delay or dose discontinuation criteria met.
4) Applies to on treatment subjects only- Pregnant or breastfeeding females. If breastfeeding, agree to stop breastfeeding prior to the participation in the study and not to resume breastfeeding during treatment with luspatercept and until 3 months after the last dose.
5) Subject has any significant medical condition, laboratory abnormality, psychiatric illness, or is considered vulnerable by local regulations (eg, imprisoned or institutionalized) that would prevent the subject from participating in the study.
6) Subject has any condition including the presence of laboratory abnormalities, which places the subject at unacceptable risk if he/she were to participate in the study.
7) Subject has any condition that confounds the ability to interpret data from the study.

Calendario

(Última actualización: 07/05/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
26/04/2019	17/12/2019	24/01/2020	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
18/03/2020	No aportado	No aportado	19/06/2023	No aportado

Promotor

Celgene Corp. United States

Route 206 And Province Line Road

Contact Person

GSM-CT

003223527611

clinical.trials@bms.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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ceic@iislafe.es

961246605

Centros

Cerrado (05/05/2025)

COMPLEJO ASISTENCIAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Servicio de Hematología

Cerrado (01/12/2022)

COMPLEJO HOSPITALARIO REGIONAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Servicio de Hematología

Cerrado (24/04/2023)

HOSPITAL GENERAL DE ASTURIAS

Oviedo

ASTURIAS

Departamento de Hematologia

Cerrado (19/09/2023)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN

Madrid

MADRID

Servicio de Hematología

Cerrado (14/09/2023)

HOSPITAL UNIVERSITARI I POLITÈCNIC LA FE

Valencia

VALENCIA

Servicio de Hematología

Cerrado (19/01/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematología

Cerrado (09/02/2022)

HOSPITAL UNIVERSITARIO DE CRUCES

Barakaldo

VIZCAYA/BIZKAIA

Servicio de Hematología

Cerrado (17/01/2024)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematologia

Medicamentos

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

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 3B, open-label, single-arm, rollover study to evaluate long-term safety of Luspatercept in subjects who have participated in other Luspatercept (ACE-536) clinical trials.

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	154
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
National One-center	safety	NO

Information

Identifier
2022-502498-40-00 (CTIS)

Protocol Code
ACE-536-LTFU-001

Transitioned 2018-002915-93

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

Investigated Disease
myelodysplastic syndrome (MDS); beta ()-thalassemia (THAL); myelofibrosis (MF)

Scientific Title
A Phase 3b, open-label, single-arm, rollover study to evaluate long-term safety in subjects who have participated in other luspatercept (ACE-536, also known as BMS 986346) clinical trials.

Rationale

Not provided

Main Objective

To evaluate the long-term safety (including progression to acute myeloid leukemia (AML) and/or other malignancies/pre-malignancies) of luspatercept in subjects who have participated in other luspatercept clinical trials.

Primary Endpoints

Adverse events (AEs)
Progression to high/very high-risk myelodysplastic syndrome (MDS)
Progression to Acute myeloid leukemia (AML) (MDS and myelofibrosis [MF] only)
Development of other malignancies/premalignancies

Temporary moments of secondary assessment

Not provided

Secondary Objective

To follow subjects for overall survival. To evaluate treatment emergent EMH (extramedullary hematopoiesis) masses.

Secondary Endpoints

Overall survival
Treatment-emergent EMH masses

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subjects must meet all the following criteria to be enrolled in this study: 1) Subject is 18 years at the time of signing the informed consent form (ICF).
2) Subject is willing and able to adhere to the study visit schedule and other protocol requirements.

3) Subject has been participating in a luspatercept trial and continues to fulfill all the requirements of the parent protocol and the subject has been either: a) Assigned to luspatercept treatment, continues to receive clinical benefit in the opinion of the investigator and should continue to receive luspatercept treatment, OR b) Assigned to placebo arm in the parent protocol (at the time of unblinding or in follow-up) and should cross over to luspatercept treatment, OR c) Assigned to the Follow-up Phase of the parent protocol, previously treated with luspatercept or placebo in the parent protocol who shall continue into Long-term Posttreatment Follow-up Phase in the rollover study until the follow-up commitments are met (unless requirements are met as per parent protocol to cross over to luspatercept treatment).
4) Subject understands and voluntarily signs an informed consent document prior to any studyrelated assessments or procedures being conducted.
5) Subject demonstrates compliance, as assessed by the investigator, with the parent study protocol requirements.
6) Applies to on treatment subjects only- females of childbearing potential (FCBP) defined as a sexually mature woman who: 1) has achieved menarche at some point, 2) has 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) and must: a) Have two negative pregnancy tests as verified by the investigator prior to starting study therapy. A medically supervised serum pregnancy test (conducted locally) is to be obtained and verified negative in all female subjects of childbearing potential at enrollment (for details refer to Section 6.1.7). She must agree to ongoing pregnancy testing during the course of the study, and after end of study therapy. This applies even if the subject practices true abstinence* from heterosexual contact. b) 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, 35 days prior to starting investigational product (IP), during the study therapy (including dose interruptions), and for 84 days after discontinuation of study therapy.
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Exclusion criteria

1) Applies to on treatment subjects only- Concomitant use of any medications/procedures that are prohibited in the parent luspatercept protocol.
2) Subject has met one or more criteria for study discontinuation as stipulated in the parent luspatercept protocol.
3) Applies to on treatment subjects only- More than 26 days between last luspatercept dose in the parent protocol and first dose into ACE-536-LTFU-001 protocol unless dose delay or dose discontinuation criteria met.
4) Applies to on treatment subjects only- Pregnant or breastfeeding females. If breastfeeding, agree to stop breastfeeding prior to the participation in the study and not to resume breastfeeding during treatment with luspatercept and until 3 months after the last dose.
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7) Subject has any condition that confounds the ability to interpret data from the study.

Calendar

(Last Update: 07/05/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
26/04/2019	17/12/2019	24/01/2020	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
18/03/2020	Not aported	Not aported	19/06/2023	Not aported

Sponsor

Celgene Corp. United States

Route 206 And Province Line Road

Contact Person

GSM-CT

003223527611

clinical.trials@bms.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Closed (05/05/2025)

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Salamanca

SALAMANCA

Servicio de Hematología

Closed (01/12/2022)

COMPLEJO HOSPITALARIO REGIONAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Servicio de Hematología

Closed (24/04/2023)

HOSPITAL GENERAL DE ASTURIAS

Oviedo

ASTURIAS

Departamento de Hematologia

Closed (19/09/2023)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN

Madrid

MADRID

Servicio de Hematología

Closed (14/09/2023)

HOSPITAL UNIVERSITARI I POLITÈCNIC LA FE

Valencia

VALENCIA

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Barakaldo

VIZCAYA/BIZKAIA

Servicio de Hematología

Closed (17/01/2024)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematologia

Medication

Reblozyl 25 mg powder for solution for injection

SOLUTION FOR INJECTION

SUBCUTANEOUS USE

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