This study is to evaluate the safety and tolerability of Epcoritamab in Combination with Anti-Neoplastic Agents in Subjects with Non-Hodgkin Lymphoma

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	74
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, farmacogenómica	NO

Información

Identificador
2023-505347-38-00 (CTIS)

Cod. Protocolo
M22-132

Transicionado 2021-005725-24

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

Enfermedad investigada
B-cell Non-Hodgkin's lymphoma, diffuse large B-cell lymphoma

Título Científico
Phase 1b/2, Open-Label Study to Evaluate Safety and Tolerability of Epcoritamab in Combination with Anti-Neoplastic Agents in Subjects with Non-Hodgkin Lymphoma

Justificación

No aportado

Objetivo Principal

The primary objectives of the study are to characterize the safety, toxicity and tolerability profiles of epcoritamab when co-administered with anti-neoplastic agents in subjects with B-cell NHL and to determine the recommended dose for further investigation of epcoritamab when co-administered with anti-neoplastic agents in subjects with B-cell NHL.

Variables de Evaluación Primaria

The primary endpoint is DLTs of epcoritamab in combination with antineoplastic agents.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the anti-NHL activity of epcoritamab when given in combination with anti-neoplastic agents in subjects with B-cell NHL.
To characterize the pharmacokinetics of epcoritamab when given in combination with anti-neoplastic agents in subjects with B-cell NHL.

Variables de Evaluación Secundaria

Best overall response (BOR) by Lugano 2014 criteria as assessed by investigator for epcoritamab in combination with other antineoplastic agents.
Antilymphoma activity of epcoritamab in combination with other antineoplastic agents: - Duration of response determined per Lugano 2014 criteria as assessed by investigator. - Progression free survival determined per Lugano 2014 criteria as assessed by investigator. - Complete response during the study determined per Lugano 2014 criteria as assessed by investigator. - Time to response determined per Lugano 2014 criteria as assessed by investigator. - Time to next antilymphoma therapy.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Adult male or female, at least 18 years old (Arms 1, 2, 3, and 4) Diagnosis of DLBCL (de novo or histologically transformed from follicular lymphoma or nodal marginal zone lymphoma) with histologically confirmed CD20+ disease, inclusive of the following according to WHO 2016 classification and documented in pathology report: DLBCL, not otherwise specified (NOS) - High-grade B cell lymphoma with MYC and BCL-2 and/or BCL-6 translocations per World Health Organization (WHO) 2016 ("double-hit" or "triple-hit") Note: High-grade B-cell lymphomas NOS or other double-/triple-hit lymphomas (with histologies not consistent with DLBCL) are not eligible - FL Grade 3B OR FL with histologically confirmed CD20+ Grade 1 to 3a and no evidence of histologic transformation to an aggressive lymphoma at most recent representative tumor biopsy, according to WHO 2016 classification. OR MCL with histologically confirmed CD20+ disease at most recent representative tumor biopsy according to the WHO 2016 classification with evidence of overexpression of cyclin D1 in association with relevant markers or evidence of t(11;14) assessed by flow cytometry, FISH, or PCR Subject must have Eastern Cooperative Oncology Group (ECOG) performance status 0 2, except for Arms 6, 7 and 8where ECOG performance status must be 0-1 Subject must have 1 or more measurable disease sites: A positron emission tomography/computed tomography (PET/CT) scan demonstrating PET-positive lesion(s) AND - At least 1 measurable nodal lesion (long axis > 1.5 cm) or 1 measurable extra-nodal lesion (long axis > 1.0 cm) on CT scan or MRI

Criterios de Exclusión

Diagnosis of High-grade B-cell lymphomas NOS or other double- /triple-hit lymphomas (with histologies not consistent with DLBCL)
Subjects who have had prior treatment with epcoritamab or any other bispecific antibody targeting CD3 and CD20

Calendario

(Última actualización: 27/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
25/04/2022	25/04/2022	14/06/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
08/06/2026	No aportado	No aportado	No aportado	No aportado

Promotor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinial Trial Helpdesk

+4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario La Paz

Paseo de la Castellana, 261 28046 Madrid

ceic.hulp@salud.madrid.org

917277413

Centros

Activo (13/06/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

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

Clinica Universidad De Navarra

Madrid

MADRID

NA

Activo (11/10/2022)

Complejo Asistencial Universitario De Salamanca

Salamanca

SALAMANCA

Servicio de Hematología

Activo (23/08/2022)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

Servicio de Hematología

Activo (29/06/2022)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematología

Activo (09/02/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Servicio de Hematología

Activo (22/09/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Servicio de Hematología

Activo (18/07/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

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

Institut Catala D´oncologia

Badalona

BARCELONA

NA

Activo (13/10/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Activo (09/01/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología

Medicamentos

Revlimid 25 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Truxima 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

Adriblastin® 50 mg Stechampulle
SOLUTION FOR INJECTION
INTRAVENOUS

Código ATC: L01DB01 - DOXORUBICINA
Principios Activos: N/A

Experimental

Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

IMBRUVICA 140 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L01EL01 - IBRUTINIB
Principios Activos: N/A

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Huérfano

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-

Principios Activos: N/A

Experimental

IMBRUVICA 140 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L01EL01 - IBRUTINIB
Principios Activos: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

Decortin® H 20 mg Tabletten
TABLET
ORAL

Código ATC: H02AB06 - PREDNISOLONA
Principios Activos: N/A

Experimental

Golcadomide
CAPSULE
ORAL

-
Principios Activos: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-
Principios Activos: N/A

Experimental

Decortin® H 5 mg Tabletten
TABLET
ORAL

Código ATC: H02AB06 - PREDNISOLONA
Principios Activos: N/A

Experimental

Truxima 100 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

PIRTOBRUTINIB
FILM-COATED TABLET
ORAL

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

-

Principios Activos: N/A

Experimental

Cyclophosphamide Injection 500 mg.

SOLUTION FOR INJECTION
INTRAVENOUS

Código ATC: L01AA01 - CICLOFOSFAMIDA
Principios Activos: N/A

Experimental

Revlimid 20 mg hard capsules

CAPSULE, HARD
ORAL

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

Experimental

Polivy 30 mg powder for concentrate for solution for infusion.

SOLUTION FOR INFUSION
INTRAVENOUS

Código ATC: L01FX14 - POLATUZUMAB VEDOTINA
Principios Activos: N/A

Experimental

Epcoritamab (GEN3013)

SOLUTION FOR INJECTION
SUBCUTANEOUS

-

Principios Activos: N/A

Huérfano

Experimental

Sin resultados

This study is to evaluate the safety and tolerability of Epcoritamab in Combination with Anti-Neoplastic Agents in Subjects with Non-Hodgkin Lymphoma

State	Type of participants	Age Ranges
End of recruitment	Not provided	Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	74
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, pharmacogenomics	NO

Information

Identifier
2023-505347-38-00 (CTIS)

Protocol Code
M22-132

Transitioned 2021-005725-24

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

Investigated Disease
B-cell Non-Hodgkin's lymphoma, diffuse large B-cell lymphoma

Scientific Title
Phase 1b/2, Open-Label Study to Evaluate Safety and Tolerability of Epcoritamab in Combination with Anti-Neoplastic Agents in Subjects with Non-Hodgkin Lymphoma

Rationale

Not provided

Main Objective

The primary objectives of the study are to characterize the safety, toxicity and tolerability profiles of epcoritamab when co-administered with anti-neoplastic agents in subjects with B-cell NHL and to determine the recommended dose for further investigation of epcoritamab when co-administered with anti-neoplastic agents in subjects with B-cell NHL.

Primary Endpoints

The primary endpoint is DLTs of epcoritamab in combination with antineoplastic agents.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the anti-NHL activity of epcoritamab when given in combination with anti-neoplastic agents in subjects with B-cell NHL.
To characterize the pharmacokinetics of epcoritamab when given in combination with anti-neoplastic agents in subjects with B-cell NHL.

Secondary Endpoints

Best overall response (BOR) by Lugano 2014 criteria as assessed by investigator for epcoritamab in combination with other antineoplastic agents.
Antilymphoma activity of epcoritamab in combination with other antineoplastic agents: - Duration of response determined per Lugano 2014 criteria as assessed by investigator. - Progression free survival determined per Lugano 2014 criteria as assessed by investigator. - Complete response during the study determined per Lugano 2014 criteria as assessed by investigator. - Time to response determined per Lugano 2014 criteria as assessed by investigator. - Time to next antilymphoma therapy.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Adult male or female, at least 18 years old (Arms 1, 2, 3, and 4) Diagnosis of DLBCL (de novo or histologically transformed from follicular lymphoma or nodal marginal zone lymphoma) with histologically confirmed CD20+ disease, inclusive of the following according to WHO 2016 classification and documented in pathology report: DLBCL, not otherwise specified (NOS) - High-grade B cell lymphoma with MYC and BCL-2 and/or BCL-6 translocations per World Health Organization (WHO) 2016 ("double-hit" or "triple-hit") Note: High-grade B-cell lymphomas NOS or other double-/triple-hit lymphomas (with histologies not consistent with DLBCL) are not eligible - FL Grade 3B OR FL with histologically confirmed CD20+ Grade 1 to 3a and no evidence of histologic transformation to an aggressive lymphoma at most recent representative tumor biopsy, according to WHO 2016 classification. OR MCL with histologically confirmed CD20+ disease at most recent representative tumor biopsy according to the WHO 2016 classification with evidence of overexpression of cyclin D1 in association with relevant markers or evidence of t(11;14) assessed by flow cytometry, FISH, or PCR Subject must have Eastern Cooperative Oncology Group (ECOG) performance status 0 2, except for Arms 6, 7 and 8where ECOG performance status must be 0-1 Subject must have 1 or more measurable disease sites: A positron emission tomography/computed tomography (PET/CT) scan demonstrating PET-positive lesion(s) AND - At least 1 measurable nodal lesion (long axis > 1.5 cm) or 1 measurable extra-nodal lesion (long axis > 1.0 cm) on CT scan or MRI

Exclusion criteria

Diagnosis of High-grade B-cell lymphomas NOS or other double- /triple-hit lymphomas (with histologies not consistent with DLBCL)
Subjects who have had prior treatment with epcoritamab or any other bispecific antibody targeting CD3 and CD20

Calendar

(Last Update: 27/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
25/04/2022	25/04/2022	14/06/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
08/06/2026	Not aported	Not aported	Not aported	Not aported

Sponsor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinial Trial Helpdesk

+4961117201520

global-clinical-trials@abbvie.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitario La Paz

Paseo de la Castellana, 261 28046 Madrid

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Sites

Active (13/06/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

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

Clinica Universidad De Navarra

Madrid

MADRID

NA

Active (11/10/2022)

Complejo Asistencial Universitario De Salamanca

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SALAMANCA

Servicio de Hematología

Active (23/08/2022)

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València

VALENCIA

Servicio de Hematología

Active (29/06/2022)

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Barcelona

BARCELONA

Servicio de Hematología

Active (09/02/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Servicio de Hematología

Active (22/09/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Servicio de Hematología

Active (18/07/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

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

Institut Catala D´oncologia

Badalona

BARCELONA

NA

Active (13/10/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Active (09/01/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología

Medication

Revlimid 25 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Truxima 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01FA01 - RITUXIMAB
Active Principles: N/A

Experimental

Adriblastin® 50 mg Stechampulle
SOLUTION FOR INJECTION
INTRAVENOUS

ATC code: L01DB01 - DOXORUBICINA
Active Principles: N/A

Experimental

Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

IMBRUVICA 140 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L01EL01 - IBRUTINIB
Active Principles: N/A

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Active Principles: N/A

Orphan

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-

Active Principles: N/A

Experimental

IMBRUVICA 140 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L01EL01 - IBRUTINIB
Active Principles: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-
Active Principles: N/A

Experimental

Decortin® H 20 mg Tabletten
TABLET
ORAL

ATC code: H02AB06 - PREDNISOLONA
Active Principles: N/A

Experimental

Golcadomide
CAPSULE
ORAL

-
Active Principles: N/A

Experimental

Venetoclax
FILM-COATED TABLET
ORAL

-
Active Principles: N/A

Experimental

Decortin® H 5 mg Tabletten
TABLET
ORAL

ATC code: H02AB06 - PREDNISOLONA
Active Principles: N/A

Experimental

Truxima 100 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

PIRTOBRUTINIB
FILM-COATED TABLET
ORAL

ATC code: L01FA01 - RITUXIMAB
Active Principles: N/A
Experimental

-
Active Principles: N/A
Experimental

Cyclophosphamide Injection 500 mg.
SOLUTION FOR INJECTION
INTRAVENOUS

ATC code: L01AA01 - CICLOFOSFAMIDA
Active Principles: N/A
Experimental

Revlimid 20 mg hard capsules
CAPSULE, HARD
ORAL

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

Polivy 30 mg powder for concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS

ATC code: L01FX14 - POLATUZUMAB VEDOTINA
Active Principles: N/A
Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Active Principles: N/A
Orphan
Experimental

No results