A Phase 3, Multicenter, Randomized, Open Label Study of Venetoclax and Dexamethasone Compared with Pomalidomide and Dexamethasone in Subjects with t(11;14)-Positive Relapsed or Refractory Multiple Myeloma

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	171
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética, farmacodinamica, dosis, farmacogenética	NO

Información

Identificador
2023-506112-40-00 (CTIS)

Cod. Protocolo
M13-494

Transicionado 2017-003838-88

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
R/R Multiple Myeloma

Título Científico
A Phase 3, Multicenter, Randomized, Open Label Study of Venetoclax and Dexamethasone Compared with Pomalidomide and Dexamethasone in Subjects with t(11;14)-Positive Relapsed or Refractory Multiple Myeloma

Justificación

No aportado

Objetivo Principal

To compare progression-free survival (PFS) in subjects with t(11;14)-positive MM treated with venetoclax in combination with dexamethasone versus pomalidomide in combination with dexamethasone.

Variables de Evaluación Primaria

The primary efficacy endpoint is progression-free survival (PFS) per Independent Review Committee (IRC) based on IMWG criteria. PFS is defined as the time in days from subject randomization to the date of the first documented progressive disease (PD) or death due to any cause, whichever occurs first.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

The secondary objectives are to compare, between treatment arms (where applicable), the following: overall response rate (ORR); rate of very good partial response (VGPR) or better per International Myeloma Working Group (IMWG) criteria (see Appendix D); overall survival (OS); minimal residual disease (MRD) negativity rate; patient reported outcomes (PROs) evaluated using Patient Reported Outcomes Measurement Information System (PROMIS) Fatigue Short Form (SF) 7a, Brief Pain Inventory Short Form (BPI-SF), European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) MM Module20 (EORTC QLQ-MY20), and EORTC QLQ Core 30 (EORTC QLQC30); duration of response (DOR); time to disease progression (TTP); time to response (TTR); pharmacokinetics (PK) of venetoclax; and safety.

Variables de Evaluación Secundaria

Overall response rate (ORR) per the independent review committee (IRC)
Rate of very good partial response (VGPR) or better per the IRC
Overall survival (OS)
Minimal residual disease (MRD) negativity rate
Time to deterioration in disease symptoms as measured by the disease symptom domain of the EORTC QLQ-MY20
Time to deterioration in physical functioning as measured by the physical functioning domain of EORTC QLQ-C30
Other Patient reported outcomes (PROs) assessed using Patient Reported Outcomes Measurement Information System (PROMIS) Fatigue Short Form 7a, Brief Pain Inventory Short Form [(BPI-SF]), EuroQoL 5 Dimension 5 Level (EQ5D5L) and remaining domains of EORTC QLQ-MY20, and EORTC QLQ-C30 survey instruments
Duration of response (DOR)
Time to disease progression (TTP)
Time to response (TTR)

Pharmacokinetics of venetoclax
Safety

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subjects must voluntarily sign and date an informed consent, approved by an Independent Ethics Committee (IEC)/Institutional Review Board (IRB), prior to the initiation of any screening or study-specific procedures. Subjects should have laboratory values meeting the following criteria within the screening period prior to the first dose of study drug: Absolute neutrophil count (ANC) 1000/L; subject may use growth factor support to achieve ANC eligibility criteria; Platelets: 50,000/mm3. For subjects with > 50% myeloma involvement in the marrow, a platelet count of 30,000 mm3. Subjects may not have received a platelet transfusion within 72 hours prior to the platelet count used for eligibility; Hemoglobin 8.0 g/dL; subject may receive red blood cell (RBC) transfusions in accordance with institutional guidelines to meet this criteria; AST and ALT 3 × upper limit of normal (ULN); Total bilirubin 1.5 x ULN (subjects with documented Gilbert's syndrome, may have bilirubin > 1.5 × ULN); Creatinine clearance 30 mL/min, measured by 24-hour urine collection or calculated using the Cockcroft-Gault formula); Serum calcium corrected for albumin 14.0 mg/dL (3.5 mmol/L) or ionized calcium (6.5mg/dL (1.6mmol/L). Subjects should be willing or able to comply with procedures required in this protocol. Subjects should be willing and able to receive antithrombotic prophylactic treatment. Documented diagnosis of multiple myeloma based on standard IMWG criteria. Subject has an ECOG performance status 2 Subject has documented disease progression on or within 60 days of completion of their last therapy. Subject has received at least 2 prior lines of therapy. A line of therapy consists of at least 1 complete cycle of a single agent, a regimen consisting of a combination of several drugs, or a planned sequential therapy of various regimens. Subjects must not be incarcerated and must be freely willing and able to provide informed consent (e.g., adults under legal protection measure [e.g., under guardianship/curatorship] or unable to express their consent and select adults under psychiatric care). Investigator's discretion should be applied. Subject must have received at least 2 consecutive cycles of lenalidomide and be relapsed/refractory to lenalidomide as defined by one of the following: Subject experienced PD on or within 60 days of completing treatment. Subject exhibited PR or better but relapsed within 6 months after stopping treatment. Subject must have received at least 2 consecutive cycles of a proteasome inhibitor (bortezomib, carfilzomib or ixazomib). Subject has measurable disease at Screening, defined by at least 1 of the following: Serum M-protein 0.5 g/dL (5 g/L); OR Urine M-protein 200 mg/24 hours; OR Involved serum immunoglobulin free light chain (FLC) 10 mg/dL (100 mg/L), provided serum FLC ratio is abnormal Subject has MM positive for t(11;14) as determined by an analytically validated FISH assay per centralized laboratory testing. A negative serum pregnancy test for all female subjects (except those of non-childbearing potential) within 10 to 14 days prior to initiating therapy and a negative urine pregnancy test within 24 hours for all female subjects (except those of non-childbearing potential) at baseline prior to the first dose of study drug. If female, subject must be either postmenopausal, OR permanently surgically sterile OR for women of childbearing potential practicing at least 2 protocol-specified methods of birth control that are effective from at least 30 days before starting study drugs through at least 30 days after the last dose of any study drug. If male, and subject is sexually active with female partner(s) of childbearing potential, he must agree, from Study Day 1 through 30 days after the last dose of study drug, to practice the protocol-specified contraception. Adult male or female subjects 18 years old.

Criterios de Exclusión

Subject has history of treatment with venetoclax or another BCL-2 inhibitor or pomalidomide. Female who is pregnant, breastfeeding, or considering becoming pregnant during the study and for at least 30 days after the last dose of study drug. Male who is considering fathering a child or donating sperm and/or semen during the study and

for at least 30 days after the last dose of study drug. Subject who have been treated with any systemic anti-myeloma therapies within 5 half-lives or 2 weeks prior to randomization, whichever is longer (or 2 weeks if half-life unknown), and through the last dose of any study drug. Subject who have been treated with anti-myeloma radiotherapy within 2 weeks prior to randomization. Subject who have received corticosteroid therapy at a dose equivalent to > 4 mg daily of dexamethasone or a single dose of corticosteroid equivalent dose > 40 mg of dexamethasone within 2 weeks prior to randomization. Subject who have used systemic strong or moderate inhibitor or inducer of cytochrome P450 (CYP) 3A within 1 week prior to the first dose of study drugs. Subject who have used systemic strong inhibitor of CYP1A2 within 1 week prior to first dose. Subject who have consumed grapefruit, grapefruit products, Seville oranges (including marmalade containing Seville oranges), or starfruit within 3 days prior to first dose. Subject who anticipate the use of prohibited medications or foods during study participation. Subject has a history of other active malignancies, including myelodysplastic syndromes (MDS), within the past 3 years with the following exceptions: Adequately treated in situ carcinoma of the cervix uteri or the breast; Basal cell carcinoma of the skin or localized squamous cell carcinoma of the skin; Prostate cancer Gleason grade 6 or lower AND with stable Prostate Specific Antigen (PSA) levels off treatment; or Previous malignancy with no current evidence of disease, and which was confined and surgically resected (or treated with other modalities) with curative intent and unlikely to impact survival during the duration of the study. Subject has evidence of ongoing graft-versus-host disease (GvHD) if prior stem cell transplant (SCT). Subject must not have received any live vaccines within 8 weeks prior to randomization Subject has had prior treatment with the following: Allogeneic or syngeneic SCT within 16 weeks prior to randomization; or Autologous SCT within 12 weeks prior to randomization Subject has known central nervous system involvement of multiple myeloma. Subject has a history of clinically significant renal, neurologic, psychiatric, endocrinologic, metabolic, immunologic, cardiovascular, pulmonary or hepatic disease within the last 6 months that, in the opinion of the investigator, would adversely affect participation in this study. Subject has a history of known allergies, hypersensitivities, or intolerance to any of the study drug or excipients, or thalidomide derivatives. Subject has the following conditions: Nonsecretory multiple myeloma; Active plasma cell leukemia i.e., either 20% of peripheral white blood cells or > 2.0 × 109/L circulating plasma cells by standard differential; Waldenström's macroglobulinemia; Primary amyloidosis; POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes); Known human immunodeficiency virus (HIV) infection; Active hepatitis B (hepatitis B surface antigen [HBsAg] positive) or C infection based on screening central laboratory blood testing at screening; Significant cardiovascular disease, including uncontrolled angina, arrhythmia, recent myocardial infarction within 6 months prior to first dose, congestive heart failure NYHA Class 3; Major surgery within 4 weeks prior to first dose or planned during study participation; Acute infections within 14 days prior to first dose requiring therapy (antibiotic, antifungal, or antiviral); Uncontrolled diabetes or hypertension within 14 days prior to first dose; or Peripheral neuropathy Grade 3 or Grade 2 with pain within 2 weeks prior to first dose.

Calendario

(Última actualización: 06/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
04/10/2018	28/12/2018	03/01/2019	06/02/2019	20/08/2019

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
17/06/2022	No aportado	No aportado	03/07/2025	No aportado

Promotor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinical Trials Helpdesk

4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Centros

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

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

N/A

Cerrado (07/06/2023)

COMPLEJO UNIVERSITARIO LA PAZ

Madrid

MADRID

Cerrado (17/12/2025)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE OURENSE

Ourense

OURENSE

Servicio de Hematología

Cerrado (07/05/2024)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

Scio. de Hematología

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

Hospital Costa Del Sol

Marbella

MÁLAGA

N/A

Cerrado (21/09/2022)

HOSPITAL DE LEON COMPLEJO ASISTENCIAL UNIVERSITARIO DE LEON

León

LEÓN

Scio. de Hematología

Cerrado (03/07/2023)

HOSPITAL UNIVERSITARI SON ESPASES

Palma de Mallorca

BALEARES

Servicio de Hematología

Cerrado (29/11/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Cerrado (26/07/2022)

HOSPITAL UNIVERSITARIO DE CANARIAS

San Cristóbal de La Laguna

STA. CRUZ DE TENERIFE

Scio. de Hematología

Cerrado (15/12/2025)

HOSPITAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Scio. de Hematología

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

Hospital Universitario De Toledo

Toledo

TOLEDO

Servicio de Hematologia

Cerrado (19/01/2026)

HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ

Madrid

MADRID

Start FJD - Scio. de Hematología

Cerrado (24/11/2022)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Scio. de Hematología

Cerrado (22/04/2024)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Scio. de Hematología

Cerrado (28/10/2025)

HOSPITAL VIRGEN DE LA SALUD

Toledo

TOLEDO

Servicio de Hematología

Cerrado (12/11/2025)

HOSPITAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Scio. de Hematología y Hemoterapia

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

Institut Catala D'oncologia

Girona

GERONA

N/A

Cerrado (01/07/2026)

Institut Catala D'oncologia

Girona

GERONA

ICO Girona - Scio. de Hematología

Medicamentos

Venetoclax
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Huérfano Experimental

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Huérfano Experimental

-
-
ORAL

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

Sin resultados

A Phase 3, Multicenter, Randomized, Open Label Study of Venetoclax and Dexamethasone Compared with Pomalidomide and Dexamethasone in Subjects with t(11;14)-Positive Relapsed or Refractory Multiple Myeloma

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	171
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics, pharmacodynamics, dose, pharmacogenetics	NO

Information

Identifier
2023-506112-40-00 (CTIS)

Protocol Code
M13-494

Transitioned 2017-003838-88

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

Investigated Disease
R/R Multiple Myeloma

Scientific Title
A Phase 3, Multicenter, Randomized, Open Label Study of Venetoclax and Dexamethasone Compared with Pomalidomide and Dexamethasone in Subjects with t(11;14)-Positive Relapsed or Refractory Multiple Myeloma

Rationale

Not provided

Main Objective

To compare progression-free survival (PFS) in subjects with t(11;14)-positive MM treated with venetoclax in combination with dexamethasone versus pomalidomide in combination with dexamethasone.

Primary Endpoints

The primary efficacy endpoint is progression-free survival (PFS) per Independent Review Committee (IRC) based on IMWG criteria. PFS is defined as the time in days from subject randomization to the date of the first documented progressive disease (PD) or death due to any cause, whichever occurs first.

Temporary moments of secondary assessment

Not provided

Secondary Objective

The secondary objectives are to compare, between treatment arms (where applicable), the following: overall response rate (ORR); rate of very good partial response (VGPR) or better per International Myeloma Working Group (IMWG) criteria (see Appendix D); overall survival (OS); minimal residual disease (MRD) negativity rate; patient reported outcomes (PROs) evaluated using Patient Reported Outcomes Measurement Information System (PROMIS) Fatigue Short Form (SF) 7a, Brief Pain Inventory Short Form (BPI-SF), European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ) MM Module20 (EORTC QLQ-MY20), and EORTC QLQ Core 30 (EORTC QLQC30); duration of response (DOR); time to disease progression (TTP); time to response (TTR); pharmacokinetics (PK) of venetoclax; and safety.

Secondary Endpoints

Overall response rate (ORR) per the independent review committee (IRC)
Rate of very good partial response (VGPR) or better per the IRC
Overall survival (OS)
Minimal residual disease (MRD) negativity rate
Time to deterioration in disease symptoms as measured by the disease symptom domain of the EORTC QLQ-MY20
Time to deterioration in physical functioning as measured by the physical functioning domain of EORTC QLQ-C30
Other Patient reported outcomes (PROs) assessed using Patient Reported Outcomes Measurement Information System (PROMIS) Fatigue Short Form 7a, Brief Pain Inventory Short Form [(BPI-SF]), EuroQoL 5 Dimension 5 Level (EQ5D5L) and remaining domains of EORTC QLQ-MY20, and EORTC QLQ-C30 survey instruments
Duration of response (DOR)
Time to disease progression (TTP)
Time to response (TTR)

Pharmacokinetics of venetoclax
Safety

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subjects must voluntarily sign and date an informed consent, approved by an Independent Ethics Committee (IEC)/Institutional Review Board (IRB), prior to the initiation of any screening or study-specific procedures. Subjects should have laboratory values meeting the following criteria within the screening period prior to the first dose of study drug: Absolute neutrophil count (ANC) 1000/L; subject may use growth factor support to achieve ANC eligibility criteria; Platelets: 50,000/mm3. For subjects with > 50% myeloma involvement in the marrow, a platelet count of 30,000 mm3. Subjects may not have received a platelet transfusion within 72 hours prior to the platelet count used for eligibility; Hemoglobin 8.0 g/dL; subject may receive red blood cell (RBC) transfusions in accordance with institutional guidelines to meet this criteria; AST and ALT 3 × upper limit of normal (ULN); Total bilirubin 1.5 x ULN (subjects with documented Gilbert's syndrome, may have bilirubin > 1.5 × ULN); Creatinine clearance 30 mL/min, measured by 24-hour urine collection or calculated using the Cockcroft-Gault formula); Serum calcium corrected for albumin 14.0 mg/dL (3.5 mmol/L) or ionized calcium (6.5mg/dL (1.6mmol/L). Subjects should be willing or able to comply with procedures required in this protocol. Subjects should be willing and able to receive antithrombotic prophylactic treatment. Documented diagnosis of multiple myeloma based on standard IMWG criteria. Subject has an ECOG performance status 2 Subject has documented disease progression on or within 60 days of completion of their last therapy. Subject has received at least 2 prior lines of therapy. A line of therapy consists of at least 1 complete cycle of a single agent, a regimen consisting of a combination of several drugs, or a planned sequential therapy of various regimens. Subjects must not be incarcerated and must be freely willing and able to provide informed consent (e.g., adults under legal protection measure [e.g., under guardianship/curatorship] or unable to express their consent and select adults under psychiatric care). Investigator's discretion should be applied. Subject must have received at least 2 consecutive cycles of lenalidomide and be relapsed/refractory to lenalidomide as defined by one of the following: Subject experienced PD on or within 60 days of completing treatment. Subject exhibited PR or better but relapsed within 6 months after stopping treatment. Subject must have received at least 2 consecutive cycles of a proteasome inhibitor (bortezomib, carfilzomib or ixazomib). Subject has measurable disease at Screening, defined by at least 1 of the following: Serum M-protein 0.5 g/dL (5 g/L); OR Urine M-protein 200 mg/24 hours; OR Involved serum immunoglobulin free light chain (FLC) 10 mg/dL (100 mg/L), provided serum FLC ratio is abnormal Subject has MM positive for t(11;14) as determined by an analytically validated FISH assay per centralized laboratory testing. A negative serum pregnancy test for all female subjects (except those of non-childbearing potential) within 10 to 14 days prior to initiating therapy and a negative urine pregnancy test within 24 hours for all female subjects (except those of non-childbearing potential) at baseline prior to the first dose of study drug. If female, subject must be either postmenopausal, OR permanently surgically sterile OR for women of childbearing potential practicing at least 2 protocol-specified methods of birth control that are effective from at least 30 days before starting study drugs through at least 30 days after the last dose of any study drug. If male, and subject is sexually active with female partner(s) of childbearing potential, he must agree, from Study Day 1 through 30 days after the last dose of study drug, to practice the protocol-specified contraception. Adult male or female subjects 18 years old.

Exclusion criteria

Subject has history of treatment with venetoclax or another BCL-2 inhibitor or pomalidomide. Female who is pregnant, breastfeeding, or considering becoming pregnant during the study and for at least 30 days after the last dose of study drug. Male who is considering fathering a child or donating sperm and/or semen during the study and

for at least 30 days after the last dose of study drug. Subject who have been treated with any systemic anti-myeloma therapies within 5 half-lives or 2 weeks prior to randomization, whichever is longer (or 2 weeks if half-life unknown), and through the last dose of any study drug. Subject who have been treated with anti-myeloma radiotherapy within 2 weeks prior to randomization. Subject who have received corticosteroid therapy at a dose equivalent to > 4 mg daily of dexamethasone or a single dose of corticosteroid equivalent dose > 40 mg of dexamethasone within 2 weeks prior to randomization. Subject who have used systemic strong or moderate inhibitor or inducer of cytochrome P450 (CYP) 3A within 1 week prior to the first dose of study drugs. Subject who have used systemic strong inhibitor of CYP1A2 within 1 week prior to first dose. Subject who have consumed grapefruit, grapefruit products, Seville oranges (including marmalade containing Seville oranges), or starfruit within 3 days prior to first dose. Subject who anticipate the use of prohibited medications or foods during study participation. Subject has a history of other active malignancies, including myelodysplastic syndromes (MDS), within the past 3 years with the following exceptions: Adequately treated in situ carcinoma of the cervix uteri or the breast; Basal cell carcinoma of the skin or localized squamous cell carcinoma of the skin; Prostate cancer Gleason grade 6 or lower AND with stable Prostate Specific Antigen (PSA) levels off treatment; or Previous malignancy with no current evidence of disease, and which was confined and surgically resected (or treated with other modalities) with curative intent and unlikely to impact survival during the duration of the study. Subject has evidence of ongoing graft-versus-host disease (GvHD) if prior stem cell transplant (SCT). Subject must not have received any live vaccines within 8 weeks prior to randomization Subject has had prior treatment with the following: Allogeneic or syngeneic SCT within 16 weeks prior to randomization; or Autologous SCT within 12 weeks prior to randomization Subject has known central nervous system involvement of multiple myeloma. Subject has a history of clinically significant renal, neurologic, psychiatric, endocrinologic, metabolic, immunologic, cardiovascular, pulmonary or hepatic disease within the last 6 months that, in the opinion of the investigator, would adversely affect participation in this study. Subject has a history of known allergies, hypersensitivities, or intolerance to any of the study drug or excipients, or thalidomide derivatives. Subject has the following conditions: Nonsecretory multiple myeloma; Active plasma cell leukemia i.e., either 20% of peripheral white blood cells or > 2.0 × 109/L circulating plasma cells by standard differential; Waldenström's macroglobulinemia; Primary amyloidosis; POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes); Known human immunodeficiency virus (HIV) infection; Active hepatitis B (hepatitis B surface antigen [HBsAg] positive) or C infection based on screening central laboratory blood testing at screening; Significant cardiovascular disease, including uncontrolled angina, arrhythmia, recent myocardial infarction within 6 months prior to first dose, congestive heart failure NYHA Class 3; Major surgery within 4 weeks prior to first dose or planned during study participation; Acute infections within 14 days prior to first dose requiring therapy (antibiotic, antifungal, or antiviral); Uncontrolled diabetes or hypertension within 14 days prior to first dose; or Peripheral neuropathy Grade 3 or Grade 2 with pain within 2 weeks prior to first dose.

Calendar

(Last Update: 06/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
04/10/2018	28/12/2018	03/01/2019	06/02/2019	20/08/2019

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
17/06/2022	Not aported	Not aported	03/07/2025	Not aported

Sponsor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinical Trials Helpdesk

4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitario 12 de Octubre

Glorieta de Málaga, S/N 28041 Madrid

ceic@h12o.es

917792613

Sites

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

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

N/A

Closed (07/06/2023)

COMPLEJO UNIVERSITARIO LA PAZ

Madrid

MADRID

Closed (17/12/2025)

COMPLEXO HOSPITALARIO UNIVERSITARIO DE OURENSE

Ourense

OURENSE

Servicio de Hematología

Closed (07/05/2024)

HOSPITAL COSTA DEL SOL

Marbella

MÁLAGA

Scio. de Hematología

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

Hospital Costa Del Sol

Marbella

MÁLAGA

N/A

Closed (21/09/2022)

HOSPITAL DE LEON COMPLEJO ASISTENCIAL UNIVERSITARIO DE LEON

León

LEÓN

Scio. de Hematología

Closed (03/07/2023)

HOSPITAL UNIVERSITARI SON ESPASES

Palma de Mallorca

BALEARES

Servicio de Hematología

Closed (29/11/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Closed (26/07/2022)

HOSPITAL UNIVERSITARIO DE CANARIAS

San Cristóbal de La Laguna

STA. CRUZ DE TENERIFE

Scio. de Hematología

Closed (15/12/2025)

HOSPITAL UNIVERSITARIO DE SALAMANCA

Salamanca

SALAMANCA

Scio. de Hematología

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

Hospital Universitario De Toledo

Toledo

TOLEDO

Servicio de Hematologia

Closed (19/01/2026)

HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ

Madrid

MADRID

Start FJD - Scio. de Hematología

Closed (24/11/2022)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Scio. de Hematología

Closed (22/04/2024)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Scio. de Hematología

Closed (28/10/2025)

HOSPITAL VIRGEN DE LA SALUD

Toledo

TOLEDO

Servicio de Hematología

Closed (12/11/2025)

HOSPITAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Scio. de Hematología y Hemoterapia

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

Institut Catala D'oncologia

Girona

GERONA

N/A

Closed (01/07/2026)

Institut Catala D'oncologia

Girona

GERONA

ICO Girona - Scio. de Hematología

Medication

Venetoclax
FILM-COATED TABLET
ORAL

-
Active Principles: N/A
Orphan Experimental

Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A
Orphan Experimental

Imnovid 3 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A
Orphan Experimental

Imnovid 2 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A
Orphan Experimental

Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A
Orphan Experimental

-
-
ORAL

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A
Experimental

No results