Open Label 2-Arm Study of Venetoclax in Combination with Azacitidine Versus Best Supportive Care after Allogeneic Stem Cell Transplantation in Subjects with Acute Myeloid Leukemia (AML)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	304
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Tiene resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador

2023-507222-17-00 (CTIS)

Cod. Protocolo

M19-063

Transicionado 2019-002621-30

Área terapéutica

Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada

Acute Myeloid Leukaemia

Título Científico

A Randomized, Open Label Phase 3 Study Evaluating Safety and Efficacy of Venetoclax in combination with Azacitidine after allogeneic Stem Cell Transplantation in Subjects with Acute Myeloid Leukemia (AML) (VIALE-T)

Justificación

No aportado

Objetivo Principal

Part I: To determine the recommended Phase 3 dose of venetoclax in combination with azacitidine in AML patients when given as maintenance therapy following allogeneic SCT.
Part II:To evaluate the efficacy of venetoclax in combination with azacitidine to improve OS in AML patients compared to BSC when given as maintenance therapy following allogeneic SCT.

Variables de Evaluación Primaria

Part I: The primary endpoint is the frequency of DLTs of venetoclax in combination with azacitidine
Part II: OS defined as the time from randomization to death from any cause

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 2: To confirm the safety of venetoclax in combination with azacitidine after allogeneic SCT in subjects diagnosed with AML.
To determine the efficacy of venetoclax in combination with azacitidine as measured by RFS.
To determine the effect of venetoclax in combination with azacitidine on the frequency and severity of GvHD.
To determine the effect of venetoclax in combination with azacitidine on Quality of Life (QoL).
To determine the effect of venetoclax in combination with azacitidine on minimal residual disease levels.

Variables de Evaluación Secundaria

IRC-assessed morphologic RFS IRC-assessed composite relapse-free survival GvHD-free, relapse free survival (GRFS) GvHD rate at 90 days after randomization (Arm B) or initiation of treatment (Arm A). "Higher grade GvHD" is defined as Grade 2 or higher for aGvHD and moderate or severe for cGvHD as defined by the investigator following National Institutes of Health (NIH) criteria. Change from baseline (Cycle 1 Day 1 [predose]) at 6 months in physical functioning after randomization (Arm B) or initiation of study treatment (Arm A) in adult subjects, as measured by the EORTC QLQ-C30 physical functioning domain Fatigue Change from baseline at 6 months after randomization (Arm B) or initiation of study treatment (Arm A) in adult subjects defined as Fatigue measured as Patient Reported Outcome (PRO) using Patient Reported Outcomes Measurement Information System (PROMIS) Cancer Fatigue SF 7a Measurable residual disease conversion rate The rate will be calculated only among subjects with MRD 103 at baseline (Cycle 1 Day 1 [predose]). The MRD conversion rate will be defined as proportion of subjects who convert to MRD < 103 after randomization (Arm B) or initiation of treatment (Arm A) Time to deterioration in Global Health Status (GHS)/QoL in adult subjects - defined as time from randomization to death from any cause, or the first-time deterioration of 10 points from baseline (Cycle 1 Day 1 [predose]) in GHS/QoL score as measured by the European

Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Version 3, whichever occurs first

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Adult male or female 18 years old for Part 1 and, male or female at least 12 years old for Part 2. (Notes a - b): a) C1D1 must occur within 28 to 100 days of this subsequent transplant date. b) If there is a subsequent (second) graft failure after reconsent during the registration period, the subject will not be permitted to enroll into the study. No known active severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Subject must be diagnosed with AML by World Health Organization (WHO) criteria (2017) and either be planning for allogeneic stem cell transplantation or have received allogeneic stem cell transplantation within the past 60 days. Blast percentage in bone marrow prior to pre-transplant conditioning must be < 10%. Blast count in peripheral blood must be "0" and malignant Blast percentage in bone marrow must be < 5% after transplant within 7 days prior to Cycle 1 Day 1. Bilirubin 3 × ULN* within 7 days prior to Cycle 1 Day 1. For Part 1: ANC 1,500/µL, measured twice at least 2 days apart (approximately 48 hours) and within 1 week prior to Cycle 1 Day 1. Subjects should not have granulocyte-colony stimulating factor (G-CSF) treatment for 7 days before first ANC count. For Part 2: ANC 1,000/µL, measured twice at least 2 days apart (approximately 48 hours) and within 1 week prior to Cycle 1 Day 1 or prior to dosing on Cycle 1 Day 1. Subjects should not have granulocyte- colony stimulating factor (G-CSF) treatment for 7 days before first ANC count. Part 1: Platelet count 80,000/µL measured twice at least 2 days apart (approximately 48 hours) and within 1 week prior to Cycle 1 Day 1. Subjects should not have supportive treatment (e.g., transfusions and/or growth factors) for 7 days before first platelet count. Part 2: Platelet count 50,000/µL measured twice at least 2 days apart (approximately 48 hours) and within 1 week prior to Cycle 1 Day 1 or prior to dosing on Cycle 1 Day 1. Subjects should not have supportive treatment (e.g., transfusions and/or growth factors) for 7 days before first platelet count. Adequate renal function as demonstrated by a creatinine clearance > 30 mL/min; calculated by the Cockcroft Gault formula or measured by 24- hour urine collection. Subjects 17 years old must have a Karnofsky Performance Scale (KPS) score > 50 and Subjects 12 to 16 years old must have a Lansky Play- Performance Scale (LPPS) score > 40. Part 2: If a subject is 12 to 16 at the time of screening and turns 17 during the study, the subject will continue with the LPPS. Cycle 1 Day 1 administration of 1st dose of the study drug(s) must occur within 28 to 100 days after transplant. Subjects may enter into Screening upon the first instance of meeting the count recovery criteria without the need for supportive care (e.g., growth factors and/or platelet transfusions) for at least 7 days prior. Upon entering screening, subjects must maintain count thresholds on at least 2 occasions (approximately 48 hours apart) in the absence of supportive care (platelet transfusion/G-CSF within 7 days). If graft failure occurs during the registration period and a subsequent transplant is planned, the subject can be reconsented for the study.

Criterios de Exclusión

Subjects with favorable cytogenetic risk per NCCN 2016 criteria and in first complete remission prior to transplant are not eligible to enroll in this study.
History of disease progression during prior treatment with venetoclax.
History of any other malignancy within 2 years prior to study entry, except for: Adequately treated in situ carcinoma of the cervix uteri or carcinoma in situ of breast; Basal cell carcinoma of the skin or localized squamous cell carcinoma of the skin; Previous malignancy confined and surgically resected (or treated with other modalities) with curative intent; Myelodysplastic Syndrome; Myeloproliferative neoplasm (only allowed if it transformed to AML and AML should be the indication for marrow transplantation).
Known infection with HIV or subjects with active hepatitis B virus (HBV) or hepatitis C virus (HCV) with high viral

titers.
Presence of clinical or laboratory symptoms/signs of extramedullary myeloid malignancy.

Calendario

(Última actualización: 28/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
13/04/2020	24/07/2020	03/09/2020	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
29/01/2024	No aportado	No aportado	No aportado	23/09/2025

Promotor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinical Trials Helpdesk

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global-clinical-trials@abbvie.com

Monetary support: N/A

Tipo de promotor: Comercial

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CEIm Provincial de Sevilla

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Centros

Cerrado (26/03/2026)

COMPLEJO UNIVERSITARIO LA PAZ

Madrid

MADRID

N/A

Cerrado (17/07/2026)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

N/A

Cerrado (24/02/2026)

HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA

Valencia

VALENCIA

N/A

Cerrado (30/03/2026)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

N/A

Activo (13/05/2022)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN

Madrid

MADRID

N/A

Cerrado (02/03/2026)

HOSPITAL RAMÓN Y CAJAL

Madrid

MADRID

N/A

Cerrado (04/03/2026)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

N/A

Medicamentos

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

AZACITIDINE
POWDER FOR SUSPENSION FOR INJECTION
INTRAVENOUS (IV) OR SUBCUTANEOUS (SC)

-
Principios Activos: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

Tiene resultados

Open Label 2-Arm Study of Venetoclax in Combination with Azacitidine Versus Best Supportive Care after Allogeneic Stem Cell Transplantation in Subjects with Acute Myeloid Leukemia (AML)

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years) , Teens (12-17 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	304
Results	**Low level of intervention**	**Rare disease**
Has results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2023-507222-17-00 (CTIS)

Protocol Code
M19-063

Transitioned 2019-002621-30

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Acute Myeloid Leukaemia

Scientific Title
A Randomized, Open Label Phase 3 Study Evaluating Safety and Efficacy of Venetoclax in combination with Azacitidine after allogeneic Stem Cell Transplantation in Subjects with Acute Myeloid Leukemia (AML) (VIALE-T)

Rationale

Not provided

Main Objective

Part I: To determine the recommended Phase 3 dose of venetoclax in combination with azacitidine in AML patients when given as maintenance therapy following allogeneic SCT.
Part II:To evaluate the efficacy of venetoclax in combination with azacitidine to improve OS in AML patients compared to BSC when given as maintenance therapy following allogeneic SCT.

Primary Endpoints

Part I: The primary endpoint is the frequency of DLTs of venetoclax in combination with azacitidine
Part II: OS defined as the time from randomization to death from any cause

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 2: To confirm the safety of venetoclax in combination with azacitidine after allogeneic SCT in subjects diagnosed with AML.
To determine the efficacy of venetoclax in combination with azacitidine as measured by RFS.
To determine the effect of venetoclax in combination with azacitidine on the frequency and severity of GvHD.
To determine the effect of venetoclax in combination with azacitidine on Quality of Life (QoL).
To determine the effect of venetoclax in combination with azacitidine on minimal residual disease levels.

Secondary Endpoints

IRC-assessed morphologic RFS IRC-assessed composite relapse-free survival GvHD-free, relapse free survival (GRFS) GvHD rate at 90 days after randomization (Arm B) or initiation of treatment (Arm A). "Higher grade GvHD" is defined as Grade 2 or higher for aGvHD and moderate or severe for cGvHD as defined by the investigator following National Institutes of Health (NIH) criteria. Change from baseline (Cycle 1 Day 1 [predose]) at 6 months in physical functioning after randomization (Arm B) or initiation of study treatment (Arm A) in adult subjects, as measured by the EORTC QLQ-C30 physical functioning domain Fatigue Change from baseline at 6 months after randomization (Arm B) or initiation of study treatment (Arm A) in adult subjects defined as Fatigue measured as Patient Reported Outcome (PRO) using Patient Reported Outcomes Measurement Information System (PROMIS) Cancer Fatigue SF 7a Measurable residual disease conversion rate The rate will be calculated only among subjects with MRD 103 at baseline (Cycle 1 Day 1 [predose]). The MRD conversion rate will be defined as proportion of subjects who convert to MRD < 103 after randomization (Arm B) or initiation of treatment (Arm A) Time to deterioration in Global Health Status (GHS)/QoL in adult subjects - defined as time from randomization to death from any cause, or the first-time deterioration of 10 points from baseline (Cycle 1 Day 1 [predose]) in GHS/QoL score as measured by the European

Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) Version 3, whichever occurs first

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Adult male or female 18 years old for Part 1 and, male or female at least 12 years old for Part 2. (Notes a - b): a) C1D1 must occur within 28 to 100 days of this subsequent transplant date. b) If there is a subsequent (second) graft failure after reconsent during the registration period, the subject will not be permitted to enroll into the study. No known active severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Subject must be diagnosed with AML by World Health Organization (WHO) criteria (2017) and either be planning for allogeneic stem cell transplantation or have received allogeneic stem cell transplantation within the past 60 days. Blast percentage in bone marrow prior to pre-transplant conditioning must be < 10%. Blast count in peripheral blood must be "0" and malignant Blast percentage in bone marrow must be < 5% after transplant within 7 days prior to Cycle 1 Day 1. Bilirubin 3 × ULN* within 7 days prior to Cycle 1 Day 1. For Part 1: ANC 1,500/µL, measured twice at least 2 days apart (approximately 48 hours) and within 1 week prior to Cycle 1 Day 1. Subjects should not have granulocyte-colony stimulating factor (G-CSF) treatment for 7 days before first ANC count. For Part 2: ANC 1,000/µL, measured twice at least 2 days apart (approximately 48 hours) and within 1 week prior to Cycle 1 Day 1 or prior to dosing on Cycle 1 Day 1. Subjects should not have granulocyte- colony stimulating factor (G-CSF) treatment for 7 days before first ANC count. Part 1: Platelet count 80,000/µL measured twice at least 2 days apart (approximately 48 hours) and within 1 week prior to Cycle 1 Day 1. Subjects should not have supportive treatment (e.g., transfusions and/or growth factors) for 7 days before first platelet count. Part 2: Platelet count 50,000/µL measured twice at least 2 days apart (approximately 48 hours) and within 1 week prior to Cycle 1 Day 1 or prior to dosing on Cycle 1 Day 1. Subjects should not have supportive treatment (e.g., transfusions and/or growth factors) for 7 days before first platelet count. Adequate renal function as demonstrated by a creatinine clearance > 30 mL/min; calculated by the Cockcroft Gault formula or measured by 24- hour urine collection. Subjects 17 years old must have a Karnofsky Performance Scale (KPS) score > 50 and Subjects 12 to 16 years old must have a Lansky Play- Performance Scale (LPPS) score > 40. Part 2: If a subject is 12 to 16 at the time of screening and turns 17 during the study, the subject will continue with the LPPS. Cycle 1 Day 1 administration of 1st dose of the study drug(s) must occur within 28 to 100 days after transplant. Subjects may enter into Screening upon the first instance of meeting the count recovery criteria without the need for supportive care (e.g., growth factors and/or platelet transfusions) for at least 7 days prior. Upon entering screening, subjects must maintain count thresholds on at least 2 occasions (approximately 48 hours apart) in the absence of supportive care (platelet transfusion/G-CSF within 7 days). If graft failure occurs during the registration period and a subsequent transplant is planned, the subject can be reconsented for the study.

Exclusion criteria

Subjects with favorable cytogenetic risk per NCCN 2016 criteria and in first complete remission prior to transplant are not eligible to enroll in this study.
History of disease progression during prior treatment with venetoclax.
History of any other malignancy within 2 years prior to study entry, except for: Adequately treated in situ carcinoma of the cervix uteri or carcinoma in situ of breast; Basal cell carcinoma of the skin or localized squamous cell carcinoma of the skin; Previous malignancy confined and surgically resected (or treated with other modalities) with curative intent; Myelodysplastic Syndrome; Myeloproliferative neoplasm (only allowed if it transformed to AML and AML should be the indication for marrow transplantation).
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titers.
Presence of clinical or laboratory symptoms/signs of extramedullary myeloid malignancy.

Calendar

(Last Update: 28/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
13/04/2020	24/07/2020	03/09/2020	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
29/01/2024	Not aported	Not aported	Not aported	23/09/2025

Sponsor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Closed (26/03/2026)

COMPLEJO UNIVERSITARIO LA PAZ

Madrid

MADRID

N/A

Closed (17/07/2026)

HOSPITAL CLÍNIC DE BARCELONA

Barcelona

BARCELONA

N/A

Closed (24/02/2026)

HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA

Valencia

VALENCIA

N/A

Closed (30/03/2026)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

N/A

Active (13/05/2022)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN

Madrid

MADRID

N/A

Closed (02/03/2026)

HOSPITAL RAMÓN Y CAJAL

Madrid

MADRID

N/A

Closed (04/03/2026)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO

Sevilla

SEVILLA

N/A

Medication

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

AZACITIDINE
POWDER FOR SUSPENSION FOR INJECTION
INTRAVENOUS (IV) OR SUBCUTANEOUS (SC)

-
Active Principles: N/A
Experimental

Venetoclax
FILM-COATED TABLET
ORAL USE

-
Active Principles: N/A
Experimental

Has results