Estudio para comparar la eficacia y seguridad de glofitamab como agente único frente al régimen elegido por el investigador en pacientes con linfoma de células del manto en recidiva o refractario

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	137
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-503206-37-00 (CTIS)

Cod. Protocolo
GO43878

Área terapéutica
·Atención a la salud [N] - Medio ambiente y salud pública [N06]
·Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Linfoma de células del manto (LCM)

Título Científico
Estudio Fase III, multicéntrico, abierto, aleatorizado para evaluar glofitamab como agente único frente al régimen elegido por el investigador en pacientes con linfoma de células del manto en recidiva o refractario

Justificación

No aportado

Objetivo Principal

Evaluar la eficacia de glofitamab como agente único en comparación con el régimen elegido por el investigador de bendamustina con rituximab (BR) o lenalidomida con rituximab (R-Len) con respecto a la supervivencia libre de progresión (SLP).

Variables de Evaluación Primaria

SLP determinada por el Comité de revisión independiente con ciego (CRIC

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Evaluar la eficacia de glofitamab en monoterapia en comparación con la tasa de respuesta completa (RC), la tasa de respuesta objetiva (TRO) y la supervivencia global (SG), según el investigador.
Evaluar la calidad de vida relacionada con la salud de los participantes
tratados con glofitamab como agente único en comparación con la pauta
elegida por el investigador de BR o R-Len.
Evaluar la eficacia de la monoterapia con glofitamab en comparación con el régimen elegido por el investigador de BR o R-Len sobre la base de la SLP evaluada por el investigador, la tasa de RC evaluada por el investigador, la TRO evaluada por el investigador, la DRC evaluada por el investigador, la DR evaluada por el investigador, la DRC evaluada por el BIRC, la DR evaluada por el BIRC y la SSC evaluada por el investigador
Evaluar la seguridad y la tolerabilidad de glofitamab en monoterapia en comparación con el régimen elegido por del investigador de BR o R-Len
Evaluar la calidad de vida relacionada con la salud de los participantes tratados con glofitamab en monoterapia en comparación con un BR o R-Len elegido por el investigador en función del tiempo transcurrido hasta el deterioro de los síntomas del linfoma, así como la proporción de participantes que experimentaron una mejoría clínicamente significativa del funcionamiento físico o la fatiga
Caracterizar el perfil farmacocinético (FC) de glofitamab en participantes con LCM
Evaluar la respuesta inmunitaria al glofitama

Variables de Evaluación Secundaria

BIRC-assessed CR rate
BIRC-assessed ORR
OS
Time to deterioration in physical functioning and fatigue as assessed by the European Organization for Research

and Treatment of Cancer (EORTC) quality of life (QoL)-C30
Investigator-assessed PFS
Investigator-assessed CR rate
Investigator-assessed OR rate
Investigator-assessed DOCR
Investigator-assessed DOR
BIRC-assessed DOCR
BIRC-assessed DOR
Investigator-assessed EFS
Incidence and severity of adverse events, with severity determined according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0 grading scale, except cytokine-release syndrome (CRS), immune effector cell associated neurotoxicity syndrome (ICANS) and hemophagocytic lymphohistiocytosis (HLH) which will be graded using American Society for Transplantation and Cellular Therapy (ASTCT) grading criteria (Lee et al., 2019; Hines et al., 2023
Change from baseline in selected vital signs
Change from baseline in selected clinical laboratory test results
Frequency, severity, and interference of side effects as assessed by the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
Proportion of participants reporting each response option for item General Population, Question 5 (GP5) from the Functional Assessment of Cancer Therapy General (FACT-G) at each assessment timepoint by treatment arm
Time to deterioration in lymphoma symptoms, defined as the time from randomization to the first documentation of a 3-point or more decrease in score as assessed by the Functional Assessment of Cancer Therapy Lymphoma Lymphoma Subscale (FACT-Lym LYMS) questionnaire
Proportion of participants experiencing a clinically meaningful improvement (3-point or more increase) in lymphoma symptoms as assessed through use of the FACT-Lym LYMS
Proportion of participants experiencing a clinically meaningful improvement in physical functioning (10-point or more increase) and/or fatigue (10-point or more decrease) as assessed by the EORTC QLQ-C30
Change from baseline in physical functioning, fatigue, and lymphoma symptoms at each cycle as assessed by the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and FACT-Lym LYMS
Serum concentration of glofitamab at specified timepoints
Prevalence of anti-drug antibodies (ADAs) at baseline and incidence of ADAs during the study

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Presencia de la enfermedad confirmada mediante una tomografía PET en el momento de la selección (puntuación Deauville de 4 o 5) de acuerdo con las ¿Recomendaciones para la evaluación inicial, la estadificación y la evaluación de la respuesta del linfoma Hodgkin y no Hodgkin: Clasificación de Lugano¿ con al menos una lesión diana ávida de FDG.
En casos raros de LCM no ávido de FDG con al menos una lesión medible localizada en un área susceptible de biopsia, como el tracto gastrointestinal, y en la que se pueda obtener una biopsia para confirmar un diagnóstico histológico, un participante puede ser apto.
Presentar LCM confirmado histológicamente, que evidencie sobreexpresión de ciclina D1 o presencia de t(11:14), en los 12 meses anteriores a la incorporación al estudio
Enfermedad en recidiva o refractaria
Al menos una (¿1) línea de tratamiento sistémico previo
- Inclusión de un inhibidor de BTK
La terapia previa debe haber incluido un inhibidor de BTK más otra opción de terapia sistémica (por ejemplo, una

pauta que contenga un anticuerpo monoclonal CD20, quimioterapia previa, terapia con agentes dirigidos como bortezomib, etc.)
- Progresión o recaída:
Los participantes deben haber experimentado una progresión o recaída en cualquier momento del tratamiento con inhibidores de BTK, o no haber logrado una respuesta parcial (RP) en las 12 semanas siguientes al tratamiento con inhibidores de BTK.
- Exclusión de la Intolerancia al Inhibidor de BTK:
Se debe excluir a los participantes intolerantes al tratamiento con inhibidores de BTK que no puedan completar al menos 12 semanas de tratamiento con inhibidores de BTK.
- Terapias locales:
Las terapias locales (por ejemplo, radioterapia) no se considerarán como líneas de terapia
Función renal adecuada, definida como un aclaramiento estimado de creatinina ¿ 30 ml/min.
Función hematológica adecuada

Criterios de Exclusión

- Antecedentes de otras neoplasias malignas que pudiesen afectar al cumplimiento del protocolo o a la interpretación de los resultados.
- Los pacientes con una neoplasia previa o concurrente cuya historia natural o tratamiento no pueda potencialmente interferir con la adherencia o la evaluación de la seguridad o eficacia de la pauta en investigación son aptos para este estudio.
LCM leucemizado, no ganglionar
Trasplante previo de órganos sólidos, trasplante alogénico previo de células madre
Tratamiento previo con glofitamab u otros anticuerpos biespecíficos dirigidos tanto a CD20 como a CD3 y también tratamiento con terapia celular CAR-T.
Linfoma del SNC primario o secundario en el momento del reclutamiento o antecedentes de linfoma del SNC
Presencia de infecciones bacterianas, víricas, fúngicas, micobacterianas, parasitarias u otras infecciones activas graves en el momento de la inscripción en el estudio. Los participantes deben haberse recuperado de cualquier infección grave o potencialmente grave (a juicio del investigador) al menos 2 semanas antes del primer tratamiento del estudio.
Antecedentes clínicamente significativos de enfermedad hepática cirrótic

Calendario

(Última actualización: 28/09/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
06/10/2023	29/11/2023	30/11/2023	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
No aportado	No aportado	No aportado	No aportado	No aportado

Promotor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.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

Activo (30/11/2023)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematology

Activo (29/11/2023)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Activo (30/11/2023)

Hospital General Universitario Morales Meseguer

Murcia

MURCIA

Hematology

Activo (24/04/2024)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Activo (30/11/2023)

Hospital Universitario Puerta Del Mar

Cadiz

CÁDIZ

Hematology

Medicamentos

Lenalidomide Accord 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

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

Experimental

Gazyvaro 1,000 mg concentrate for solution for infusion.
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01XC15 - OBINUTUZUMAB
Principios Activos: N/A

Huérfano Experimental

Glofitamab
SOLUTION FOR INFUSION
IV INFUSION

-
Principios Activos: N/A

Huérfano Experimental

Bendamustin Baxter 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01AA09 - BENDAMUSTINA
Principios Activos: N/A

Experimental

Columvi 10 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

-
Principios Activos: N/A

Experimental

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

Código ATC: L01XC02 - RITUXIMAB
Principios Activos: N/A

Experimental

Bendamustin Hikma 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01AA09 - BENDAMUSTINA
Principios Activos: N/A

Experimental

Lenalidomide Accord 15 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Lenalidomide Accord 20 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

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

Experimental

Lenalidomide Accord 10 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Bendamustin cell pharm® 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01AA09 - BENDAMUSTINA
Principios Activos: N/A

Experimental

Sin resultados

A Study to Compare the Efficacy and Safety of Glofitamab as a Single Agent Versus Investigators Choice in Patients with Relapsed/Refractory Mantle Cell Lymphoma

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	137
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-503206-37-00 (CTIS)

Protocol Code
GO43878

Therapeutic area
·Health Care [N] - Environment and Public Health [N06]
·Diseases [C] - Cancer [C04]

Investigated Disease
Mantle Cell Lymphoma (MCL)

Scientific Title
A PHASE III, OPEN-LABEL, MULTICENTER RANDOMIZED STUDY EVALUATING GLOFITAMAB AS A SINGLE AGENT VERSUS INVESTIGATORS CHOICE IN PATIENTS WITH RELAPSED/REFRACTORY MANTLE CELL LYMPHOMA

Rationale

Not provided

Main Objective

To evaluate the efficacy of glofitamab monotherapy compared with an investigators choice of bendamustine with rituximab (BR) or lenalidomide with rituximab (R-Len) with respect to progression-free survival (PFS)

Primary Endpoints

PFS as determined by the Blinded independent Review Committee (BIRC)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of glofitamab monotherapy compared with an investigators choice of BR or R-Len with respect to complete response (CR) rate, objective response rate (ORR), overall survival (OS)
To evaluate the health-related quality of life of participants treated with glofitamab monotherapy compared with an investigators choice of BR or R-Len
To evaluate the efficacy of glofitamab monotherapy compared with an investigators choice of BR or R-Len on the basis of investigator-assessed PFS, investigator-assessed CR rate, investigator-assessed ORR, investigator-assessed DOCR, investigator-assessed DOR, BIRC-assessed DOCR, BIRC-assessed DOR and investigator-assessed EFS
To evaluate the safety and tolerability of glofitamab monotherapy compared with an investigators choice of BR or R-Len
To evaluate the health-related quality of life of participants treated with glofitamab monotherapy compared with an investigators choice of BR or R-Len on the basis of time to deterioration in lymphoma symptoms as well as proportion of participants experiencing clinically meaningful improvement in physical functioning and / or fatigue
To characterize glofitamab pharmacokinetic (PK) profile in participants with MCL
To evaluate the immune response to glofitamab

Secondary Endpoints

BIRC-assessed CR rate
BIRC-assessed ORR
OS
Time to deterioration in physical functioning and fatigue as assessed by the European Organization for Research and Treatment of Cancer (EORTC) quality of life (QoL)-C30
Investigator-assessed PFS
Investigator-assessed CR rate

Investigator-assessed OR rate
Investigator-assessed DOCR
Investigator-assessed DOR
BIRC-assessed DOCR
BIRC-assessed DOR
Investigator-assessed EFS
Incidence and severity of adverse events, with severity determined according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0 grading scale, except cytokine-release syndrome (CRS), immune effector cell associated neurotoxicity syndrome (ICANS) and hemophagocytic lymphohistiocytosis (HLH) which will be graded using American Society for Transplantation and Cellular Therapy (ASTCT) grading criteria (Lee et al., 2019; Hines et al., 2023
Change from baseline in selected vital signs
Change from baseline in selected clinical laboratory test results
Frequency, severity, and interference of side effects as assessed by the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE)
Proportion of participants reporting each response option for item General Population, Question 5 (GP5) from the Functional Assessment of Cancer Therapy General (FACT-G) at each assessment timepoint by treatment arm
Time to deterioration in lymphoma symptoms, defined as the time from randomization to the first documentation of a 3-point or more decrease in score as assessed by the Functional Assessment of Cancer Therapy Lymphoma Lymphoma Subscale (FACT-Lym LYMS) questionnaire
Proportion of participants experiencing a clinically meaningful improvement (3-point or more increase) in lymphoma symptoms as assessed through use of the FACT-Lym LYMS
Proportion of participants experiencing a clinically meaningful improvement in physical functioning (10-point or more increase) and/or fatigue (10-point or more decrease) as assessed by the EORTC QLQ-C30
Change from baseline in physical functioning, fatigue, and lymphoma symptoms at each cycle as assessed by the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and FACT-Lym LYMS
Serum concentration of glofitamab at specified timepoints
Prevalence of anti-drug antibodies (ADAs) at baseline and incidence of ADAs during the study

Temporary moments of secondary assessment

Not provided

Inclusion criteria

PET-positive disease at screening (Deauville score of 4 or 5) according to the Recommendations for Initial Evaluation, Staging, and Response Assessment of Hodgkin and Non-Hodgkin Lymphoma: The Lugano Classification with at least one target FDG-avid lesion In rare cases of non-FDG-avid MCL with at least one measurable lesion located in an area suitable for biopsy, such as the gastrointestinal tract and a biopsy can be obtained to confirm a histological diagnosis, a participant may be eligible Histologically-confirmed MCL, demonstrating either overexpression of cyclin D1 or the presence of t(11:14) within 12 months of study entry Relapsed or refractory disease At least one (>= 1) line of prior systemic therapy: - Inclusion of BTK inhibitor Prior therapy must have included a BTK inhibitor plus another systemic therapy option (e.g., a regimen containing a CD20 monoclonal antibody, prior chemotherapy, targeted agent therapy such as bortezomib, etc.) Progression or Relapse: Participants must have progressed or relapsed at any time on BTK inhibitor therapy, or failed to achieve a partial response (PR) within 12 weeks of BTK inhibitor therapy Exclusion of BTK Inhibitor Intolerance: Participants intolerant to BTK inhibitor therapy who are unable to complete at least 12 weeks of BTK inhibitor therapy should be excluded Local Therapies: Local therapies (e.g., radiotherapy) will not be considered as lines of therapy Adequate renal function, defined as an estimated creatinine clearance 30 mL/min Adequate hematologic function

Exclusion criteria

History of other malignancy that could affect compliance with the protocol or interpretation of results - Patients with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the compliance of or safety or efficacy assessment of the investigational regimen are eligible for this study
Leukemic, non-nodal MCL
Prior solid organ transplantation, prior allogeneic stem cell transplant
Prior treatment with glofitamab or other bispecific antibodies targeting both CD20 and CD3 and also treatment with chimeric antigen receptor T-cell (CAR-T) cell therapy
Primary or secondary central nervous system (CNS) lymphoma at the time of recruitment or history of CNS lymphoma
Presence of severe active bacterial, viral, fungal, mycobacterial, parasitic, or other infections at the time of study enrolment. Participants must have recovered from any severe or potentially serious infection (as assessed by the investigator) at least 2 weeks before the first study treatment
Clinically significant history of cirrhotic liver disease

Calendar

(Last Update: 28/09/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
06/10/2023	29/11/2023	30/11/2023	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
Not aported	Not aported	Not aported	Not aported	Not aported

Sponsor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc Tauli

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937458454-937458451

Sites

Active (30/11/2023)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematology

Active (29/11/2023)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Active (30/11/2023)

Hospital General Universitario Morales Meseguer

Murcia

MURCIA

Hematology

Active (24/04/2024)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Hematology

Active (30/11/2023)

Hospital Universitario Puerta Del Mar

Cadiz

CÁDIZ

Hematology

Medication

Lenalidomide Accord 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

RoActemra 20 mg/mL concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

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

Experimental

Gazyvaro 1,000 mg concentrate for solution for infusion.
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01XC15 - OBINUTUZUMAB
Active Principles: N/A

Orphan
Experimental

Glofitamab
SOLUTION FOR INFUSION
IV INFUSION

-
Active Principles: N/A

Orphan
Experimental

Bendamustin Baxter 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01AA09 - BENDAMUSTINA
Active Principles: N/A

Experimental

Columvi 10 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

-
Active Principles: N/A

Experimental

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

ATC code: L01XC02 - RITUXIMAB
Active Principles: N/A

Experimental

Bendamustin Hikma 2,5 mg/ml Pulver für ein Konzentrat zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01AA09 - BENDAMUSTINA
Active Principles: N/A

Experimental

Lenalidomide Accord 15 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

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ORAL

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

Experimental

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Active Principles: N/A

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

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SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01AA09 - BENDAMUSTINA
Active Principles: N/A

Experimental

No results