Zimberelimab and Domvanalimab in Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy in Patients With Untreated Metastatic NonSmall Cell Lung Cancer.

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	398
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-509825-38-00 (CTIS)

Cod. Protocolo
GS-US-626-6216

Transicionado 2022-000578-25

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

Enfermedad investigada
Metastatic NonSmall Cell Lung Cancer

Título Científico
A Randomized, Open-Label, Phase 3 Study to Evaluate Zimberelimab and Domvanalimab in Combination with Chemotherapy Versus Pembrolizumab With Chemotherapy for the First-Line Treatment of Patients With Metastatic NonSmall Cell Lung Cancer With No Epidermal Growth Factor Receptor or Anaplastic Lymphoma Kinase Genomic

Tumor Aberrations

Justificación

No aportado

Objetivo Principal

To compare the effect of domvanalimab (DOM) + zimberelimab (ZIM) in combination with chemotherapy relative to pembrolizumab (PEMBRO) in combination with chemotherapy (Group A vs Group B) on overall survival (OS) in participants with positive programmed cell death ligand 1 (PD-L1) expression (1% tumor cells [SP263 scoring method] [TC])
To compare the effect of DOM+ZIM in combination with chemotherapy relative to PEMBRO in combination with chemotherapy (Group A vs Group B) on OS in all randomized participants

Variables de Evaluación Primaria

OS is defined as the time from the date of randomization to the date of death from any cause (both in participants with positive PD-L1 expression [1% TC] and in all randomized participants as dual primary endpoints)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare the effect of DOM + ZIM in combination with chemotherapy relative to PEMBRO in combination with chemotherapy (Group A versusvs Group B) in participants with positive PD-L1 expression (1% TC) as well as in all randomized participants on:
Progression-free survival (PFS) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by blinded independent central review (BICR)
Overall response rate (ORR) as assessed by BICR according to RECIST v1.1

Variables de Evaluación Secundaria

PFS is defined as the time from the date of randomization until progressive disease (PD) as assessed by BICR according to RECIST v1.1 or death from any cause, whichever comes first. ORR is defined as the proportion of participants who have achieved a complete response (CR) or partial response (PR) that is confirmed at least 4 weeks later as assessed by BICR according to RECIST v1.1
DOR is defined as the time from the first response (CR or PR), to the first documented PD, as assessed by BICR according to RECIST v1.1, or death from any cause, whichever comes first.
Incidence, severity, seriousness, and relatedness of treatment-emergent adverse events (TEAEs) and incidence and severity of clinical laboratory abnormalities

Time to first symptom deterioration in NSCLC SAQ shortness of breath domain
Time to first deterioration in NSCLC-SAQ total score

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Members of all genders, races, and ethnic groups are eligible for this study. Participants must meet all the following inclusion criteria to be eligible for participation in this study (no waivers for participant eligibility will be permitted).
Provide adequate tumor tissue from locations not radiated prior to biopsy to allow central evaluation of PD-L1 expression using the investigational VENTANA PD-L1 (SP263) assay prior to randomization. Bone biopsies, cytology, and fine needle aspirates are not suitable tissues. If no tissue is available, a new biopsy will need to be obtained prior to enrollment in the study (Section 6.3.9).
Have not received prior systemic treatment for metastatic NSCLC. Participants who received chemotherapy for nonmetastatic disease are eligible if the treatment was completed at least 12 months prior to the start of study treatment.
Measurable disease per RECIST v1.1 criteria by investigator assessment (Appendix 7). Tumor lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.
ECOG performance status score of 0 or 1.
see protocol for organ function requirement.
Participants assigned male at birth and participants assigned female at birth of childbearing potential who engage in heterosexual intercourse must agree to use protocol-specified method(s) of contraception from screening visit until 6 months after the last dose of chemotherapy and 120 days after the last dose of DOM, ZIM, or PEMBRO (or longer according to local regulatory requirements), as described in of the study protocol.
Participants assigned male at birth and participants assigned female at birth, 18 years of age or older, able to understand and give written informed consent.
Life expectancy 3 months
Pathologically documented NSCLC that meets both criteria below: a) Have documented evidence of Stage IV NSCLC disease at the time of enrollment (based on AJCC, Eighth Edition). b) Have documented negative test results for actionable EGFR and ALK mutations and ALK gene rearrangements. Note: tumor testing for actionable EGFR or ALK mutations or ALK gene rearrangements is not required for participants with nonsquamoussquamous NSCLC tumor histology if status is unknown (Section 6.3.9).
Have no actionable genomic alterations such as ROS proto-oncogene 1, neurotrophic tyrosine receptor kinase, proto-oncogene B-raf, RET mutations, or other driver oncogenes with approved frontline therapies. Testing of actionable genomic alterations required by local regulations will be performed locally. Note: see Appendix Table 1 for requirements in Germany and Appendix Table 5 for requirements in Argentina (Appendix 14).

Criterios de Exclusión

Participants who meet any of the following exclusion criteria at screening/Day 1 are not eligible to be enrolled in this study (no waivers for participant eligibility will be offered or permitted): Have mixed SCLC and NSCLC histology. Have untreated central nervous system (CNS) metastases and/or carcinomatous meningitis. Participants with previously treated brain metastases may participate provided they have stable CNS disease for at least 4 weeks prior to enrollment and all neurologic symptoms have returned to baseline, have no evidence of new or enlarging brain metastases and are not requiring use of steroids for at least 14 days prior to the start of study treatment. All participants with carcinomatous meningitis are excluded regardless of clinical stability. Meet any of the following criteria for cardiac disease: a) Myocardial infarction or unstable angina pectoris within 6 months of enrollment. b)

History of serious ventricular arrhythmia (ie, ventricular tachycardia or ventricular fibrillation), high-grade atrioventricular block, or other cardiac arrhythmias requiring antiarrhythmic medications (except for atrial fibrillation that is well controlled with antiarrhythmic medication). c) New York Heart Association Class III or greater congestive heart failure or known left ventricular ejection fraction less than 40%. Active chronic inflammatory bowel disease (ulcerative colitis, Crohns disease) or gastrointestinal perforation within 6 months of enrollment. Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease. Has received radiotherapy within 2 weeks prior to first dose of study intervention or radiotherapy to the lung that is > 30 Gy within 6 months of the first study treatment. Has had an allogenic tissue/solid organ transplant. Have received a live virus vaccination within 30 days of planned treatment start. Seasonal flu and COVID-19 vaccines that do not contain live virus are permitted. Have active infection requiring treatment (eg, antibiotics). Have known history of HIV-1 or 2 with uncontrolled viral load (ie, 200 copies/mL or CD4+ T-cell count < 350 cells/L), or taking medications that may interfere with metabolism of study drugs. No HIV testing is required unless mandated by local health authority. Have known acute hepatitis B, known chronic hepatitis B infection with active untreated disease, or known active hepatitis C infection. In participants with a history of hepatitis B virus or hepatitis C virus, participants with detectable viral loads will be excluded. No hepatitis testing is required unless mandated by local health authority. Positive serum pregnancy test or participants who are breastfeeding or have plans to breastfeed during the study period and for the required duration of contraception use after the last dose of study drug Have other concurrent medical or psychiatric conditions that, in the investigators opinion, may be likely to confound study interpretation or prevent completion of study procedures and follow-up examinations. Received prior treatment with any anti-programmed cell death protein 1 (anti-PD-1), anti-PD-L1, or any other antibody targeting an immune checkpoint. Participants who received programmed cell death protein 1/programmed cell death ligand PD-1/PD-L1 inhibitors as a part of treatment for early stage or locally advanced stage NSCLC are not eligible. Known hypersensitivity to the study drug, its metabolites, or formulation excipient. Requirement for ongoing therapy with or prior use of any prohibited medications listed in Section 5.6.3 of the protocol Have an active second malignancy or have had an active second malignancy within 3 years prior to enrollment. Participants with a history of malignancy that has been completely treated, with no evidence of active cancer for at least 3 years prior to enrollment, or with surgically cured tumors with low risk of recurrence (eg, nonmelanoma skin cancer, histologically confirmed complete excision of carcinoma in situ, or similar) are allowed to enroll. Have an active autoimmune disease that required systemic treatment in past 2 years (ie, with use of disease-modifying agents, corticosteroids, or immunosuppressive drugs). Replacement therapy (eg, thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment. Are receiving chronic systemic steroids (> 10 mg/day prednisone equivalent). Use of topical, inhalational, intranasal, and intraocular steroids will be permitted. Have significant third-space fluid retention (eg, ascites or pleural effusion) and is not amenable for required repeated drainage.

Calendario

(Última actualización: 26/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
03/11/2022	01/12/2022	21/12/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
22/03/2024	No aportado	No aportado	No aportado	No aportado

Promotor

Gilead Sciences Inc. United States

333 Lakeside Drive

Contact Person

EU CT Support

+442085872977

clinical.trials@gilead.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Provincial de Sevilla

Avenida Doctor Fedriani 3 41009 Sevilla

administracion.eecc.hvm.sspa@juntadeandalucia.es

955043127

Centros

Activo (09/02/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Oncología

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Oncology

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

Clinica Universidad De Navarra

Madrid

MADRID

Oncology

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

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

Oncology

Activo (19/04/2023)

Corporació Sanitaria Parc Tauli

Sabadell

BARCELONA

Oncología

Activo (30/05/2023)

FUNDACION INSTITUTO VALENCIANO DE ONCOLOGIA

València

VALENCIA

Oncología

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

Fundacion Instituto Valenciano De Oncologia

Valencia

VALENCIA

Oncology

Activo (18/09/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Oncología

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Oncology

Activo (07/07/2023)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Servicio de Oncología

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Oncology

Activo (19/05/2023)

HOSPITAL UNIVERSITARI DE SANT JOAN DE REUS

Reus

TARRAGONA

Oncología

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

Hospital Universitari Dexeus Grupo Quironsalud

Barcelona

BARCELONA

Oncology

Activo (01/12/2022)

HOSPITAL UNIVERSITARI QUIR¿N DEXEUS

Barcelona

BARCELONA

Oncología

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncology

Activo (10/03/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Oncología

Activo (14/12/2022)

HOSPITAL UNIVERSITARIO DE JAEN

Jaén

JAÉN

Oncología

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

Hospital Universitario De Jaen

Jaen

JAÉN

Oncology

Activo (29/12/2022)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Oncología

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Oncology

Activo (23/01/2023)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Oncología

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

Hospital Universitario La Paz

Madrid

MADRID

Oncology

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Oncology

Activo (22/02/2023)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Oncología

Activo (03/02/2023)

HOSPITAL UNIVERSITARIO REGIONAL DE MALAGA

Málaga

MÁLAGA

Oncología

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

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Oncology

Activo (01/12/2022)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Oncología

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

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Oncology

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

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Oncology

Activo (30/06/2023)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Servicio de Oncología

Activo (15/12/2022)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

Oncología

Activo (23/02/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Oncología

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Oncology

Activo (06/04/2023)

HOSPITAL 9 DE OCTUBRE

València

VALENCIA

Oncología

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

Hospital 9 De Octubre S.A.

Valencia

VALENCIA

Oncology

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

Institut Catala D´oncologia

Girona

GERONA

Oncology

Activo (16/12/2022)

Institut Catala D'oncologia

Girona

GERONA

Oncología

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

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Oncology

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

Salut Sant Joan De Reus

Reus

TARRAGONA

Oncology

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Oncology

Medicamentos

Zimberelimab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS USE

Código ATC: L01CD01 - PACLITAXEL
Principios Activos: N/A

Experimental

ALIMTA 500 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01BA04 - PEMETREXED
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS USE

Código ATC: L01XA02 - CARBOPLATINO
Principios Activos: N/A

Experimental

KEYTRUDA 25 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01FF02 - PEMBROLIZUMAB
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS USE

Código ATC: L01XA01 - CISPLATINO
Principios Activos: N/A

Experimental

Abraxane 5 mg/ml powder for dispersion for infusion.
DISPERSION FOR INFUSION
INTRAVENOUS USE

Código ATC: L01CD01 - PACLITAXEL
Principios Activos: N/A

Experimental

DOMVANALIMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A

Experimental

Sin resultados

Zimberelimab and Domvanalimab in Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy in Patients With Untreated Metastatic NonSmall Cell Lung Cancer.

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	398
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-509825-38-00 (CTIS)

Protocol Code
GS-US-626-6216

Transitioned 2022-000578-25

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

Investigated Disease
Metastatic NonSmall Cell Lung Cancer

Scientific Title
A Randomized, Open-Label, Phase 3 Study to Evaluate Zimberelimab and Domvanalimab in Combination with Chemotherapy Versus Pembrolizumab With Chemotherapy for the First-Line Treatment of Patients With Metastatic NonSmall Cell Lung Cancer With No Epidermal Growth Factor Receptor or Anaplastic Lymphoma Kinase Genomic

Tumor Aberrations

Rationale

Not provided

Main Objective

To compare the effect of domvanalimab (DOM) + zimberelimab (ZIM) in combination with chemotherapy relative to pembrolizumab (PEMBRO) in combination with chemotherapy (Group A vs Group B) on overall survival (OS) in participants with positive programmed cell death ligand 1 (PD-L1) expression (1% tumor cells [SP263 scoring method] [TC])
To compare the effect of DOM+ZIM in combination with chemotherapy relative to PEMBRO in combination with chemotherapy (Group A vs Group B) on OS in all randomized participants

Primary Endpoints

OS is defined as the time from the date of randomization to the date of death from any cause (both in participants with positive PD-L1 expression [1% TC] and in all randomized participants as dual primary endpoints)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare the effect of DOM + ZIM in combination with chemotherapy relative to PEMBRO in combination with chemotherapy (Group A versusvs Group B) in participants with positive PD-L1 expression (1% TC) as well as in all randomized participants on:
Progression-free survival (PFS) according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 as assessed by blinded independent central review (BICR)
Overall response rate (ORR) as assessed by BICR according to RECIST v1.1

Secondary Endpoints

PFS is defined as the time from the date of randomization until progressive disease (PD) as assessed by BICR according to RECIST v1.1 or death from any cause, whichever comes first. ORR is defined as the proportion of participants who have achieved a complete response (CR) or partial response (PR) that is confirmed at least 4 weeks later as assessed by BICR according to RECIST v1.1
DOR is defined as the time from the first response (CR or PR), to the first documented PD, as assessed by BICR according to RECIST v1.1, or death from any cause, whichever comes first.
Incidence, severity, seriousness, and relatedness of treatment-emergent adverse events (TEAEs) and incidence and severity of clinical laboratory abnormalities

Time to first symptom deterioration in NSCLC SAQ shortness of breath domain
Time to first deterioration in NSCLC-SAQ total score

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Members of all genders, races, and ethnic groups are eligible for this study. Participants must meet all the following inclusion criteria to be eligible for participation in this study (no waivers for participant eligibility will be permitted).
Provide adequate tumor tissue from locations not radiated prior to biopsy to allow central evaluation of PD-L1 expression using the investigational VENTANA PD-L1 (SP263) assay prior to randomization. Bone biopsies, cytology, and fine needle aspirates are not suitable tissues. If no tissue is available, a new biopsy will need to be obtained prior to enrollment in the study (Section 6.3.9).
Have not received prior systemic treatment for metastatic NSCLC. Participants who received chemotherapy for nonmetastatic disease are eligible if the treatment was completed at least 12 months prior to the start of study treatment.
Measurable disease per RECIST v1.1 criteria by investigator assessment (Appendix 7). Tumor lesions situated in a previously irradiated area are considered measurable if progression has been demonstrated in such lesions.
ECOG performance status score of 0 or 1.
see protocol for organ function requirement.
Participants assigned male at birth and participants assigned female at birth of childbearing potential who engage in heterosexual intercourse must agree to use protocol-specified method(s) of contraception from screening visit until 6 months after the last dose of chemotherapy and 120 days after the last dose of DOM, ZIM, or PEMBRO (or longer according to local regulatory requirements), as described in of the study protocol.
Participants assigned male at birth and participants assigned female at birth, 18 years of age or older, able to understand and give written informed consent.
Life expectancy 3 months
Pathologically documented NSCLC that meets both criteria below: a) Have documented evidence of Stage IV NSCLC disease at the time of enrollment (based on AJCC, Eighth Edition). b) Have documented negative test results for actionable EGFR and ALK mutations and ALK gene rearrangements. Note: tumor testing for actionable EGFR or ALK mutations or ALK gene rearrangements is not required for participants with nonsquamoussquamous NSCLC tumor histology if status is unknown (Section 6.3.9).
Have no actionable genomic alterations such as ROS proto-oncogene 1, neurotrophic tyrosine receptor kinase, proto-oncogene B-raf, RET mutations, or other driver oncogenes with approved frontline therapies. Testing of actionable genomic alterations required by local regulations will be performed locally. Note: see Appendix Table 1 for requirements in Germany and Appendix Table 5 for requirements in Argentina (Appendix 14).

Exclusion criteria

Participants who meet any of the following exclusion criteria at screening/Day 1 are not eligible to be enrolled in this study (no waivers for participant eligibility will be offered or permitted): Have mixed SCLC and NSCLC histology. Have untreated central nervous system (CNS) metastases and/or carcinomatous meningitis. Participants with previously treated brain metastases may participate provided they have stable CNS disease for at least 4 weeks prior to enrollment and all neurologic symptoms have returned to baseline, have no evidence of new or enlarging brain metastases and are not requiring use of steroids for at least 14 days prior to the start of study treatment. All participants with carcinomatous meningitis are excluded regardless of clinical stability. Meet any of the following criteria for cardiac disease: a) Myocardial infarction or unstable angina pectoris within 6 months of enrollment. b)

History of serious ventricular arrhythmia (ie, ventricular tachycardia or ventricular fibrillation), high-grade atrioventricular block, or other cardiac arrhythmias requiring antiarrhythmic medications (except for atrial fibrillation that is well controlled with antiarrhythmic medication). c) New York Heart Association Class III or greater congestive heart failure or known left ventricular ejection fraction less than 40%. Active chronic inflammatory bowel disease (ulcerative colitis, Crohns disease) or gastrointestinal perforation within 6 months of enrollment. Has a history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease. Has received radiotherapy within 2 weeks prior to first dose of study intervention or radiotherapy to the lung that is > 30 Gy within 6 months of the first study treatment. Has had an allogenic tissue/solid organ transplant. Have received a live virus vaccination within 30 days of planned treatment start. Seasonal flu and COVID-19 vaccines that do not contain live virus are permitted. Have active infection requiring treatment (eg, antibiotics). Have known history of HIV-1 or 2 with uncontrolled viral load (ie, 200 copies/mL or CD4+ T-cell count < 350 cells/L), or taking medications that may interfere with metabolism of study drugs. No HIV testing is required unless mandated by local health authority. Have known acute hepatitis B, known chronic hepatitis B infection with active untreated disease, or known active hepatitis C infection. In participants with a history of hepatitis B virus or hepatitis C virus, participants with detectable viral loads will be excluded. No hepatitis testing is required unless mandated by local health authority. Positive serum pregnancy test or participants who are breastfeeding or have plans to breastfeed during the study period and for the required duration of contraception use after the last dose of study drug Have other concurrent medical or psychiatric conditions that, in the investigators opinion, may be likely to confound study interpretation or prevent completion of study procedures and follow-up examinations. Received prior treatment with any anti-programmed cell death protein 1 (anti-PD-1), anti-PD-L1, or any other antibody targeting an immune checkpoint. Participants who received programmed cell death protein 1/programmed cell death ligand PD-1/PD-L1 inhibitors as a part of treatment for early stage or locally advanced stage NSCLC are not eligible. Known hypersensitivity to the study drug, its metabolites, or formulation excipient. Requirement for ongoing therapy with or prior use of any prohibited medications listed in Section 5.6.3 of the protocol Have an active second malignancy or have had an active second malignancy within 3 years prior to enrollment. Participants with a history of malignancy that has been completely treated, with no evidence of active cancer for at least 3 years prior to enrollment, or with surgically cured tumors with low risk of recurrence (eg, nonmelanoma skin cancer, histologically confirmed complete excision of carcinoma in situ, or similar) are allowed to enroll. Have an active autoimmune disease that required systemic treatment in past 2 years (ie, with use of disease-modifying agents, corticosteroids, or immunosuppressive drugs). Replacement therapy (eg, thyroxine, insulin, or physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency) is not considered a form of systemic treatment. Are receiving chronic systemic steroids (> 10 mg/day prednisone equivalent). Use of topical, inhalational, intranasal, and intraocular steroids will be permitted. Have significant third-space fluid retention (eg, ascites or pleural effusion) and is not amenable for required repeated drainage.

Calendar

(Last Update: 26/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
03/11/2022	01/12/2022	21/12/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
22/03/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

Gilead Sciences Inc. United States

333 Lakeside Drive

Contact Person

EU CT Support

+442085872977

clinical.trials@gilead.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Provincial de Sevilla

Avenida Doctor Fedriani 3 41009 Sevilla

administracion.eecc.hvm.sspa@juntadeandalucia.es

955043127

Sites

Active (09/02/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Oncología

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Oncology

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

Clinica Universidad De Navarra

Madrid

MADRID

Oncology

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

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

Oncology

Active (19/04/2023)

Corporació Sanitaria Parc Tauli

Sabadell

BARCELONA

Oncología

Active (30/05/2023)

FUNDACION INSTITUTO VALENCIANO DE ONCOLOGIA

València

VALENCIA

Oncología

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

Fundacion Instituto Valenciano De Oncologia

Valencia

VALENCIA

Oncology

Active (18/09/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Servicio de Oncología

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

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Oncology

Active (07/07/2023)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Servicio de Oncología

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

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Oncology

Active (19/05/2023)

HOSPITAL UNIVERSITARI DE SANT JOAN DE REUS

Reus

TARRAGONA

Oncología

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

Hospital Universitari Dexeus Grupo Quironsalud

Barcelona

BARCELONA

Oncology

Active (01/12/2022)

HOSPITAL UNIVERSITARI QUIR¿N DEXEUS

Barcelona

BARCELONA

Oncología

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Oncology

Active (10/03/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Oncología

Active (14/12/2022)

HOSPITAL UNIVERSITARIO DE JAEN

Jaén

JAÉN

Oncología

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

Hospital Universitario De Jaen

Jaen

JAÉN

Oncology

Active (29/12/2022)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Oncología

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Oncology

Active (23/01/2023)

HOSPITAL UNIVERSITARIO LA PAZ

Madrid

MADRID

Oncología

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

Hospital Universitario La Paz

Madrid

MADRID

Oncology

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Oncology

Active (22/02/2023)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Oncología

Active (03/02/2023)

HOSPITAL UNIVERSITARIO REGIONAL DE MALAGA

Málaga

MÁLAGA

Oncología

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

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Oncology

Active (01/12/2022)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Oncología

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

Hospital Universitario Reina Sofia

Cordoba

CÓRDOBA

Oncology

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

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Oncology

Active (30/06/2023)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Servicio de Oncología

Active (15/12/2022)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

Oncología

Active (23/02/2023)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Oncología

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Oncology

Active (06/04/2023)

HOSPITAL 9 DE OCTUBRE

València

VALENCIA

Oncología

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

Hospital 9 De Octubre S.A.

Valencia

VALENCIA

Oncology

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

Institut Catala D´oncologia

Girona

GERONA

Oncology

Active (16/12/2022)

Institut Catala D'oncologia

Girona

GERONA

Oncología

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

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Oncology

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

Salut Sant Joan De Reus

Reus

TARRAGONA

Oncology

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Oncology

Medication

Zimberelimab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-
Active Principles: N/A

Experimental

-
-
INTRAVENOUS USE

ATC code: L01CD01 - PACLITAXEL
Active Principles: N/A

Experimental

ALIMTA 500 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

ATC code: L01BA04 - PEMETREXED
Active Principles: N/A

Experimental

-
-
INTRAVENOUS USE

ATC code: L01XA02 - CARBOPLATINO
Active Principles: N/A

Experimental

KEYTRUDA 25 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS USE

ATC code: L01FF02 - PEMBROLIZUMAB
Active Principles: N/A

Experimental

-
-
INTRAVENOUS USE

ATC code: L01XA01 - CISPLATINO
Active Principles: N/A

Experimental

Abraxane 5 mg/ml powder for dispersion for infusion.
DISPERSION FOR INFUSION
INTRAVENOUS USE

ATC code: L01CD01 - PACLITAXEL
Active Principles: N/A

Experimental

DOMVANALIMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS USE

-
Active Principles: N/A

Experimental

No results