# A Study to Evaluate Efficacy and Safety of Mosunetuzumab in Combination with Lenalidomide in Comparison to Rituximab in Combination with Lenalidomide in Patients with Follicular 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 III | 324 |
| **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
2023-505807-21-00 (CTIS)

### Cod. Protocolo
GO42909

Transicionado 2020-005239-53

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

### Enfermedad investigada
Relapsed/refractory follicular lymphoma

### Título Científico
Phase III Randomized, Open-Label, Multicenter Study Evaluating Efficacy and Safety of Mosunetuzumab in Combination with Lenalidomide in Comparison to Rituximab in Combination with Lenalidomide with a Non-Randomized, Single Arm US Extension of Mosunetuzumab in Combination with Lenalidomide in Patients with Follicular Lymphoma After at Least One Line of Systemic Therapy

## Justificación

No aportado

## Objetivo Principal

Arm A and Arm B: To evaluate the efficacy of mosunetuzumab in combination with lenalidomide (M+Len) compared with rituximab in combination with lenalidomide (R+Len) based on progression-free survival as determined by the independent review committee (IRC) Arm C: The primary efficacy objective for the non-randomized single arm extension is to evaluate the efficacy of M + Len based on Objective response rate (ORR) as determined by the independent review committee (IRC)

## Variables de Evaluación Primaria

Arm A and Arm B : 1. Progression-free survival as determined by the IRC with use of the 2014 Lugano Response Criteria or death from any cause in the intent-to-treat (ITT) population
Arm C : 2. Objective response rate, as defined as the proportion of patients whose best overall response is a PR or a CR during the study, as determined by the IRC

## Momentos temporales de evaluación primaria

No aportado

## Objetivo Secundario

Arm A and Arm B: To evaluate the efficacy of M+Len compared with R+Len based on progression-free survival as determined by the investigator, complete response rate as determined by the IRC and investigator, objective response rate as determined by the IRC and investigator, overall survival, duration of objective response, duration of complete response (CR), time to deterioration in physical functioning and fatigue and time to deterioration in lymphoma symptoms, time to next anti-lymphoma treatment
Arm A and Arm B: To evaluate the safety and tolerability of M+Len compared with R+Len
Arm A and Arm B: To characterize the pharmacokinetic (PK) profile of M+Len and R+Len
Arm A and Arm B: To evaluate the immune response to mosunetuzumab and rituximab
Arm C: Efficacy objective for the non-randomized single arm extension is to evaluate the efficacy of M + Len
Arm C: The safety objective for the non-randomized single arm extension is to evaluate the safety of M + Len
Arm C: To characterize the pharmacokinetic (PK) profile of M+Len
Arm C: To evaluate the immune response to mosunetuzumab

## Variables de Evaluación Secundaria

1. Arm A and Arm B: Progression-free survival as determined by the investigator in the ITT population. Arm C: Progression-free survival as determined by the investigator and IRC in the ITT population.
2. Arm A, Arm B and Arm C: Complete response rate in the ITT population as determined by the IRC and investigator

3. Arm A, Arm B and Arm C: Objective response rate in the ITT population as determined by the IRC and investigator
4. Arm A, Arm B and Arm C: Overall survival in the ITT population
5. Arm A, Arm B and Arm C: Duration of objective response (DOR)
6. Arm A, Arm B and Arm C: Duration of CR
7. Arm A, Arm B and Arm C: Time to deterioration in physical functioning as measured by the European Organization for Research and Treatment of Cancer Quality of Life-Core 30 Questionnaire (EORTC QLQ-C30)
8. Arm A, Arm B and Arm C: Time to deterioration in fatigue, as measured by the EORTC QLQC30
9. Arm A, Arm B and Arm C: Time to deterioration in lymphoma symptoms, as measured by the Functional Assessment of Cancer Therapy-Lymphoma Subscale (FACT-LymS)
10. Arm A, Arm B and Arm C : Time to new anti-lymphoma treatment (TTNALT), defined as the time from randomization to the first documented administration of a new anti-lymphoma treatment
11. Arm A, Arm B and Arm C: Incidence and severity of adverse events, with severity determined according to the NCI CTCAE, v5.0, including cytokine release syndrome (CRS), with severity determined according to the American Society for Transplantation and Cellular Therapy (ASTCT) CRS grading criteria
12. Arm A, Arm B and Arm C: Change from baseline in targeted vital signs
13. Arm A, Arm B and Arm C: Change from baseline in targeted clinical laboratory test results
14. Arm A, Arm B and Arm C: Tolerability, as assessed by dose interruptions, dose reductions, and dose intensity, and study treatment discontinuation because of adverse events
15. Arm A, Arm B and Arm C: Minimum observed concentration (Cmin) of Mosunetuzumab
16. Arm A, Arm B and Arm C: Cmin of Lenalidomide
17. Arm A, Arm B and Arm C: Maximum observed concentration (Cmax) of Mosunetuzumab
18. Arm A, Arm B and Arm C: Cmax of Lenalidomide
19. Arm A, Arm B and Arm C: Area under the concentration-time curve (AUC) of Mosunetuzumab
20. Arm A, Arm B and Arm C: AUC of Lenalidomide
21. Arm A, Arm B and Arm C: Prevalence of anti-drug antibodies (ADAs) against mosunetuzumab at baseline
22. Arm A and Arm B: Prevalence of ADAs against rituximab at baseline
23. Arm A, Arm B and Arm C: Incidence of ADAs against mosunetuzumab during the study
24. Arm A and Arm B: Incidence of ADAs against rituximab during the study
25. Arm A and Arm B: Cmin of Rituximab
26. Arm A and Arm B: Cmax of Rituximab
27. Arm A and Arm B: AUC of Rituximab

## Momentos temporales de evaluación secundaria

No aportado

## Criterios de Inclusión

Histologically documented CD20 + follicular lymphoma (FL) (Grades 1-3a)
Requiring systemic therapy assessed by investigator based on tumor size and/or Groupe d'Etude des Lymphomes Folliculaires (GELF) criteria
Received at least one prior systemic lymphoma therapy, which included prior immunotherapy or chemoimmunotherapy
Availability of a representative tumor specimen and the corresponding pathology report at the time of relapse/persistence for confirmation of the diagnosis of FL
Agreement to comply with all local requirements of the lenalidomide risk minimization plan, which includes the global pregnancy prevention program
Adequate hematologic and organ function

## Criterios de Exclusión

Any history of Grade 3b FL and transformation of indolent disease to diffuse large B-cell lymphoma (DLBCL or transformed FL)
Known active bacterial, viral, fungal, or other infection, or any major episode of infection requiring treatment with IV antibiotics within 4 weeks of Day 1 of Cycle 1
Documented refractoriness to lenalidomide, defined as no response within 6 months of therapy
Positive SARS-CoV-2 test within 7 days prior to enrollment.
Known or suspected history of central nervous system (CNS) lymphoma or leptomeningeal infiltration, HLH (hemophagocytic lymphohistiocytosis) and progressive multifocal leukoencephalopathy (PML)
Evidence of any significant, uncontrolled concomitant disease that could affect compliance with the protocol or interpretation of results, including, but not limited to, significant cardiovascular disease or significant pulmonary disease

# Calendario

(Última actualización: 01/07/2026)

| Autorización | Inicio de Ensayo | Inclusión Primer Paciente | Interrumpido | Reiniciado |
|---|---|---|---|---|
| 06/09/2021 | 30/11/2021 | 14/12/2021 | No aportado | No aportado |

| Fin de reclutamiento | Fin prematuro (España) | Fin prematuro (Global) | Fin del ensayo en España | Fin del ensayo global |
|---|---|---|---|---|
| 31/05/2023 | 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 Provincial de Sevilla

**Avenida Doctor Fedriani 3 41009 Sevilla**

**administracion.eecc.hvm.sspa@juntadeandalucia.es**

**955043127**

# Centros

Activo (01/12/2021)

**HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA**

València

VALENCIA

Activo (23/03/2022)

**HOSPITAL G. UNIVERSITARIO J.M. MORALES MESEGUER**

Murcia

MURCIA

Activo (25/04/2022)

**HOSPITAL UNIVERSITARIO DONOSTIA**

Donostia/San Sebastián

GUIPÚZCOA

Activo (30/11/2021)

**HOSPITAL UNIVERSITARIO LA PAZ**

Madrid

MADRID

Activo (30/11/2021)

**Hospital Universitario Virgen Del Rocio**

Sevilla

SEVILLA

# Medicamentos

### Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

### Revlimid 20 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

### Mosunetuzumab
SOLUTION FOR INFUSION
IV INFUSION

-
Principios Activos: N/A

Experimental

### Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

### Revlimid 15 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

### Mosunetuzumab
SOLUTION FOR INFUSION
IV INFUSION

-
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

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

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

Experimental

# Sin resultados

# A Study to Evaluate Efficacy and Safety of Mosunetuzumab in Combination with Lenalidomide in Comparison to Rituximab in Combination with Lenalidomide in Patients with Follicular 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 III | 324 |
| **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
2023-505807-21-00 (CTIS)

### Protocol Code
GO42909

Transitioned 2020-005239-53

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

### Investigated Disease
Relapsed/refractory follicular lymphoma

### Scientific Title
Phase III Randomized, Open-Label, Multicenter Study Evaluating Efficacy and Safety of Mosunetuzumab in Combination with Lenalidomide in Comparison to Rituximab in Combination with Lenalidomide with a Non-Randomized, Single Arm US Extension of Mosunetuzumab in Combination with Lenalidomide in Patients with Follicular Lymphoma After at Least One Line of Systemic Therapy

## Rationale

Not provided

## Main Objective

Arm A and Arm B: To evaluate the efficacy of mosunetuzumab in combination with lenalidomide (M+Len) compared with rituximab in combination with lenalidomide (R+Len) based on progression-free survival as determined by the independent review committee (IRC) Arm C: The primary efficacy objective for the non-randomized single arm extension is to evaluate the efficacy of M + Len based on Objective response rate (ORR) as determined by the independent review committee (IRC)

## Primary Endpoints

Arm A and Arm B : 1. Progression-free survival as determined by the IRC with use of the 2014 Lugano Response Criteria or death from any cause in the intent-to-treat (ITT) population
Arm C : 2. Objective response rate, as defined as the proportion of patients whose best overall response is a PR or a CR during the study, as determined by the IRC

## Temporary moments of secondary assessment

Not provided

## Secondary Objective

Arm A and Arm B: To evaluate the efficacy of M+Len compared with R+Len based on progression-free survival as determined by the investigator, complete response rate as determined by the IRC and investigator, objective response rate as determined by the IRC and investigator, overall survival, duration of objective response, duration of complete response (CR), time to deterioration in physical functioning and fatigue and time to deterioration in lymphoma symptoms, time to next anti-lymphoma treatment
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Arm C: Efficacy objective for the non-randomized single arm extension is to evaluate the efficacy of M + Len
Arm C: The safety objective for the non-randomized single arm extension is to evaluate the safety of M + Len
Arm C: To characterize the pharmacokinetic (PK) profile of M+Len
Arm C: To evaluate the immune response to mosunetuzumab

## Secondary Endpoints

1. Arm A and Arm B: Progression-free survival as determined by the investigator in the ITT population. Arm C: Progression-free survival as determined by the investigator and IRC in the ITT population.
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25. Arm A and Arm B: Cmin of Rituximab
26. Arm A and Arm B: Cmax of Rituximab
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## Temporary moments of secondary assessment

Not provided

## Inclusion criteria

Histologically documented CD20 + follicular lymphoma (FL) (Grades 1-3a)
Requiring systemic therapy assessed by investigator based on tumor size and/or Groupe d'Etude des Lymphomes Folliculaires (GELF) criteria
Received at least one prior systemic lymphoma therapy, which included prior immunotherapy or chemoimmunotherapy
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Adequate hematologic and organ function

## Exclusion criteria

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Documented refractoriness to lenalidomide, defined as no response within 6 months of therapy
Positive SARS-CoV-2 test within 7 days prior to enrollment.
Known or suspected history of central nervous system (CNS) lymphoma or leptomeningeal infiltration, HLH (hemophagocytic lymphohistiocytosis) and progressive multifocal leukoencephalopathy (PML)
Evidence of any significant, uncontrolled concomitant disease that could affect compliance with the protocol or interpretation of results, including, but not limited to, significant cardiovascular disease or significant pulmonary disease

# Calendar

(Last Update: 01/07/2026)

| Authorization | Start of Trial | First patient inclusion | Halted | Restarted |
|---|---|---|---|---|
| 06/09/2021 | 30/11/2021 | 14/12/2021 | Not aported | Not aported |

| End of recruitment | Premature end (Spain) | Premature End (Global) | Trial end (Spain) | Trial end (Global) |
|---|---|---|---|---|
| 31/05/2023 | 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 Provincial de Sevilla

**Avenida Doctor Fedriani 3 41009 Sevilla**

**administracion.eecc.hvm.sspa@juntadeandalucia.es**

**955043127**

# Sites

Active (01/12/2021)

**HOSPITAL CLINICO UNIVERSITARIO DE VALENCIA**

València

VALENCIA

Active (23/03/2022)

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MURCIA

Active (25/04/2022)

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Donostia/San Sebastián

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Madrid

MADRID

Active (30/11/2021)

**Hospital Universitario Virgen Del Rocio**

Sevilla

SEVILLA

# Medication

### Revlimid 5 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

### Revlimid 20 mg hard capsules
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ORAL

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

Experimental

### Mosunetuzumab
SOLUTION FOR INFUSION
IV INFUSION

-
Active Principles: N/A

Experimental

### Revlimid 10 mg hard capsules
CAPSULE, HARD
ORAL

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

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### Revlimid 15 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

### Mosunetuzumab
SOLUTION FOR INFUSION
IV INFUSION

-
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

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

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

Experimental

# No results