# 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** |
| EC Finalizado | 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: 22/10/2026)

| 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 | 30/06/2026 | 06/10/2026 |

# 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**

**ceic@h12o.es**

**917792613**

# 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 |
|---|---|---|
| Finished CT | 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)
5. Tolerability, as assessed by dose modifications, dose intensity, and study treatment discontinuation because of adverse events
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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) >=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
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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

# Calendar

(Last Update: 22/10/2026)

| 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 | 30/06/2026 | 06/10/2026 |

# 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

**Glorieta de Málaga, S/N 28041 Madrid**

**ceic@h12o.es**

**917792613**

# Sites

Active (04/03/2022)

**HOSPITAL CLINIC DE BARCELONA**

Barcelona

BARCELONA

Active (18/01/2022)

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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