A study to look at how safe and effective glofitamab plus R-CHOP in ctDNA high-risk people with untreated diffuse large B-cell 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 II	40
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Multicéntrico internacional	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-504994-19-00 (CTIS)

Cod. Protocolo
GO43075

Transicionado 2021-001647-28

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

Enfermedad investigada
Diffuse Large B-Cell Lymphoma

Título Científico
A Phase II Study Evaluating the Safety and Efficacy of Glofitamab in Combination with Rituximab (R) Plus Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) in Circulating Tumor (ct)DNA High-Risk Patients with Untreated Diffuse Large B-Cell Lymphoma

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of glofitamab in combination with R-CHOP in circulating-tumor DNA (ctDNA) high-risk patients with previously untreated DLBCL based on end of treatment (EOT) complete response (CR) rate as determined by the investigator according to 2014 Lugano Response Criteria

Variables de Evaluación Primaria

1. EOT CR rate, as determined by the investigator according to the 2014 Lugano Response Criteria for Malignant Lymphoma

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of glofitamab in combination with R-CHOP in ctDNA high-risk patients with previously untreated DLBCL based on objective response rate (ORR) at the EOT, progression-free survival (PFS) and overall survival (OS) as determined by the investigator according to 2014 Lugano Response Criteria
To evaluate the safety of glofitamab in combination with R-CHOP in ctDNA high-risk participants with DLBCL
To characterize the serum pharmacokinetics (PK) profile of glofitamab in combination with R-CHOP
To evaluate potential effects of anti-drug antibodies (ADAs)

Variables de Evaluación Secundaria

1. ORR at the EOT, as determined by the investigator according to the 2014 Lugano Response Criteria
2. PFS, as determined by the investigator according to the 2014 Lugano Response Criteria or death due to any cause, whichever occurs first
3. OS
4. Incidence and severity of adverse events, with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0 (NCI CTCAE v5.0)
5. Tolerability, as assessed by dose modifications, dose intensity, and study treatment discontinuation because of adverse events
6. Serum concentrations of glofitamab at specified timepoints
7. Serum trough concentrations of glofitamab at specified timepoints
8. Maximum concentration (Cmax) of glofitamab at specified timepoints
9. Area under the concentrationtime curve (AUC) of glofitamab at specified timepoints
10. Relationship between ADA status and efficacy, safety, or PK endpoints

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Previously untreated patients with cluster of differential (CD20)-positive DLBCL, including diagnoses by the 2016 World Health Organization (WHO) classification of lymphoid neoplasms International Prognostic Index (IPI): 1-5 Life expectancy of >=6 months Adequate biomarker blood samples prior to initiation of R-CHOP on Day 1 of Cycle 1 and on Day 1 of Cycle 2 submitted for screening for determination of ctDNA status At least one bi-dimensionally fluorodeoxyglucose (FDG)-avid measurable lymphoma lesion on positron emission tomography/computed tomography (PET/CT) scan Left ventricular ejection fraction (LVEF) >=50%, as determined on cardiac multiple-gated acquisition (MUGA) scan or cardiac echocardiogram (ECHO)

Criterios de Exclusión

Contraindication to any of the individual components of R-CHOP, including prior receipt of anthracyclines, history of severe allergic or anaphylactic reactions to murine monoclonal antibodies, or known sensitivity or allergy to murine products
Prior treatment for indolent lymphoma
Prior solid organ or allogeneic stem cell transplant
Positive SARS-CoV-2 test within 7 days prior to enrollment. Rapid antigen test result is also acceptable
Prior therapy for DLBCL and high-grade B-cell lymphoma (HGBCL) with the exception of palliative, short-term treatment with corticosteroids
Pregnant or breastfeeding, or intending to become pregnant during the study or within 12 months after the final dose of R-CHOP, 3 months after the final dose of tocilizumab (if applicable), or 2 months after the final dose of glofitamab

Calendario

(Última actualización: 10/12/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
09/12/2021	18/01/2022	28/01/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
10/04/2024	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 Hospital Universitario 12 de Octubre

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Centros

Activo (04/03/2022)

HOSPITAL CLINIC DE BARCELONA

Barcelona

BARCELONA

Activo (18/01/2022)

HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)

Salamanca

SALAMANCA

Activo (25/03/2022)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Activo (24/01/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medicamentos

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION

IV INFUSION

Código ATC: L04AC07 - TOCILIZUMAB

Principios Activos: N/A

Experimental

Glofitamab

SOLUTION FOR INFUSION

IV INFUSION

-

Principios Activos: N/A

Experimental

Sin resultados

A study to look at how safe and effective glofitamab plus R-CHOP in ctDNA high-risk people with untreated diffuse large B-cell 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 II	40
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
International multicenter	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-504994-19-00 (CTIS)

Protocol Code
GO43075

Transitioned 2021-001647-28

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

Investigated Disease
Diffuse Large B-Cell Lymphoma

Scientific Title
A Phase II Study Evaluating the Safety and Efficacy of Glofitamab in Combination with Rituximab (R) Plus Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone (CHOP) in Circulating Tumor (ct)DNA High-Risk Patients with Untreated Diffuse Large B-Cell Lymphoma

Rationale

Not provided

Main Objective

To evaluate the efficacy of glofitamab in combination with R-CHOP in circulating-tumor DNA (ctDNA) high-risk patients with previously untreated DLBCL based on end of treatment (EOT) complete response (CR) rate as determined by the investigator according to 2014 Lugano Response Criteria

Primary Endpoints

1. EOT CR rate, as determined by the investigator according to the 2014 Lugano Response Criteria for Malignant Lymphoma

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of glofitamab in combination with R-CHOP in ctDNA high-risk patients with previously untreated DLBCL based on objective response rate (ORR) at the EOT, progression-free survival (PFS) and overall survival (OS) as determined by the investigator according to 2014 Lugano Response Criteria
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To characterize the serum pharmacokinetics (PK) profile of glofitamab in combination with R-CHOP
To evaluate potential effects of anti-drug antibodies (ADAs)

Secondary Endpoints

1. ORR at the EOT, as determined by the investigator according to the 2014 Lugano Response Criteria
2. PFS, as determined by the investigator according to the 2014 Lugano Response Criteria or death due to any cause, whichever occurs first
3. OS
4. Incidence and severity of adverse events, with severity determined according to National Cancer Institute Common Terminology Criteria for Adverse Events, Version 5.0 (NCI CTCAE v5.0)
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9. Area under the concentrationtime curve (AUC) of glofitamab at specified timepoints
10. Relationship between ADA status and efficacy, safety, or PK endpoints

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Previously untreated patients with cluster of differential (CD20)-positive DLBCL, including diagnoses by the 2016 World Health Organization (WHO) classification of lymphoid neoplasms International Prognostic Index (IPI): 1-5 Life expectancy of >=6 months Adequate biomarker blood samples prior to initiation of R-CHOP on Day 1 of Cycle 1 and on Day 1 of Cycle 2 submitted for screening for determination of ctDNA status At least one bi-dimensionally fluorodeoxyglucose (FDG)-avid measurable lymphoma lesion on positron emission tomography/computed tomography (PET/CT) scan Left ventricular ejection fraction (LVEF) >=50%, as determined on cardiac multiple-gated acquisition (MUGA) scan or cardiac echocardiogram (ECHO)

Exclusion criteria

Contraindication to any of the individual components of R-CHOP, including prior receipt of anthracyclines, history of severe allergic or anaphylactic reactions to murine monoclonal antibodies, or known sensitivity or allergy to murine products
Prior treatment for indolent lymphoma
Prior solid organ or allogeneic stem cell transplant
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Calendar

(Last Update: 10/12/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
09/12/2021	18/01/2022	28/01/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
10/04/2024	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

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Sites

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SALAMANCA

Active (25/03/2022)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

Madrid

MADRID

Active (24/01/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medication

RoActemra 20 mg/mL concentrate for solution for infusion

SOLUTION FOR INFUSION

IV INFUSION

ATC code: L04AC07 - TOCILIZUMAB

Active Principles: N/A

Experimental

Glofitamab

SOLUTION FOR INFUSION

IV INFUSION

-

Active Principles: N/A

Experimental

No results