A Study to Evaluate the Safety and Pharmacokinetics of a Modified Tafasitamab IV Dosing Regimen Combined with Lenalidomide in Patients with Worsening (relapsed) or Unresponsive (refractory) Diffuse Large B-Cell Lymphoma (R/R DLBCL) (MINDway)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	13
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-507993-42-00 (CTIS)

Cod. Protocolo
MOR208C115

Transicionado 2021-003855-40

Área terapéutica
·Enfermedades [C] - Cáncer [C04]
·Enfermedades [C] - Hematología [C15]

Enfermedad investigada
Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

Título Científico
A Phase 1b/2, Open-Label, Multicenter Study to Evaluate the Safety and Pharmacokinetics of a Modified

Tafasitamab IV Dosing Regimen Combined with Lenalidomide (LEN) in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) (MINDway)

Justificación

No aportado

Objetivo Principal

To evaluate the safety and tolerability of tafasitamab administered once every 2 weeks (Q2W)/once every 4 weeks (Q4W) in combination with lenalidomide in R/R DLBCL patients
To determine a recommended dose for tafasitamab Q2W/Q4W administration in combination with lenalidomide in R/R DLBCL patients

Variables de Evaluación Primaria

Incidence and severity of TEAEs (TEAE, treatment-emergent adverse event)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the pharmacokinetic profile of tafasitamab after Q2W/Q4W dosing in combination with lenalidomide To assess anti-tumor activity of tafasitamab after Q2W/Q4W dosing in combination with lenalidomide To assess the incidence of anti-drug antibodies to tafasitamab

Variables de Evaluación Secundaria

Tafasitamab serum concentrations after 3 (Ctrough and Cmax) and 12 (Ctrough) treatment cycles
Best Objective Response Rate (ORR) by Investigator assessment up to treatment Cycle 12 based on Cheson et al. (2007)
Duration of Response (DoR) by Investigator assessment based on Cheson et al. (2007)
Progression-Free Survival (PFS) by Investigator assessment based on Cheson et al. (2007)
Number and percentage of patients developing anti- tafasitamab antibodies up to treatment Cycle 12

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Capable of giving signed informed consent as described in Appendix 2: Regulatory, Ethical, and Trial Oversight Considerations, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol. 2. Patient must be at least 18 years of age and of legal age (whichever is higher) in the jurisdiction in which the study is taking place at the time of signing the informed consent. 3. One of the following histologically confirmed diagnoses: DLBCL not otherwise specified (NOS) T cell/histiocyte-rich large B-cell lymphoma (THRLBCL) Epstein-Barr virus (EBV) positive DLBCL of the elderly (EBV-positive DLBCL) Grade 3b Follicular Lymphoma Composite lymphoma with a DLBCL component with a subsequent DLBCL relapse, according to the Revised European American Lymphoma/World Health Organization (REAL/WHO) classification. Additionally, patients with the evidence of histological transformation to DLBCL from an earlier diagnosis of low-grade lymphoma (i.e., an indolent pathology such as follicular lymphoma, marginal zone lymphoma, chronic lymphocytic leukemia) into DLBCL with a subsequent DLBCL relapse are also eligible. 4. Tumor tissue for retrospective central pathology review must be provided as an adjunct to participation in this study. If archival formalin fixed paraffin embedded tumor tissue acquired 3 years prior to screening is not available, a fresh tumor tissue sample from the patient should be obtained. Archival formalin fixed- paraffin embedded tumor tissue acquired >3 years prior to screening is acceptable only in cases where a fresh tumor biopsy cannot be collected due to a safety risk, e.g., due to co-morbidity, or inaccessible tumor site. 5. Patients must have:a. Relapsed and/or refractory disease as defined in Appendix 3: Study Specific Definitions b. At least one bi-dimensionally measurable disease site. The lesion must have a greatest transverse diameter of 1.5 cm and greatest perpendicular diameter of 1.0 cm at baseline. The lesion must be positive on positron emission tomography (PET) scan (for definition see Juweid et al., 2007)c. Received at least one, but no more than three previous systemic regimens for the treatment of DLBCL and one therapy line must have included a cluster of differentiation-20 (CD20) targeted therapy (e.g., rituximab [RTX])d. An Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. 6. Patients that are not eligible to undergo intensive salvage therapy including autologous stem cell transplantation (ASCT). The reason for a patients ineligibility must meet one of the criteria described below and documented in the patients source data:a. Inadequate performance status (Karnofsky performance status 80%; seeAppendix 5: Karnofsky Performance Status Scale) b. Disease not responsive to salvage chemotherapy. Responsiveness is defined as a tumor demonstrating either complete response (CR) or partial response (PR) to salvage chemotherapy c. Inadequate major organ function (any of the below): i. symptomatic congestive heart failure ii. lung function-forced vital capacity (FVC), forced expiratory volume in 1 second (FEV-1), and corrected diffusion capacity of the lung for carbon monoxide (DLCO) 60% iii. liver function-total serum bilirubin and transaminases > 2 x upper limit of normal (ULN) d. History or evidence of significant co-morbid medical or psychiatric illness which would significantly compromise the patients clinical care and chances of survival e.Inability to collect adequate stem cell graft (e.g. < 12 x 106 CD34+ cells free of tumor contamination/kg recipient body weight) 7. Patients must meet the following laboratory criteria at screening: a. Absolute neutrophil count (ANC) 1.5 × 109/L (unless secondary to bone marrow involvement by DLBCL as demonstrated by recent bone marrow aspiration and bone marrow biopsy) b. Platelet count 75 × 109/L (unless secondary to bone marrow involvement by DLBCL as demonstrated by recent bone marrow aspiration and bone marrow biopsy) c. Total serum bilirubin 2.5 × ULN unless secondary to Gilberts syndrome or documented liver involvement by lymphoma. Patients with Gilberts syndrome or documented liver involvement by lymphoma may be included if their total bilirubin is 5 × ULN (see exclusion criterion 6g) d. Alanine transaminase (ALT), aspartate transaminase (AST) and alkaline phosphatase (ALP) 3 × ULN or < 5 × ULN in cases of documented liver involvement e. Serum creatinine CL must be 60 mL/minute either measured or calculated using a standard Cockcroft and Gault formula (see Appendix 6: Cockcroft- Gault Formula)8. Patients who received previous CD19 targeted therapy (other than tafasitamab) must have CD19 positive lymphoma confirmed on a biopsy taken since completing the prior CD19 targeted therapy 9. Patients with primary refractory disease (Appendix 3: Study Specific Definitions) who received at least one, but no more than three previous systemic regimens (including a CD20 targeted therapy) for the treatment of DLBCL are eligible.

Criterios de Exclusión

1. General provisions: a. Patients who are legally institutionalized, or patients under judicial protection b. Concurrent enrollment in another interventional clinical study 2. Patients who have: a. Any other histological type of lymphoma

including primary mediastinal (thymic) large B-cell (PMBL) or Burkitt lymphoma b. Known double/triple hit genetics (high grade B-cell lymphoma) characterized by simultaneous detection of MYC with BCL2 and/or BCL6 translocation(s) defined by fluorescence in situ hybridization. MYC, BCL2, BCL6 testing prior to study enrollment is not required 3. Patients who have: a. Not discontinued (within 14 days prior to Day 1 dosing): CD20 targeted therapy, chemotherapy, radiotherapy, investigational anticancer therapy or other lymphoma-specific therapy b. Undergone major surgery (within 4 weeks prior to Day 1 dosing) or suffered from significant traumatic injury c. Received live vaccines (within 4 weeks prior to Day 1 dosing) (See Appendix 7: Covid-19: Infection Prophylaxis and Vaccines) d. Required parenteral antimicrobial therapy for active, intercurrent infections (within 14 days prior to Day 1 dosing) 4. Patients who: a.Have, in the opinion of the investigator, not recovered sufficiently from the adverse toxic effects of prior therapies b. Were previously treated with tafasitamab or IMiDs® (e.g., thalidomide, LEN) c. Have a history of hypersensitivity to compounds of similar biological or chemical composition to tafasitamab, IMiDs® and/or the excipients contained in the study treatment formulations d. Have undergone ASCT within the period 3 months prior to signing the ICF. Patients who have a more distant history of ASCT must exhibit full hematological recovery before enrollment into the study e. Have undergone previous allogenic stem cell transplantation f.Have a history of deep venous thrombosis/embolism, threatening thromboembolism or known thrombophilia or are at high risk for a thromboembolic event in the opinion of the investigator and who are not willing/able to take venous thromboembolism (VTE) prophylaxis during the entire treatment period g. Concurrently use other anticancer or experimental treatments 5. History of other malignancy that could affect compliance with the protocol or interpretation of results. Exceptions:a. Patients with any malignancy appropriately treated with curative intent and the malignancy has been in remission without treatment for > 2 years prior to enrollment are eligible b. Patients with low-grade, early-stage prostate cancer (Gleason score 6 or below, Stage 1 or 2) with no requirement for therapy at any time prior to study are eligible 6. Patients with: a. Positive hepatitis B and/or C serology (see Appendix 8: Hepatitis Virus Serology for details) b. Known seropositivity for or history of active viral infection with human immunodeficiency virus (HIV) c.Central nervous system (CNS) lymphoma involvement present or past medical history d. History or evidence of clinically significant cardiovascular, CNS and/or other systemic disease that would in the investigators opinion preclude participation in the study or compromise the patients ability to give informed consent e. History or evidence of rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption f. Gastrointestinal (GI) abnormalities (issue with absorption) including the inability to take oral medication g. History or evidence of severe hepatic impairment (total serum bilirubin > 3 mg/dL), jaundice unless secondary to Gilberts syndrome or documented liver involvement by lymphoma (see inclusion criterion 7c) h. History of hypersensitivity to any of the study treatments or its excipients or to drugs of similar chemical class i. Any other medical condition which, in the investigators opinion, makes the patient unsuitable for the study 7. Contraception provisions: Females: Due to the teratogenic potential of LEN, FCBP must follow the rules listed below (otherwise excluded): a. Not be pregnant as confirmed by a negative serum pregnancy test at screening and a medically supervised urine pregnancy test prior to starting study therapy b. Refrain from breast feeding and donating oocytes during the study and for 3 months after the last dose of study drug or according to local guidelines for LEN, whichever is longer c. Agree to ongoing pregnancy testing during the course of the study, and after study treatment has ended. This includes pregnancy testing and counseling if a patient misses her period or if there is any abnormality in her menstrual bleeding and applies even if the patient practices complete sexual abstinence d. Commit to continued abstinence from heterosexual intercourse if it is in accordance with her lifestyle (which must be reviewed on a monthly basis) or agree to use and be able to comply with the use of highly effective contraception without interruption at least 4 weeks prior to start of study drugs, during the study treatment and for 3 months after the last dose of study drug, or, for LEN, according to the local guidelines, whichever is longer. 8. Due to the teratogenic potential of lenalidomide, male participants must follow the rules listed below (otherwise excluded):a. Use an effective barrier method of contraception without interruption if the patient is sexually active with a FCBP. Male patients should refrain from donating sperm during the study participation and for 3 months after the last dose of study treatment, or according to the local guidelines for LEN, whichever is longer.

Calendario

(Última actualización: 22/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
09/03/2022	06/04/2022	26/09/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
04/01/2024	No aportado	No aportado	13/05/2026	No aportado

Promotor

Incyte Corp. United States

1801 Augustine Cut Off

Contact Person

Medical Information

+4989899270

medinfo@morphosys.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Parc Tauli

Plaça de la Torre de lAigua, s/n 08208 Sabadell

ceic@tauli.cat

937458454-937458451

Centros

Cerrado (07/02/2025)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

Cerrado (14/06/2024)

Complejo Hospitalario Infanta Leonor

Madrid

MADRID

Cerrado (13/03/2025)

HOSPITAL MD ANDERSON CANCER CENTER MADRID

Madrid

MADRID

Cerrado (23/07/2024)

HOSPITAL SON LLATZER

Palma

BALEARES

Cerrado (20/03/2025)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Activo (25/05/2022)

HOSPITAL UNIVERSITARIO QUIRONSALUD MADRID

Pozuelo de Alarcón

MADRID

Cerrado (20/01/2025)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Cerrado (17/06/2024)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Cerrado (02/04/2025)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Cerrado (22/01/2026)

Institut Catala D´oncologia

Girona

GERONA

n/a

Cerrado (13/03/2025)

MD Anderson Cancer Center

Madrid

MADRID

n/a

Medicamentos

Zelvina 10 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

MINJUVI 200 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

Código ATC: L01FX12 - TAFASITAMAB
Principios Activos: N/A

Huérfano

Experimental

Zelvina 25 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Zelvina 5 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX04 - LENALIDOMIDA
Principios Activos: N/A

Experimental

Sin resultados

A Study to Evaluate the Safety and Pharmacokinetics of a Modified Tafasitamab IV Dosing Regimen Combined with Lenalidomide in Patients with Worsening (relapsed) or Unresponsive (refractory) Diffuse Large B-Cell Lymphoma (R/R DLBCL) (MINDway)

State	Type of participants	Age Ranges
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	13
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-507993-42-00 (CTIS)

Protocol Code
MOR208C115

Transitioned 2021-003855-40

Therapeutic area
·Diseases [C] - Cancer [C04]
·Diseases [C] - Hemic and Lymphatic Diseases [C15]

Investigated Disease
Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL)

Scientific Title
A Phase 1b/2, Open-Label, Multicenter Study to Evaluate the Safety and Pharmacokinetics of a Modified

Tafasitamab IV Dosing Regimen Combined with Lenalidomide (LEN) in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL) (MINDway)

Rationale

Not provided

Main Objective

To evaluate the safety and tolerability of tafasitamab administered once every 2 weeks (Q2W)/once every 4 weeks (Q4W) in combination with lenalidomide in R/R DLBCL patients
To determine a recommended dose for tafasitamab Q2W/Q4W administration in combination with lenalidomide in R/R DLBCL patients

Primary Endpoints

Incidence and severity of TEAEs (TEAE, treatment-emergent adverse event)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the pharmacokinetic profile of tafasitamab after Q2W/Q4W dosing in combination with lenalidomide To assess anti-tumor activity of tafasitamab after Q2W/Q4W dosing in combination with lenalidomide To assess the incidence of anti-drug antibodies to tafasitamab

Secondary Endpoints

Tafasitamab serum concentrations after 3 (Ctrough and Cmax) and 12 (Ctrough) treatment cycles
Best Objective Response Rate (ORR) by Investigator assessment up to treatment Cycle 12 based on Cheson et al. (2007)
Duration of Response (DoR) by Investigator assessment based on Cheson et al. (2007)
Progression-Free Survival (PFS) by Investigator assessment based on Cheson et al. (2007)
Number and percentage of patients developing anti- tafasitamab antibodies up to treatment Cycle 12

Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Capable of giving signed informed consent as described in Appendix 2: Regulatory, Ethical, and Trial Oversight Considerations, which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol. 2. Patient must be at least 18 years of age and of legal age (whichever is higher) in the jurisdiction in which the study is taking place at the time of signing the informed consent. 3. One of the following histologically confirmed diagnoses: DLBCL not otherwise specified (NOS) T cell/histiocyte-rich large B-cell lymphoma (THRLBCL) Epstein-Barr virus (EBV) positive DLBCL of the elderly (EBV-positive DLBCL) Grade 3b Follicular Lymphoma Composite lymphoma with a DLBCL component with a subsequent DLBCL relapse, according to the Revised European American Lymphoma/World Health Organization (REAL/WHO) classification. Additionally, patients with the evidence of histological transformation to DLBCL from an earlier diagnosis of low-grade lymphoma (i.e., an indolent pathology such as follicular lymphoma, marginal zone lymphoma, chronic lymphocytic leukemia) into DLBCL with a subsequent DLBCL relapse are also eligible. 4. Tumor tissue for retrospective central pathology review must be provided as an adjunct to participation in this study. If archival formalin fixed paraffin embedded tumor tissue acquired 3 years prior to screening is not available, a fresh tumor tissue sample from the patient should be obtained. Archival formalin fixed- paraffin embedded tumor tissue acquired >3 years prior to screening is acceptable only in cases where a fresh tumor biopsy cannot be collected due to a safety risk, e.g., due to co-morbidity, or inaccessible tumor site. 5. Patients must have:a. Relapsed and/or refractory disease as defined in Appendix 3: Study Specific Definitions b. 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Disease not responsive to salvage chemotherapy. Responsiveness is defined as a tumor demonstrating either complete response (CR) or partial response (PR) to salvage chemotherapy c. Inadequate major organ function (any of the below): i. symptomatic congestive heart failure ii. lung function-forced vital capacity (FVC), forced expiratory volume in 1 second (FEV-1), and corrected diffusion capacity of the lung for carbon monoxide (DLCO) 60% iii. liver function-total serum bilirubin and transaminases > 2 x upper limit of normal (ULN) d. History or evidence of significant co-morbid medical or psychiatric illness which would significantly compromise the patients clinical care and chances of survival e.Inability to collect adequate stem cell graft (e.g. < 12 x 106 CD34+ cells free of tumor contamination/kg recipient body weight) 7. Patients must meet the following laboratory criteria at screening: a. 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1. General provisions: a. Patients who are legally institutionalized, or patients under judicial protection b. Concurrent enrollment in another interventional clinical study 2. Patients who have: a. Any other histological type of lymphoma

including primary mediastinal (thymic) large B-cell (PMBL) or Burkitt lymphoma b. Known double/triple hit genetics (high grade B-cell lymphoma) characterized by simultaneous detection of MYC with BCL2 and/or BCL6 translocation(s) defined by fluorescence in situ hybridization. MYC, BCL2, BCL6 testing prior to study enrollment is not required 3. Patients who have: a. Not discontinued (within 14 days prior to Day 1 dosing): CD20 targeted therapy, chemotherapy, radiotherapy, investigational anticancer therapy or other lymphoma-specific therapy b. Undergone major surgery (within 4 weeks prior to Day 1 dosing) or suffered from significant traumatic injury c. Received live vaccines (within 4 weeks prior to Day 1 dosing) (See Appendix 7: Covid-19: Infection Prophylaxis and Vaccines) d. Required parenteral antimicrobial therapy for active, intercurrent infections (within 14 days prior to Day 1 dosing) 4. Patients who: a.Have, in the opinion of the investigator, not recovered sufficiently from the adverse toxic effects of prior therapies b. Were previously treated with tafasitamab or IMiDs® (e.g., thalidomide, LEN) c. Have a history of hypersensitivity to compounds of similar biological or chemical composition to tafasitamab, IMiDs® and/or the excipients contained in the study treatment formulations d. Have undergone ASCT within the period 3 months prior to signing the ICF. Patients who have a more distant history of ASCT must exhibit full hematological recovery before enrollment into the study e. Have undergone previous allogenic stem cell transplantation f.Have a history of deep venous thrombosis/embolism, threatening thromboembolism or known thrombophilia or are at high risk for a thromboembolic event in the opinion of the investigator and who are not willing/able to take venous thromboembolism (VTE) prophylaxis during the entire treatment period g. Concurrently use other anticancer or experimental treatments 5. History of other malignancy that could affect compliance with the protocol or interpretation of results. Exceptions:a. Patients with any malignancy appropriately treated with curative intent and the malignancy has been in remission without treatment for > 2 years prior to enrollment are eligible b. Patients with low-grade, early-stage prostate cancer (Gleason score 6 or below, Stage 1 or 2) with no requirement for therapy at any time prior to study are eligible 6. Patients with: a. Positive hepatitis B and/or C serology (see Appendix 8: Hepatitis Virus Serology for details) b. Known seropositivity for or history of active viral infection with human immunodeficiency virus (HIV) c.Central nervous system (CNS) lymphoma involvement present or past medical history d. History or evidence of clinically significant cardiovascular, CNS and/or other systemic disease that would in the investigators opinion preclude participation in the study or compromise the patients ability to give informed consent e. History or evidence of rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption f. Gastrointestinal (GI) abnormalities (issue with absorption) including the inability to take oral medication g. History or evidence of severe hepatic impairment (total serum bilirubin > 3 mg/dL), jaundice unless secondary to Gilberts syndrome or documented liver involvement by lymphoma (see inclusion criterion 7c) h. History of hypersensitivity to any of the study treatments or its excipients or to drugs of similar chemical class i. Any other medical condition which, in the investigators opinion, makes the patient unsuitable for the study 7. Contraception provisions: Females: Due to the teratogenic potential of LEN, FCBP must follow the rules listed below (otherwise excluded): a. Not be pregnant as confirmed by a negative serum pregnancy test at screening and a medically supervised urine pregnancy test prior to starting study therapy b. Refrain from breast feeding and donating oocytes during the study and for 3 months after the last dose of study drug or according to local guidelines for LEN, whichever is longer c. Agree to ongoing pregnancy testing during the course of the study, and after study treatment has ended. This includes pregnancy testing and counseling if a patient misses her period or if there is any abnormality in her menstrual bleeding and applies even if the patient practices complete sexual abstinence d. Commit to continued abstinence from heterosexual intercourse if it is in accordance with her lifestyle (which must be reviewed on a monthly basis) or agree to use and be able to comply with the use of highly effective contraception without interruption at least 4 weeks prior to start of study drugs, during the study treatment and for 3 months after the last dose of study drug, or, for LEN, according to the local guidelines, whichever is longer. 8. Due to the teratogenic potential of lenalidomide, male participants must follow the rules listed below (otherwise excluded):a. Use an effective barrier method of contraception without interruption if the patient is sexually active with a FCBP. Male patients should refrain from donating sperm during the study participation and for 3 months after the last dose of study treatment, or according to the local guidelines for LEN, whichever is longer.

Calendar

(Last Update: 22/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
09/03/2022	06/04/2022	26/09/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
04/01/2024	Not aported	Not aported	13/05/2026	Not aported

Sponsor

Incyte Corp. United States

1801 Augustine Cut Off

Contact Person

Medical Information

+4989899270

medinfo@morphosys.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc Tauli

Plaça de la Torre de lAigua, s/n 08208 Sabadell

ceic@tauli.cat

937458454-937458451

Sites

Closed (07/02/2025)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

Closed (14/06/2024)

Complejo Hospitalario Infanta Leonor

Madrid

MADRID

Closed (13/03/2025)

HOSPITAL MD ANDERSON CANCER CENTER MADRID

Madrid

MADRID

Closed (23/07/2024)

HOSPITAL SON LLATZER

Palma

BALEARES

Closed (20/03/2025)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Active (25/05/2022)

HOSPITAL UNIVERSITARIO QUIRONSALUD MADRID

Pozuelo de Alarcón

MADRID

Closed (20/01/2025)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Closed (17/06/2024)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Closed (02/04/2025)

HOSPITAL UNIVERSITARIO Y POLITECNICO LA FE

València

VALENCIA

Closed (22/01/2026)

Institut Catala D´oncologia

Girona

GERONA

n/a

Closed (13/03/2025)

MD Anderson Cancer Center

Madrid

MADRID

n/a

Medication

Zelvina 10 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

MINJUVI 200 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

ATC code: L01FX12 - TAFASITAMAB
Active Principles: N/A

Orphan

Experimental

Zelvina 25 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

Zelvina 5 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX04 - LENALIDOMIDA
Active Principles: N/A

Experimental

No results