

Study to evaluate the effects of CLR 131 in patients with B-Cell malignancies (CLOVER-1) and expansion study to evaluate the effects of CLR 131 specifically in patients with Waldenstrom Macroglobulinemia (CLOVER-WaM)

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
65

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
Si

Cobertura geográfica
Multicéntrico internacional

Ámbitos del ensayo
seguridad, eficacia

Terapia avanzada
NO

Información

Identificador
2023-508671-37-00 (CTIS)

Cod. Protocolo
DCL-16-001

Transicionado 2020-005297-10

Área terapéutica
Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Waldenstrom Macroglobulinemia

Título Científico
An Open-Label, Multicenter, Phase 2 Study of CLR 131 in Patients with Relapsed or Refractory (R/R) Select B-Cell Malignancies (CLOVER-1) and Expansion Cohort in Patients with Waldenstrom Macroglobulinemia (CLOVER-WaM)

Justificación

No aportado

Objetivo Principal

The primary objective of the study is to determine the major response rate (MRR) of CLR 131 in patients with WM who have received at least two prior lines of therapy.

Variables de Evaluación Primaria

The primary endpoint is the MRR, which is defined as the proportion of patients following the infusion of CLR 131 with complete response (CR), very good partial response (VGPR), or partial response (PR) determined from criteria modified from the Vth Waldenstroms Macroglobulinemia Criteria for Response Assessment up to 12 months post first CLR 131 infusion in WM patients who have received at least two prior lines of therapy.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

1. To determine the overall response rate (ORR), treatment free survival (TFS), duration of response (DOR), and clinical benefit rate (CBR) in the population under study
2. To further describe the safety and tolerability (AE) profile of CLR 131 in the population under study, and in sub-populations

Variables de Evaluación Secundaria

1. Overall response rate (ORR), defined as the proportion of patients with a MR, PR, VGPR, or CR determined from criteria modified from the Vth Waldenstroms Macroglobulinemia Criteria for Response Assessment.
2. Treatment free survival (TFS), defined as the time from last CLR 131 dose to time to initiation of subsequent therapy or death.
3. Duration of response (DOR) is defined as the time from the first documentation of response (including CR, VGPR, PR) to PD or death. For DOR, patients who are alive and progression free during this study will have their event time censored on the last disease assessment.
4. Clinical benefit rate (CBR) is defined as the proportion of patients with CR, VGPR, PR, MR, and SD determined from criteria modified from the Vth Waldenstroms Macroglobulinemia Criteria for Response Assessment.
5. Safety. Adverse events (AEs), serious AE (SAEs), AEs with Grade 3, laboratory results, vital signs, electrocardiogram (ECG), and Eastern Cooperative Oncology Group (ECOG) performance status (PS).

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

1. Histologically or cytologically confirmed WM. Patients with a diagnosis of LPL may be enrolled with prior Sponsor approval.
2. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 to 2.
3. Patient is 18 years of age or older.
4. Life expectancy of at least 6 months.
5. Received at least two prior lines of therapy for WM.

Criterios de Exclusión

1. Ongoing Grade 2 or greater toxicities due to previous therapies, excluding alopecia.
10. Pregnancy or breast-feeding.
2. Prior external-beam RT resulting in greater than 20% of total bone marrow receiving greater than 20 Gy.
3. Prior total body or hemi-body irradiation. Patients who have received prior low-dose total body or hemi-body irradiation may be allowed on a case-by-case basis after discussion with Sponsor (considerations may include factors such as time since irradiation, total lifetime accumulated dose, etc.).
4. Patients with second malignancies in addition to WM, if the second malignancy has required systemic therapy in the last 2 years. Exceptions to this criterion include secondary malignancies in remission, successfully treated skin malignancies, skin malignancies only requiring topic treatment or surgical excision, or other cancer that do not require therapy.
5. Anti-cancer therapy within two weeks of initial CLR 131 infusion.
6. Major surgery within 6 weeks of enrollment.
7. History of hypersensitivity to thyroid protection medication (e.g., potassium iodide, Lugols solution, etc.).
8. Known history of human immunodeficiency virus, active or chronic hepatitis C, or hepatitis B infection.
9. Presence of active infection within 72 hours prior to dosing; patients with ongoing use of prophylactic antibiotics, antifungals, or antivirals are eligible as long as there is no evidence of active infection and the antibiotics, antifungals, or antivirals are not included on the list of prohibited medications.

Calendario

(Última actualización: 26/03/2025)

Autorización 28/04/2022	Inicio de Ensayo 10/06/2022	Inclusión Primer Paciente 11/08/2022	Interrumpido No aportado	Reiniciado No aportado
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Fin de reclutamiento 12/01/2024	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España 29/02/2024	Fin del ensayo global No aportado
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Promotor

Cellectar Biosciences Inc. United States

100 Campus Drive

Contact Person

Clinical Trial Team

16083278125

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Activo (10/06/2022)	CLINICA UNIVERSIDAD DE NAVARRA Madrid MADRID Hematología
No iniciado (---/---/----)	Clinica Universidad De Navarra Madrid MADRID Hematology
Activo (14/10/2022)	Complejo Asistencial Universitario De Salamanca Salamanca SALAMANCA Hematología
Activo (29/07/2022)	HOSPITAL CLINIC DE BARCELONA Barcelona BARCELONA Hematología
No iniciado (---/---/----)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology
No iniciado (---/---/----)	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematology
Activo (21/10/2022)	HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ Madrid MADRID Hematología
No iniciado (---/---/----)	Hospital Universitario Fundacion Jimenez Diaz Madrid MADRID Hematology

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

Hospital Unviersitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medicamentos

-

-

ORAL

Código ATC: V03AB21 - IODURO DE POTASIO

Principios Activos: N/A

Experimental

PRD8597279

STERILE SOLUTION

INTRAVENIOUS INFUSION

Principios Activos: N/A

Huérfano

Experimental

Sin resultados

Study to evaluate the effects of CLR 131 in patients with B-Cell malignancies (CLOVER-1) and expansion study to evaluate the effects of CLR 131 specifically in patients with Waldenstrom Macroglobulinemia (CLOVER-WaM)

State
Finished CT

Type of participants
Not provided

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

Gender
Both

Phases
Phase II

Expected Participants
65

Results
No results

Low level of intervention
No

Rare disease
Yes

Geographic coverage
International multicenter

Areas of the study
safety, effectiveness

Advanced therapy
NO

Information

Identifier
2023-508671-37-00 (CTIS)

Protocol Code
DCL-16-001

Transitioned 2020-005297-10

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Waldenstrom Macroglobulinemia

Scientific Title
An Open-Label, Multicenter, Phase 2 Study of CLR 131 in Patients with Relapsed or Refractory (R/R) Select B-Cell Malignancies (CLOVER-1) and Expansion Cohort in Patients with Waldenstrom Macroglobulinemia (CLOVER-WaM)

Rationale

Not provided

Main Objective

The primary objective of the study is to determine the major response rate (MRR) of CLR 131 in patients with WM who have received at least two prior lines of therapy.

Primary Endpoints

The primary endpoint is the MRR, which is defined as the proportion of patients following the infusion of CLR 131 with complete response (CR), very good partial response (VGPR), or partial response (PR) determined from criteria modified from the Vth Waldenstroms Macroglobulinemia Criteria for Response Assessment up to 12 months post first CLR 131 infusion in WM patients who have received at least two prior lines of therapy.

Temporary moments of secondary assessment

Not provided

Secondary Objective

1. To determine the overall response rate (ORR), treatment free survival (TFS), duration of response (DOR), and clinical benefit rate (CBR) in the population under study
 2. To further describe the safety and tolerability (AE) profile of CLR 131 in the population under study, and in sub-populations
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Secondary Endpoints

1. Overall response rate (ORR), defined as the proportion of patients with a MR, PR, VGPR, or CR determined from criteria modified from the Vth Waldenstroms Macroglobulinemia Criteria for Response Assessment.
 2. Treatment free survival (TFS), defined as the time from last CLR 131 dose to time to initiation of subsequent therapy or death.
 3. Duration of response (DOR) is defined as the time from the first documentation of response (including CR, VGPR, PR) to PD or death. For DOR, patients who are alive and progression free during this study will have their event time censored on the last disease assessment.
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Temporary moments of secondary assessment

Not provided

Inclusion criteria

1. Histologically or cytologically confirmed WM. Patients with a diagnosis of LPL may be enrolled with prior Sponsor approval.
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Calendar

(Last Update: 26/03/2025)

Authorization 28/04/2022	Start of Trial 10/06/2022	First patient inclusion 11/08/2022	Halted Not aported	Restarted Not aported
End of recruitment 12/01/2024	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) 29/02/2024	Trial end (Global) Not aported

Sponsor

Cellectar Biosciences Inc. United States

100 Campus Drive

Contact Person

Clinical Trial Team

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (10/06/2022)	CLINICA UNIVERSIDAD DE NAVARRA Madrid MADRID Hematología	Clinica Universidad De Navarra Madrid MADRID Hematology
Active (14/10/2022)	Complejo Asistencial Universitario De Salamanca Salamanca SALAMANCA Hematología	HOSPITAL CLINIC DE BARCELONA Barcelona BARCELONA Hematología
not initialized (---/---/----)	Hospital Clinic De Barcelona Barcelona BARCELONA Hematology	Hospital Universitario De Salamanca Salamanca SALAMANCA Hematology
Active (21/10/2022)	HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ Madrid MADRID Hematología	Hospital Universitario Fundacion Jimenez Diaz Madrid MADRID Hematology

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

Hospital Unviersitario Miguel Servet

Zaragoza

ZARAGOZA

Hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medication

-

-

ORAL

ATC code: V03AB21 - IODURO DE POTASIO

Active Principles: N/A

Experimental

PRD8597279

STERILE SOLUTION

INTRAVENIOUS INFUSION

-

Active Principles: N/A

Orphan

Experimental

No results