

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
EC Finalizado

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase II

Participantes esperados
40

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
No

Cobertura geográfica
Multicéntrico internacional

Ámbitos del ensayo
seguridad, eficacia, farmacocinética

Terapia avanzada
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 (C_{max}) 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) $\geq 50\%$, 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: 26/08/2026)

Autorización 09/12/2021	Inicio de Ensayo 18/01/2022	Inclusión Primer Paciente 28/01/2022	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento 10/04/2024	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España 30/06/2026	Fin del ensayo global 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

Glorieta de Málaga, S/N 28041 Madrid

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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 MARAÑÓN 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
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Sin resultados

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State
Finished CT

Type of participants
Not provided

Age Ranges
Older than 64 , Adults (18-64 years)

Gender
Both

Phases
Phase II

Expected Participants
40

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
International multicenter

Areas of the study
safety, effectiveness, pharmacokinetics

Advanced therapy
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

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)

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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 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) $\geq 50\%$, 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

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Calendar

(Last Update: 26/08/2026)

Authorization 09/12/2021	Start of Trial 18/01/2022	First patient inclusion 28/01/2022	Halted Not aported	Restarted Not aported
End of recruitment 10/04/2024	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) 30/06/2026	Trial end (Global) 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 Hospital Universitario 12 de Octubre

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Sites

Active (04/03/2022)	HOSPITAL CLINIC DE BARCELONA
	Barcelona BARCELONA
Active (18/01/2022)	HOSPITAL CLINICO UNIVERSITARIO DE SALAMANCA (COMPLEJO ASISTENCIAL UNIV.SA)
	Salamanca 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