This study is to find out the safety and effectiveness of Epcoritamab together with R-CHOP (rituximab, cyclophosphamide, doxorubicin HCL, vincristine, and prednisone) compared to only R-CHOP in subjects with newly diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

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	542
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2023-505277-32-00 (CTIS)

Cod. Protocolo
M20-621

Transicionado 2021-000168-31

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

Enfermedad investigada
Diffuse Large B-Cell Lymphoma (DLBCL)

Título Científico
A Phase 3, Randomized, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with R-CHOP Compared to R-CHOP in Subjects with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

(EPCORE DLBCL-2)

Justificación

No aportado

Objetivo Principal

The primary objective of this study is to evaluate whether the addition of epcoritamab to 6 cycles of standard R-CHOP followed by 2 cycles of epcoritamab can prolong progression-free survival (PFS) compared with 6 cycles of standard R-CHOP alone followed by 2 cycles of rituximab in subjects with newly diagnosed DLBCL with an IPI of 3-5.

Variables de Evaluación Primaria

The primary endpoint is PFS defined as the duration from the date of randomization to the date of any of the following (whichever occurs first). The primary analysis population is the subset of subjects with an IPI of 3-5
Death due to any causes.
Disease progression based on the independent review committee (IRC) assessment per Lugano criteria.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

The first secondary objective is to evaluate and compare PFS between the two treatment arms in subjects with newly diagnosed DLBCL with an IPI of 2-5 (i.e., all randomized subjects). The other secondary objectives are to evaluate and compare each key secondary endpoint for both the subset of subjects with an IPI of 3-5 and all randomized subjects per the hierarchical order specified in protocol Section 7.7.

Variables de Evaluación Secundaria

PFS in all randomized subjects.
CR on or after the EOT based on the IRC assessment per Lugano criteria, where EOT is defined as treatment completion or early treatment discontinuation.
OS, defined as time from randomization until death due to any causes.
MRD negativity.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Age 18 years old and < 80 years old, with a life expectancy of 12 months. Subject is planned to receive treatment with 6 cycles of standard R CHOP per investigator determination. Subject must have an IPI score of 2-5. The number of subjects with an IPI 2 of will not exceed approximately 30% of the overall sample size.

Criterios de Exclusión

Subject with history of prior systemic anti-lymphoma therapy for DLBCL (including any definitive radiotherapy with curative intent) other than corticosteroids with or without vincristine during pre-phase treatment, or non-curative intent palliative radiotherapy with the stipulation that radiated lesions cannot be selected as target lesion for response assessment. Subject has clinically significant cardiovascular disease, including: Myocardial infarction or stroke within 6 months prior to enrollment. OR The following conditions within 3 months prior to enrollment: unstable or uncontrolled disease/condition related to or affecting cardiac function (e.g., unstable angina, congestive heart failure, New York Heart Association Class III IV), uncontrolled cardiac arrhythmia OR Screening 12-lead electrocardiogram showing a baseline QT interval as corrected by Fridericia's formula > 470 msec (male) or > 480 msec (female) OR Other clinically significant ECG abnormalities within 6 months prior to enrollment unless deemed stable and appropriately treated.

Calendario

(Última actualización: 01/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
15/12/2022	26/01/2023	08/02/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
15/05/2024	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 Provincial de Sevilla

Avenida Doctor Fedriani 3 41009 Sevilla

administracion.eecc.hvm.sspa@juntadeandalucia.es

955043127

Centros

Activo (07/03/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

Activo (06/02/2023)

Clinica Universidad De Navarra

Madrid

MADRID

N/A

Cerrado (21/10/2024)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Servicio de Hematología

Activo (04/04/2023)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

Servicio de Hematología

Activo (04/03/2024)

Hospital Clínico Universitario Virgen De La Arrixaca

Murcia

MURCIA

Onco Hematología

Activo (26/01/2023)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Servicio de Hematología

Activo (25/05/2023)

HOSPITAL DEL MAR.

Barcelona

BARCELONA

Servicio de Hematología

Activo (13/09/2023)

HOSPITAL MD ANDERSON CANCER CENTER MADRID

Madrid

MADRID

Servicio de Hematología

Activo (13/06/2023)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Servicio de Hematología

Activo (26/06/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Servicio de Hematología

Activo (21/02/2023)

HOSPITAL UNIVERSITARIO INFANTA LEONOR

Madrid

MADRID

Servicio de Hematología

Activo (02/03/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Servicio de Hematología

Activo (23/02/2023)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Servicio de Hematología

Activo (08/03/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

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

Institut Catala D'oncologia

Badalona

BARCELONA

N/A

Activo (19/12/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Activo (20/11/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología

Medicamentos

Cyclophosphamide Injection 500 mg.
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

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

Experimental

Vincristine Sulfate 1 mg/ml solution for injection
SOLUTION FOR INJECTION
INTRAVENOUS INFUSION

Código ATC: L01CA02 - VINCRISTINA
Principios Activos: N/A

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Principios Activos: N/A

Huérfano
Experimental

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

Código ATC: L01FA01 - RITUXIMAB
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

Doxorubicinhydrochlorid Bendalis 2 mg/ml Injektionslösung
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

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

Experimental

Prednisone Zentiva 5 mg compresse
TABLET
ORAL

Código ATC: H02AB07 - PREDNISONA
Principios Activos: N/A

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Principios Activos: N/A

Huérfano
Experimental

Sin resultados

This study is to find out the safety and effectiveness of Epcoritamab together with R-CHOP (rituximab, cyclophosphamide, doxorubicin HCL, vincristine, and prednisone) compared to only R-CHOP in subjects with newly diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

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	542
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
2023-505277-32-00 (CTIS)

Protocol Code
M20-621

Transitioned 2021-000168-31

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

Investigated Disease
Diffuse Large B-Cell Lymphoma (DLBCL)

Scientific Title
A Phase 3, Randomized, Open-Label Study to Evaluate Safety and Efficacy of Epcoritamab in Combination with R-CHOP Compared to R-CHOP in Subjects with Newly Diagnosed Diffuse Large B-Cell Lymphoma (DLBCL)

(EPCORE DLBCL-2)

Rationale

Not provided

Main Objective

The primary objective of this study is to evaluate whether the addition of epcoritamab to 6 cycles of standard R-CHOP followed by 2 cycles of epcoritamab can prolong progression-free survival (PFS) compared with 6 cycles of standard R-CHOP alone followed by 2 cycles of rituximab in subjects with newly diagnosed DLBCL with an IPI of 3-5.

Primary Endpoints

The primary endpoint is PFS defined as the duration from the date of randomization to the date of any of the following (whichever occurs first). The primary analysis population is the subset of subjects with an IPI of 3-5
Death due to any causes.
Disease progression based on the independent review committee (IRC) assessment per Lugano criteria.

Temporary moments of secondary assessment

Not provided

Secondary Objective

The first secondary objective is to evaluate and compare PFS between the two treatment arms in subjects with newly diagnosed DLBCL with an IPI of 2-5 (i.e., all randomized subjects). The other secondary objectives are to evaluate and compare each key secondary endpoint for both the subset of subjects with an IPI of 3-5 and all randomized subjects per the hierarchical order specified in protocol Section 7.7.

Secondary Endpoints

PFS in all randomized subjects.
CR on or after the EOT based on the IRC assessment per Lugano criteria, where EOT is defined as treatment completion or early treatment discontinuation.
OS, defined as time from randomization until death due to any causes.
MRD negativity.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Age 18 years old and < 80 years old, with a life expectancy of 12 months. Subject is planned to receive treatment with 6 cycles of standard R CHOP per investigator determination. Subject must have an IPI score of 2-5. The number of subjects with an IPI 2 of will not exceed approximately 30% of the overall sample size.

Exclusion criteria

Subject with history of prior systemic anti-lymphoma therapy for DLBCL (including any definitive radiotherapy with curative intent) other than corticosteroids with or without vincristine during pre-phase treatment, or non-curative intent palliative radiotherapy with the stipulation that radiated lesions cannot be selected as target lesion for response assessment. Subject has clinically significant cardiovascular disease, including: Myocardial infarction or stroke within 6 months prior to enrollment. OR The following conditions within 3 months prior to enrollment: unstable or uncontrolled disease/condition related to or affecting cardiac function (e.g., unstable angina, congestive heart failure, New York Heart Association Class III IV), uncontrolled cardiac arrhythmia OR Screening 12-lead electrocardiogram showing a baseline QT interval as corrected by Fridericia's formula > 470 msec (male) or > 480 msec (female) OR Other clinically significant ECG abnormalities within 6 months prior to enrollment unless deemed stable and appropriately treated.

Calendar

(Last Update: 01/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
15/12/2022	26/01/2023	08/02/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
15/05/2024	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

Ceim

CEIm Provincial de Sevilla

Avenida Doctor Fedriani 3 41009 Sevilla

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955043127

Sites

Active (07/03/2023)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Servicio de Hematología

Active (06/02/2023)

Clinica Universidad De Navarra

Madrid

MADRID

N/A

Closed (21/10/2024)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Servicio de Hematología

Active (04/04/2023)

HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA

València

VALENCIA

Servicio de Hematología

Active (04/03/2024)

Hospital Clínico Universitario Virgen De La Arrixaca

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HOSPITAL DE LA SANTA CREU I SANT PAU

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Active (25/05/2023)

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Barcelona

BARCELONA

Servicio de Hematología

Active (13/09/2023)

HOSPITAL MD ANDERSON CANCER CENTER MADRID

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MADRID

Servicio de Hematología

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Servicio de Hematología

Active (21/02/2023)

HOSPITAL UNIVERSITARIO INFANTA LEONOR

Madrid

MADRID

Servicio de Hematología

Active (02/03/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

Servicio de Hematología

Active (23/02/2023)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Servicio de Hematología

Active (08/03/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Hematología

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

Institut Catala D'oncologia

Badalona

BARCELONA

N/A

Active (19/12/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Servicio de Hematología

Active (20/11/2023)

Institut Catala D'oncologia

Badalona

BARCELONA

Servicio de Hematología

Medication

Cyclophosphamide Injection 500 mg.
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

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

Experimental

Vincristine Sulfate 1 mg/ml solution for injection
SOLUTION FOR INJECTION
INTRAVENOUS INFUSION

ATC code: L01CA02 - VINCRISTINA
Active Principles: N/A

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A

Orphan
Experimental

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

ATC code: L01FA01 - RITUXIMAB
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

Doxorubicinhydrochlorid Bendalis 2 mg/ml Injektionslösung
SOLUTION FOR INJECTION
INTRAVENIOUS INFUSION

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

Experimental

Prednisone Zentiva 5 mg compresse
TABLET
ORAL

ATC code: H02AB07 - PREDNISONA
Active Principles: N/A

Experimental

Epcoritamab (GEN3013)
SOLUTION FOR INJECTION
SUBCUTANEOUS INJECTION

-
Active Principles: N/A

Orphan
Experimental

No results