This study is to find out about the Safety and Efficacy of Epcoritamab in Combination with Rituximab and Lenalidomide (R2) compared to R2 in Subjects with Relapsed or Refractory Follicular Lymphoma

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	263
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2023-505628-67-00 (CTIS)

Cod. Protocolo
M20-638

Transicionado 2021-000169-34

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

Enfermedad investigada
Relapsed and Refractory Follicular Lymphoma

Título Científico
A Phase 3, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with Rituximab and Lenalidomide (R2) compared to R2 in Subjects with Relapsed or Refractory Follicular Lymphoma (EPCORE FL-1)

Justificación

No aportado

Objetivo Principal

The primary objective of this study is to evaluate the efficacy, safety, and tolerability of epcoritamab in combination with lenalidomide and rituximab (R2) compared to R2 alone in participants with relapsed or refractory (R/R) follicular lymphoma (FL).

Variables de Evaluación Primaria

Progression-Free Survival (PFS)
Best overall response (BOR) of CR or PR, determined by Lugano criteria (Appendix F), as assessed by an Independent Review Committee (IRC)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

The secondary objective of this study is to evaluate whether epcoritamab in combination with R2 compared to R2 alone can improve clinical outcomes as measured by key secondary endpoints (including complete response [CR], overall survival [OS], and minimal residual disease [MRD] negativity) in participants with R/R FL.

Variables de Evaluación Secundaria

Percentage of Participants Achieving Complete Response (CR)
Overall Survival (OS)
Percentage of Participants Achieving Minimal Residual Disease (MRD) Negativity
Changes from baseline in Functional Assessment of Cancer Therapy Lymphoma (FACT-Lym).
PFS, BOR, and CR during the study, determined per Lugano criteria as assessed by investigator.
Duration of response (DOR), duration of complete response (DOCR), time to progression (TTP), and CR at the end of treatment (12 cycles), time to response (TTR), time to complete response (TTCR), per Lugano criteria as assessed by an IRC and by the investigator, respectively.
Event-Free Survival (EFS), defined as the duration from randomization to the date of any of the following (whichever occurs first): Disease progression determined by Lugano criteria as assessed by the investigator Initiation of any non-protocol-specified new anti lymphoma therapy for any reason Death
Time to next anti-lymphoma treatment (TTNLT).
Changes from baseline in Patient-Reported Outcome Instruments (PROs; including Patient Global Impression of Severity [PGIS], Patient Global Impression of Change [PGIC], and EuroQol 5 dimension questionnaire, 5 level [EQ 5D 5L]).

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Eastern Cooperative Oncology Group (ECOG) performance status score 0 to 2. Participant has: Fluorodeoxyglucose-positron emission tomography (FDG-PET) scan demonstrating positive lesion compatible with computed tomography (CT) or magnetic resonance image (MRI)-defined anatomical tumor sites AND >= 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. Histologically confirmed classic follicular lymphoma (FL) [previously Grade 1 to 3a FL] stage II, III, or IV with no evidence of histologic transformation to an aggressive lymphoma and CD20+ disease on most recent representative tumor biopsy based on the pathology report. Relapsed or refractory (R/R) disease to at least one prior systemic regimen that contained an anti-CD20 monoclonal antibody (mAb) in combination with chemotherapy. (Participant who received only prior anti-CD20 mAb monotherapy and/or radiation therapy is not eligible.) Eligible to receive R2 per investigator determination.

Criterios de Exclusión

Documented refractoriness to lenalidomide.
Have lenalidomide exposure within 12 months prior to randomization.

Calendario

(Última actualización: 01/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
22/09/2022	08/11/2022	14/12/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
04/06/2024	No aportado	No aportado	No aportado	No aportado

Promotor

AbbVie Deutschland GmbH & Co. KG Germany

Knollstrasse

Contact Person

Global Clinial Trial Helpdesk

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global-clinical-trials@abbvie.com

Monetary support: N/A

Tipo de promotor: Comercial

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CEIm Provincial de Sevilla

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Centros

Activo (30/11/2022)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

Activo (01/12/2022)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (08/11/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASIST. UNIVERSIT.SA)

Salamanca

SALAMANCA

Servicio de Hematología

Activo (09/12/2022)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Servicio de Hematología

Activo (20/06/2023)

HOSPITAL DEL MAR.

Barcelona

BARCELONA

Servicio de Hematología

Activo (18/09/2023)

HOSPITAL MD ANDERSON CANCER CENTER MADRID

Madrid

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Servicio de Hematología

Activo (19/06/2023)

HOSPITAL SAN PEDRO DE ALCANTARA

Cáceres

CÁCERES

Servicio de Hematología

Activo (09/01/2026)

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Hematology

Activo (04/10/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Servicio de Hematología

Activo (23/06/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Servicio de Hematología

Activo (02/02/2023)

HOSPITAL UNIVERSITARIO MARQUES DE VALDECILLA

Santander

CANTABRIA

Servicio de Hematología

Activo (09/01/2026)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (21/11/2022)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

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Servicio de Hematología

Activo (15/11/2022)

Hospital Universitario Reina Sofia

Córdoba

CÓRDOBA

Servicio de Hematología

Activo (28/12/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Servicio de Hematología

Activo (24/11/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

Activo (09/01/2026)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Activo (26/09/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Medicamentos

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

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

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Huérfano

Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-

Principios Activos: N/A

Huérfano

Experimental

Revlimid 20 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
INTRAVENIOUS INFUSION

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

Experimental

Sin resultados

This study is to find out about the Safety and Efficacy of Epcoritamab in Combination with Rituximab and Lenalidomide (R2) compared to R2 in Subjects with Relapsed or Refractory Follicular Lymphoma

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	263
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2023-505628-67-00 (CTIS)

Protocol Code
M20-638

Transitioned 2021-000169-34

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

Investigated Disease
Relapsed and Refractory Follicular Lymphoma

Scientific Title
A Phase 3, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with Rituximab and Lenalidomide (R2) compared to R2 in Subjects with Relapsed or Refractory Follicular Lymphoma (EPCORE FL-1)

Rationale

Not provided

Main Objective

The primary objective of this study is to evaluate the efficacy, safety, and tolerability of epcoritamab in combination with lenalidomide and rituximab (R2) compared to R2 alone in participants with relapsed or refractory (R/R) follicular lymphoma (FL).

Primary Endpoints

Progression-Free Survival (PFS)
Best overall response (BOR) of CR or PR, determined by Lugano criteria (Appendix F), as assessed by an Independent Review Committee (IRC)

Temporary moments of secondary assessment

Not provided

Secondary Objective

The secondary objective of this study is to evaluate whether epcoritamab in combination with R2 compared to R2 alone can improve clinical outcomes as measured by key secondary endpoints (including complete response [CR], overall survival [OS], and minimal residual disease [MRD] negativity) in participants with R/R FL.

Secondary Endpoints

Percentage of Participants Achieving Complete Response (CR)
Overall Survival (OS)
Percentage of Participants Achieving Minimal Residual Disease (MRD) Negativity
Changes from baseline in Functional Assessment of Cancer Therapy Lymphoma (FACT-Lym).
PFS, BOR, and CR during the study, determined per Lugano criteria as assessed by investigator.
Duration of response (DOR), duration of complete response (DOCR), time to progression (TTP), and CR at the end of treatment (12 cycles), time to response (TTR), time to complete response (TTCR), per Lugano criteria as assessed by an IRC and by the investigator, respectively.
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Time to next anti-lymphoma treatment (TTNLT).
Changes from baseline in Patient-Reported Outcome Instruments (PROs; including Patient Global Impression of Severity [PGIS], Patient Global Impression of Change [PGIC], and EuroQol 5 dimension questionnaire, 5 level [EQ 5D 5L]).

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Eastern Cooperative Oncology Group (ECOG) performance status score 0 to 2. Participant has: Fluorodeoxyglucose-positron emission tomography (FDG-PET) scan demonstrating positive lesion compatible with computed tomography (CT) or magnetic resonance image (MRI)-defined anatomical tumor sites AND >= 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. Histologically confirmed classic follicular lymphoma (FL) [previously Grade 1 to 3a FL] stage II, III, or IV with no evidence of histologic transformation to an aggressive lymphoma and CD20+ disease on most recent representative tumor biopsy based on the pathology report. Relapsed or refractory (R/R) disease to at least one prior systemic regimen that contained an anti-CD20 monoclonal antibody (mAb) in combination with chemotherapy. (Participant who received only prior anti-CD20 mAb monotherapy and/or radiation therapy is not eligible.) Eligible to receive R2 per investigator determination.

Exclusion criteria

Documented refractoriness to lenalidomide.
Have lenalidomide exposure within 12 months prior to randomization.

Calendar

(Last Update: 01/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
22/09/2022	08/11/2022	14/12/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
04/06/2024	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

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Sites

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Active (26/09/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Medication

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

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

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A

Orphan
Experimental

Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A

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Experimental

Revlimid 20 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
INTRAVENIOUS INFUSION

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

Experimental

No results