A long-term follow-up study for patients treated with Galapagos CAR T cell therapies

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

Información

Identificador
2023-510173-34-00 (CTIS)

Cod. Protocolo
LTF-CL-001

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

Enfermedad investigada
Relapsed/refractory B-Cell non-Hodgkin lymphoma
Relapsed/refractory multiple myeloma
Relapsed or refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

Título Científico
A long-term follow-up study for patients treated with Galapagos CAR T-cell therapies

Justificación

No aportado

Objetivo Principal

To evaluate the long-term safety of GLPG CAR T cell products for up to 15 years post CAR T cell product infusion

Variables de Evaluación Primaria

The type and incidence of targeted adverse events (AEs)
The type and incidence of serious AEs (SAEs) considered related to the GLPG CAR T-cell therapy
The pattern of vector integration sites, if vector sequences are detected in new malignancies, or in at least 1% of peripheral blood mononuclear cells (PBMCs)
The incidence of detectable replication-competent lentivirus (RCL) in peripheral blood
Cause-specific mortality

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the long-term efficacy of GLPG CAR T-cell products for up to 15 years post CAR T-cell product infusion
To evaluate the persistence of GLPG CAR Tcell products for up to 15 years post CAR Tcell product infusion

Variables de Evaluación Secundaria

Disease progression status
Time to subsequent anticancer therapy
Overall survival
The incidence of detectable CAR transgene in peripheral blood over time

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subject must sign and date the ICF as approved by the Independent Ethics Committee (IEC)/Institutional Review

Board (IRB), prior to any study-related procedures.
Subjects has been treated with a GLPG CAR T-cell therapy in a clinical trial or Managed Access Program.

Criterios de Exclusión

There are no exclusion criteria for this study.

Calendario

(Última actualización: 28/11/2025)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
21/06/2024	09/09/2024	15/10/2024	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

Galapagos Cell Therapeutics Belgium

Schalienhoevedreef 20t

Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

No iniciado (--/--/----)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Medicamentos

BCMACP03
DISPERSION FOR INFUSION
INTRAVENIOUS INFUSION

-
Principios Activos: N/A

Experimental

19CP02
DISPERSION FOR INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A

Experimental

BCN-CP01
DISPERSION FOR INFUSION
INTRAVENOUS USE

-
Principios Activos: N/A

Experimental

Sin resultados

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

Information

Identifier
2023-510173-34-00 (CTIS)

Protocol Code
LTF-CL-001

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

Investigated Disease
Relapsed/refractory B-Cell non-Hodgkin lymphoma
Relapsed/refractory multiple myeloma
Relapsed or refractory Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)

Scientific Title
A long-term follow-up study for patients treated with Galapagos CAR T-cell therapies

Rationale

Not provided

Main Objective

To evaluate the long-term safety of GLPG CAR T cell products for up to 15 years post CAR T cell product infusion

Primary Endpoints

The type and incidence of targeted adverse events (AEs)
The type and incidence of serious AEs (SAEs) considered related to the GLPG CAR T-cell therapy
The pattern of vector integration sites, if vector sequences are detected in new malignancies, or in at least 1% of peripheral blood mononuclear cells (PBMCs)
The incidence of detectable replication-competent lentivirus (RCL) in peripheral blood
Cause-specific mortality

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the long-term efficacy of GLPG CAR T-cell products for up to 15 years post CAR T-cell product infusion
To evaluate the persistence of GLPG CAR Tcell products for up to 15 years post CAR Tcell product infusion

Secondary Endpoints

Disease progression status
Time to subsequent anticancer therapy
Overall survival
The incidence of detectable CAR transgene in peripheral blood over time

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subject must sign and date the ICF as approved by the Independent Ethics Committee (IEC)/Institutional Review

Board (IRB), prior to any study-related procedures.
Subjects has been treated with a GLPG CAR T-cell therapy in a clinical trial or Managed Access Program.

Exclusion criteria

There are no exclusion criteria for this study.

Calendar

(Last Update: 28/11/2025)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
21/06/2024	09/09/2024	15/10/2024	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

Galapagos Cell Therapeutics Belgium

Schalienhoevedreef 20t

Contact Person

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Monetary support: N/A

Sponsor type: Commercial

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Sites

not initialized (--/--/----)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Hematology

Medication

BCMACP03
DISPERSION FOR INFUSION
INTRAVENIOUS INFUSION

-
Active Principles: N/A

Experimental

19CP02
DISPERSION FOR INFUSION
INTRAVENOUS USE

-
Active Principles: N/A

Experimental

BCN-CP01
DISPERSION FOR INFUSION
INTRAVENOUS USE

-
Active Principles: N/A

Experimental

No results