EFFICACY AND SAFETY TRIAL OF EPCORITAMAB WITH OR WITHOUT LENALIDOMIDE AS FIRST LINE THERAPY FOR SUBJECTS WITH DIFFUSE LARGE B-CELL LYMPHOMA.

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	38
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
2023-504832-16-00 (CTIS)

Cod. Protocolo
No aportado

Transicionado 2021-005744-29

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

Enfermedad investigada
DIFFUSE LARGE B CELL LYMPHOMA

Título Científico
A Randomized, Open-Label, Multicenter, Global, Phase 2 Trial to Evaluate the Efficacy and Safety of Epcoritamab (GEN3013; DuoBody®-CD3×CD20) as Monotherapy or in Combination with Lenalidomide as First-Line Therapy for Anthracycline-Ineligible Subjects with Diffuse Large B-Cell Lymphoma

Justificación

No aportado

Objetivo Principal

Evaluate the clinical efficacy of epcoritamab monotherapy or epcoritamab and lenalidomide

Variables de Evaluación Primaria

Complete response (CR) rate determined by Lugano criteria

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Evaluate other efficacy measures of epcoritamab monotherapy or epcoritamab and lenalidomide
Evaluate safety and tolerability of epcoritamab monotherapy or epcoritamab and lenalidomide
Evaluate immunogenicity
Assess the pharmacokinetics of epcoritamab
Evaluate patient-reported outcomes related to lymphoma symptoms

Variables de Evaluación Secundaria

Duration of response (DOR) determined by Lugano criteria
Duration of complete response (DOCR) determined by Lugano criteria
Time to response (TTR) determined by Lugano criteria
Overall response rate (ORR) determined by Lugano criteria
Progression-free survival (PFS) determined by Lugano criteria
Time to next (anti-lymphoma) therapy (TTNT).
Rate and duration of minimal residual disease (MRD) negative status
Overall survival (OS)
Incidence of dose-limiting toxicities (DLTs)
Incidence and severity of adverse events (AEs)
Incidence and severity of changes in laboratory values
Incidence of antidrug antibodies (ADAs) to epcoritamab
PK parameters (clearance, volume of distribution, area under-the- concentration-time curve [AUC0-last and AUC0-], maximum concentration [Cmax], time of Cmax [Tmax], predose values, and halflife [t½])
Changes in lymphoma symptoms as measured by the Functional Assessment of Cancer Therapy Lymphoma (FACT-Lym)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Must have newly diagnosed CD20+ large cell lymphoma.
Is ineligible for anthracycline-based therapy/cytotoxic chemotherapy due to: oBeing age 80 years; AND/OR oBeing age 75 years and having important comorbid condition(s), which are likely to have a negative impact on tolerability of anthracycline-based therapy/cytotoxic chemotherapy, Have Immune Effector Cell-Associated Encephalopathy (ICE) score of at least 8 out of 10.
Have Ann Arbor Stage II-IV disease.
Have ECOG PS of 0, 1, or 2; (ECOG PS of 3 may be considered if impairment is attributed to current lymphoma/DLBCL and if pre-phase treatment during the screening phase results in an improvement of ECOG PS to 2 prior to enrollment.)
Have measurable disease as per Lugano criteria.
Have acceptable organ function based on baseline bloodwork.
Must have fresh (preferred) or archival biopsy material at screening.

Criterios de Exclusión

Has known active, clinically significant bacterial, viral, fungal, mycobacterial, parasitic, or other infection at trial enrollment, including COVID-19 infection.
Has suspected active or inadequately treated latent tuberculosis.
Has a known history of seropositivity for HIV. Note: HIV testing is required at screening only if required per local health authorities or institutional standards.
Has severe cardiovascular disease (other than those eligibility criteria that preclude the subject from receiving anthracycline-based therapy/cytotoxic chemotherapy).
Has been exposed to/received any of the following prior therapies, treatments, or procedures within the specified timeframes: oMajor surgery within 4 weeks prior to the first dose of epcoritamab; oNon-investigational antineoplastic agents or any investigational drug within 4 weeks or 5 half-lives, whichever is shorter, prior to the first dose of epcoritamab; oAutologous hematopoietic stem cell transplantation (HSCT), CAR-T, allogeneic stem cell transplantation, or solid organ transplantation; oLive, attenuated vaccines within 30 days prior to initiation of epcoritamab; oInvestigational vaccines within 28 days before the planned first dose of epcoritamab (ie, experimental and/or non-authorized SARS-CoV-2 vaccinations and therapies are not allowed); oInvasive investigational medical device use within 28 days before the planned first dose of epcoritamab.
Has primary central nervous system (CNS) tumor or known CNS involvement or intracranial involvement as confirmed by mandatory brain magnetic resonance imaging/computed tomography (MRI/CT) scan at screening and, if clinically indicated, by lumbar puncture.
Has a seizure disorder requiring anti-epileptic therapy or experienced a seizure within 6 months of signing an informed consent form.
Has known past or current malignancy other than inclusion diagnosis, with exceptions as stated in protocol.
Has known or suspected allergies, hypersensitivity, or intolerance to either of the trial treatments or has known or suspected contraindication to the use of all locally available anti-cytokine therapies per local guidelines for management of cytokine release syndrome (CRS).
Has active hepatitis B virus (HBV) (DNA polymerase chain reaction [PCR]-positive) or hepatitis C virus (HCV) (RNA PCR-positive) infection, current alcohol abuse, or cirrhosis.
Has active cytomegalovirus (CMV) infection (DNA PCR-positive) requiring treatment.

Calendario

(Última actualización: 16/06/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
24/10/2022	24/01/2023	05/05/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
14/05/2025	01/06/2026	No aportado	No aportado	10/06/2026

Promotor

Genmab A/S Denmark

Kalvebod Brygge 43

Contact Person

Information

+4570202728

clinicaltrials@genmab.com

Monetary support: N/A

Tipo de promotor: Comercial

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915867007

Centros

Activo (26/06/2023)

Complejo Hospitalario Gregorio Marañón

Madrid

MADRID

Activo (18/08/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Haematology

Activo (19/07/2023)

HOSPITAL SAN PEDRO DE ALCANTARA

Cáceres

CÁCERES

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

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Haematology

Activo (24/10/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Activo (18/04/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Activo (28/02/2023)

HOSPITAL UNIVERSITARIO PUERTA DEL MAR

Cádiz

CÁDIZ

Activo (31/01/2023)

HOSPITAL UNIVERSITARIO RAMON Y CAJAL

Madrid

MADRID

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

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Activo (14/06/2023)

HOSPITAL UNIVERSITARIO VIRGEN DE VALME

Sevilla

SEVILLA

Activo (20/04/2023)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

Activo (31/01/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

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

Institut Catala D´oncologia

Badalona

BARCELONA

Oncology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Haematology

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

Institut Catala D'oncologia

Badalona

BARCELONA

Oncology

Activo (14/08/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medicamentos

[redacted]

-
-
SUBCUTANEOUS

Código ATC: L04AC03 - ANAKINRA
Principios Activos: N/A

Experimental

[redacted]

-
-
INTRAVENOUS

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

[redacted]

-
-
INTRAVENOUS

Código ATC: L04AC07 - TOCILIZUMAB
Principios Activos: N/A

Experimental

[redacted]

-
-
INTRAVENOUS

Código ATC: R06AA02 - DIFENHIDRAMINA
Principios Activos: N/A

Experimental

[redacted]

-
-
ORAL

Código ATC: N02BE01 - PARACETAMOL
Principios Activos: N/A

Experimental

[redacted]

-
-
INTRAVENOUS

Código ATC: L04AC11 - SILTUXIMAB
Principios Activos: N/A

Experimental

[redacted]

Epcoritamab
SOLUTION FOR INJECTION
SUBCUTANEOUS

-

Principios Activos: N/A

Huérfano

Experimental

[redacted]

-
-
ORAL

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

Experimental

Epcoritamab
SOLUTION FOR INJECTION
SUBCUTANEOUS

-

Principios Activos: N/A

Huérfano **Experimental**

Sin resultados

EFFICACY AND SAFETY TRIAL OF EPCORITAMAB WITH OR WITHOUT LENALIDOMIDE AS FIRST LINE THERAPY FOR SUBJECTS WITH DIFFUSE LARGE B-CELL LYMPHOMA.

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64
Gender	**Phases**	**Expected Participants**
Both	Phase II	38
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
2023-504832-16-00 (CTIS)

Protocol Code
No aportado

Transitioned 2021-005744-29

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

Investigated Disease
DIFFUSE LARGE B CELL LYMPHOMA

Scientific Title
A Randomized, Open-Label, Multicenter, Global, Phase 2 Trial to Evaluate the Efficacy and Safety of Epcoritamab (GEN3013; DuoBody®-CD3×CD20) as Monotherapy or in Combination with Lenalidomide as First-Line Therapy for Anthracycline-Ineligible Subjects with Diffuse Large B-Cell Lymphoma

Rationale

Not provided

Main Objective

Evaluate the clinical efficacy of epcoritamab monotherapy or epcoritamab and lenalidomide

Primary Endpoints

Complete response (CR) rate determined by Lugano criteria

Temporary moments of secondary assessment

Not provided

Secondary Objective

Evaluate other efficacy measures of epcoritamab monotherapy or epcoritamab and lenalidomide
Evaluate safety and tolerability of epcoritamab monotherapy or epcoritamab and lenalidomide
Evaluate immunogenicity
Assess the pharmacokinetics of epcoritamab
Evaluate patient-reported outcomes related to lymphoma symptoms

Secondary Endpoints

Duration of response (DOR) determined by Lugano criteria
Duration of complete response (DOCR) determined by Lugano criteria
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Changes in lymphoma symptoms as measured by the Functional Assessment of Cancer Therapy Lymphoma (FACT-Lym)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Must have newly diagnosed CD20+ large cell lymphoma.
Is ineligible for anthracycline-based therapy/cytotoxic chemotherapy due to: oBeing age 80 years; AND/OR oBeing age 75 years and having important comorbid condition(s), which are likely to have a negative impact on tolerability of anthracycline-based therapy/cytotoxic chemotherapy, Have Immune Effector Cell-Associated Encephalopathy (ICE) score of at least 8 out of 10.
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Exclusion criteria

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Has active cytomegalovirus (CMV) infection (DNA PCR-positive) requiring treatment.

Calendar

(Last Update: 16/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
24/10/2022	24/01/2023	05/05/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
14/05/2025	01/06/2026	Not aported	Not aported	10/06/2026

Sponsor

Genmab A/S Denmark

Kalvebod Brygge 43

Contact Person

Information

+4570202728

clinicaltrials@genmab.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

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Complejo Hospitalario Gregorio Marañón

Madrid

MADRID

Active (18/08/2023)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Haematology

Active (19/07/2023)

HOSPITAL SAN PEDRO DE ALCANTARA

Cáceres

CÁCERES

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

Hospital San Pedro De Alcantara

Caceres

CÁCERES

Haematology

Active (24/10/2023)

HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA

Badalona

BARCELONA

Active (18/04/2023)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Active (28/02/2023)

HOSPITAL UNIVERSITARIO PUERTA DEL MAR

Cádiz

CÁDIZ

Active (31/01/2023)

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MADRID

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

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SEVILLA

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Active (20/04/2023)

HOSPITAL UNIVERSITARIO VIRGEN MACARENA

Sevilla

SEVILLA

Active (31/01/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

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

Institut Catala D´oncologia

Badalona

BARCELONA

Oncology

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

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L'hospitalet De Llobregat

BARCELONA

Haematology

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

Institut Catala D'oncologia

Badalona

BARCELONA

Oncology

Active (14/08/2023)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Medication

-
-
SUBCUTANEOUS

ATC code: L04AC03 - ANAKINRA
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L04AC07 - TOCILIZUMAB
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: R06AA02 - DIFENHIDRAMINA
Active Principles: N/A

Experimental

-
-
ORAL

ATC code: N02BE01 - PARACETAMOL
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L04AC11 - SILTUXIMAB
Active Principles: N/A

Experimental

Epcoritamab
SOLUTION FOR INJECTION
SUBCUTANEOUS

-
Active Principles: N/A

Orphan

Experimental

-
-
ORAL

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

Experimental

Epcoritamab
SOLUTION FOR INJECTION
SUBCUTANEOUS

-

Active Principles: N/A

Orphan Experimental

No results