A Trial to Learn if Odronextamab Combined with Chemotherapy is Safe and Well-Tolerated and How Well it Works Compared to Rituximab Combined with Chemotherapy for Adult Participants with Follicular Lymphoma

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	513
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2022-502113-28-00 (CTIS)

Cod. Protocolo
R1979-ONC-2075

Área terapéutica
Enfermedades [C] - Hematología [C15]|

Enfermedad investigada
Follicular lymphoma

Título Científico
A Phase 3, Open-Label, Randomized Study To Compare the Efficacy and Safety of Odronextamab (REGN1979), an Anti-CD20 x Anti-CD3 Bispecific Antibody, Combined with Chemotherapy versus Rituximab Combined with Chemotherapy in Previously Untreated Participants with Follicular Lymphoma (OLYMPIA-2)

Justificación

No aportado

Objetivo Principal

Part 1
Assess the safety, tolerability, and dose limiting toxicities (DLTs) of odronextamab in combination with chemotherapy in participants with previously untreated follicular lymphoma (FL) and participants with relapsed or refractory (R/R) FL (Part 1A only), and to determine an optimal dosing regimen of odronextamab (Part 1B) in previously untreated participants with FL to combine with CHOP/CVP in Part 2.
Part 2
To compare the efficacy of odronextamab in combination with chemotherapy versus rituximab in combination with chemotherapy in participants with previously untreated FL as measured by complete response rate at 30 months (CR30) per independent central review.

Variables de Evaluación Primaria

Part 1: Incidence of dose limiting toxicities (DLTs) for odronextamab in combination with chemotherapy
Part 1: Incidence of treatment-emergent adverse events (TEAEs) of odronextamab in combination with chemotherapy
Part 1: Severity of treatment-emergent adverse events (TEAEs) of odronextamab in combination with chemotherapy
Part 2: Complete Response rate at 30 months (CR30) assessed by independent central review (ICR)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 1: To characterize the pharmacokinetics (PK) of odronextamab in combination with chemotherapy
Part 1: To assess the immunogenicity of odronextamab in combination with chemotherapy
Part 1: To evaluate the preliminary anti-tumor activity of odronextamab in combination with chemotherapy
Part 2: To compare the efficacy per independent central review between odronextamab in combination with chemotherapy versus rituximab in combination with chemotherapy as measured by: Progression-free survival (PFS)
Part 2: To compare the efficacy of odronextamab in combination with chemotherapy versus rituximab in combination with chemotherapy as measured by CR30 per investigator
Part 2: To compare changes over time in patient reported physical functioning between odronextamab in combination with chemotherapy versus rituximab in combination with chemotherapy
Part 2: To compare additional measures of efficacy of odronextamab in combination with chemotherapy compared to rituximab in combination with chemotherapy.
Part 2: To evaluate safety and tolerability of odronextamab in combination with chemotherapy compared to rituximab in combination with chemotherapy
Part 2: To evaluate the PK of odronextamab in combination with chemotherapy
Part 2: To assess the immunogenicity of odronextamab in combination with chemotherapy.
Part 2: To evaluate the impact of odronextamab in combination with chemotherapy compared to rituximab in combination with chemotherapy on changes over time in patient reported outcomes, including health related quality

of life (HRQoL), functioning (other than physical functioning) and symptoms
Part 2: To evaluate the overall impact of treatment toxicity using the Global Population item 5 (GP5 Item) of the validated FACT-G (Functional Assessment of Cancer Therapy-General) questionnaire

Variables de Evaluación Secundaria

Part 1 and 2: Odronextamab concentrations in serum when administered with chemotherapy
Part 1 and 2: Odronextamab concentrations in serum when administered as monotherapy
Part 1 and 2: Incidence of anti-odronextamab antibodies (ADAs)
Part 1 and 2: Titers of ADAs to odronextamab
Part 1 and 2: Incidence of neutralizing antibodies (NAb) to odronextamab
Part 1: Best overall response (BOR) as assessed by the investigator
Part 2: Progression free survival (PFS) as assessed by ICR
Part 2: Event-free survival (EFS) as assessed by ICR
Part 2: CR30 as assessed by local investigator
Part 2: Change in patient reported physical functioning scale scores on the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Cancer-30 (EORTC-QLQ-C30)
Part 2: PFS as assessed by local investigator
Part 2: EFS as assessed by local investigator
Part 2: Overall Survival (OS)
Part 2: Best Overall response (BOR) as assessed by local investigator
Part 2: BOR as assessed by ICR
Part 2: Duration of response (DOR) assessed by ICR
Part 2: DOR as assessed by local investigator
Part 2: Time to next anti-lymphoma treatment (TTNT)
Part 2: Incidence of TEAEs
Part 2: Severity of TEAEs
Part 2: Change in patient reported health related quality of life (HRQoL) as measured by EORTC-QLQ-C30
Part 2: Change in cancer disease as measured by EORTC-QLQ-C30
Part 2: Change in treatment related symptoms as measured by EORTC-QLQ-C30
Part 2: Change in patient-reported lymphoma disease as measured by the Lymphoma Subscale of the Functional Assessment of Cancer Treatment-Lymphoma (FACT-LymS)
Part 2: Change in treatment-related symptoms as measured by the FACT-LymS
Part 2: Change in patient-reported general health status per EuroQol-5 Dimensions-5 Levels (EQ-5D-5L)
Part 2: Change in patient-reported treatment side effects burden per Functional Assessment of Cancer TherapyGeneral Global Population Item 5 (FACT-5 GP5)
Part 2: Change in Patient Global Impression of Severity (PGIS)
Part 2: Change in Patient Global Impression of Change (PGIC)
Part 2: Change in score of the FACT-G GP5 item in the patient population

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Have diagnosis of cluster of differentiation 20 positive (CD20+) FL grade 1-3a, stage II bulky or stage III / IV
Have measurable disease on cross sectional imaging documented by diagnostic computed tomography [CT], or magnetic resonance imaging [MRI] imaging, as described in the protocol

Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
Adequate bone marrow and hepatic function
NOTE: Other protocol defined inclusion criteria apply

Criterios de Exclusión

Participants with central nervous system lymphoma or leptomeningeal lymphoma
Participants with histological evidence of transformation to a high-grade or diffuse large B-cell lymphoma
Participants with Waldenström macroglobulinemia (WM, lymphoplasmacytic lymphoma), grade 3b follicular lymphoma, chronic lymphocytic leukemia or small lymphocytic lymphoma
Recent major surgery and history or organ transplantation
A malignancy other than NHL unless the participant is adequately and definitively treated and any other significant active disease or medical condition that could interfere with the conduct of the study or put the participant at significant risk, as described in the protocol
NOTE: Other protocol defined exclusion criteria apply

Calendario

(Última actualización: 03/07/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
24/10/2023	01/02/2024	01/02/2024	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

Regeneron Pharmaceuticals Inc. United States

777 Old Saw Mill River Road

Contact Person

Head EU Regulatory

00353818882469

medical.information_EU@regeneron.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CElm Parc Tauli

Plaça de la Torre de lAigua, s/n 08208 Sabadell

ceic@tauli.cat

937458454-937458451

Centros

Activo (31/01/2024)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Activo (06/02/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Activo (14/02/2025)

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

Hematology

Activo (16/05/2024)

Fundacion Instituto Valenciano De Oncologia

Valencia

VALENCIA

Hematology

Activo (17/02/2025)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

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

Hospital Clinico Universitario Lozano Blesa

Zaragoza

ZARAGOZA

Hematology

Activo (11/02/2025)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

Hematology

Activo (31/01/2024)

Hospital Universitari Mutua Terrassa

Terrassa

BARCELONA

Hematology

Activo (16/05/2024)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Activo (18/06/2025)

Hospital Universitario De Cruces

Barakaldo

VIZCAYA/BIZKAIA

Hematology

Activo (04/02/2025)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Activo (08/03/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Cerrado (21/03/2025)

Hospital Universitario De Toledo Ute

Toledo

TOLEDO

Hematology

Activo (23/04/2024)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Activo (19/02/2024)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Activo (04/02/2025)

Hospital Universitario Lucus Augusti

Lugo

LUGO

Hematology

Activo (14/05/2024)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (26/01/2024)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Activo (31/01/2024)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Activo (12/02/2025)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Activo (14/05/2024)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

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

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (18/03/2024)

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Hematology

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Activo (17/01/2024)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

PREDNISOLONE
ORODISPERSIBLE TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

PREDNISONE
TABLET
ORAL

-
Principios Activos: N/A

Experimental

Truxima 100 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

Código ATC: L01FX34 - ODRONEXTAMAB
Principios Activos: N/A

Huérfano
Experimental

DOXORUBICIN HYDROCHLORIDE
SOLUTION FOR INJECTION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

VINCRISTINE SULFATE
INJECTION
INJECTION

-
Principios Activos: N/A

Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

Código ATC: L01FX34 - ODRONEXTAMAB
Principios Activos: N/A

Huérfano
Experimental

CYCLOPHOSPHAMIDE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

Truxima 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A

Experimental

Sin resultados

A Trial to Learn if Odronextamab Combined with Chemotherapy is Safe and Well-Tolerated and How Well it Works Compared to Rituximab Combined with Chemotherapy for Adult Participants with Follicular Lymphoma

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	513
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2022-502113-28-00 (CTIS)

Protocol Code
R1979-ONC-2075

Therapeutic area
Diseases [C] - Hemic and Lymphatic Diseases [C15]|

Investigated Disease
Follicular lymphoma

Scientific Title
A Phase 3, Open-Label, Randomized Study To Compare the Efficacy and Safety of Odronextamab (REGN1979), an Anti-CD20 x Anti-CD3 Bispecific Antibody, Combined with Chemotherapy versus Rituximab Combined with Chemotherapy in Previously Untreated Participants with Follicular Lymphoma (OLYMPIA-2)

Rationale

Not provided

Main Objective

Part 1
Assess the safety, tolerability, and dose limiting toxicities (DLTs) of odronextamab in combination with chemotherapy in participants with previously untreated follicular lymphoma (FL) and participants with relapsed or refractory (R/R) FL (Part 1A only), and to determine an optimal dosing regimen of odronextamab (Part 1B) in previously untreated participants with FL to combine with CHOP/CVP in Part 2.
Part 2
To compare the efficacy of odronextamab in combination with chemotherapy versus rituximab in combination with chemotherapy in participants with previously untreated FL as measured by complete response rate at 30 months (CR30) per independent central review.

Primary Endpoints

Part 1: Incidence of dose limiting toxicities (DLTs) for odronextamab in combination with chemotherapy
Part 1: Incidence of treatment-emergent adverse events (TEAEs) of odronextamab in combination with chemotherapy
Part 1: Severity of treatment-emergent adverse events (TEAEs) of odronextamab in combination with chemotherapy
Part 2: Complete Response rate at 30 months (CR30) assessed by independent central review (ICR)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 1: To characterize the pharmacokinetics (PK) of odronextamab in combination with chemotherapy
Part 1: To assess the immunogenicity of odronextamab in combination with chemotherapy
Part 1: To evaluate the preliminary anti-tumor activity of odronextamab in combination with chemotherapy
Part 2: To compare the efficacy per independent central review between odronextamab in combination with chemotherapy versus rituximab in combination with chemotherapy as measured by: Progression-free survival (PFS)
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Part 2: To assess the immunogenicity of odronextamab in combination with chemotherapy.
Part 2: To evaluate the impact of odronextamab in combination with chemotherapy compared to rituximab in combination with chemotherapy on changes over time in patient reported outcomes, including health related quality

of life (HRQoL), functioning (other than physical functioning) and symptoms
Part 2: To evaluate the overall impact of treatment toxicity using the Global Population item 5 (GP5 Item) of the validated FACT-G (Functional Assessment of Cancer Therapy-General) questionnaire

Secondary Endpoints

Part 1 and 2: Odronextamab concentrations in serum when administered with chemotherapy
Part 1 and 2: Odronextamab concentrations in serum when administered as monotherapy
Part 1 and 2: Incidence of anti-odronextamab antibodies (ADAs)
Part 1 and 2: Titers of ADAs to odronextamab
Part 1 and 2: Incidence of neutralizing antibodies (NAb) to odronextamab
Part 1: Best overall response (BOR) as assessed by the investigator
Part 2: Progression free survival (PFS) as assessed by ICR
Part 2: Event-free survival (EFS) as assessed by ICR
Part 2: CR30 as assessed by local investigator
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Part 2: Change in patient-reported treatment side effects burden per Functional Assessment of Cancer TherapyGeneral Global Population Item 5 (FACT-5 GP5)
Part 2: Change in Patient Global Impression of Severity (PGIS)
Part 2: Change in Patient Global Impression of Change (PGIC)
Part 2: Change in score of the FACT-G GP5 item in the patient population

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Have diagnosis of cluster of differentiation 20 positive (CD20+) FL grade 1-3a, stage II bulky or stage III / IV
Have measurable disease on cross sectional imaging documented by diagnostic computed tomography [CT], or magnetic resonance imaging [MRI] imaging, as described in the protocol

Eastern Cooperative Oncology Group (ECOG) performance status of 0-2
Adequate bone marrow and hepatic function
NOTE: Other protocol defined inclusion criteria apply

Exclusion criteria

Participants with central nervous system lymphoma or leptomeningeal lymphoma
Participants with histological evidence of transformation to a high-grade or diffuse large B-cell lymphoma
Participants with Waldenström macroglobulinemia (WM, lymphoplasmacytic lymphoma), grade 3b follicular lymphoma, chronic lymphocytic leukemia or small lymphocytic lymphoma
Recent major surgery and history or organ transplantation
A malignancy other than NHL unless the participant is adequately and definitively treated and any other significant active disease or medical condition that could interfere with the conduct of the study or put the participant at significant risk, as described in the protocol
NOTE: Other protocol defined exclusion criteria apply

Calendar

(Last Update: 03/07/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
24/10/2023	01/02/2024	01/02/2024	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

Regeneron Pharmaceuticals Inc. United States

777 Old Saw Mill River Road

Contact Person

Head EU Regulatory

00353818882469

medical.information_EU@regeneron.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc Tauli

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937458454-937458451

Sites

Active (31/01/2024)

Clinica Universidad De Navarra

Madrid

MADRID

Hematology

Active (06/02/2024)

Clinica Universidad De Navarra

Pamplona

NAVARRA

Hematology

Active (14/02/2025)

Complejo Hospitalario Universitario De Ourense

Ourense

OURENSE

Hematology

Active (16/05/2024)

Fundacion Instituto Valenciano De Oncologia

Valencia

VALENCIA

Hematology

Active (17/02/2025)

Hospital Clinico Universitario De Valencia

Valencia

VALENCIA

Hematology

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

Hospital Clinico Universitario Lozano Blesa

Zaragoza

ZARAGOZA

Hematology

Active (11/02/2025)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

Hematology

Active (31/01/2024)

Hospital Universitari Mutua Terrassa

Terrassa

BARCELONA

Hematology

Active (16/05/2024)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Active (18/06/2025)

Hospital Universitario De Cruces

Barakaldo

VIZCAYA/BIZKAIA

Hematology

Active (04/02/2025)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Active (08/03/2024)

Hospital Universitario De Salamanca

Salamanca

SALAMANCA

Hematology

Closed (21/03/2025)

Hospital Universitario De Toledo Ute

Toledo

TOLEDO

Hematology

Active (23/04/2024)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Active (19/02/2024)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Active (04/02/2025)

Hospital Universitario Lucus Augusti

Lugo

LUGO

Hematology

Active (14/05/2024)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Active (26/01/2024)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Active (31/01/2024)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

Active (12/02/2025)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Active (14/05/2024)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

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

Institut Catala D'oncologia

Badalona

BARCELONA

Hematology

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Active (18/03/2024)

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Hematology

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

University Clinical Hospital Virgen De La Arrixaca

Murcia

MURCIA

Hematology

Active (17/01/2024)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

PREDNISOLONE
ORODISPERSIBLE TABLET
ORAL USE

-

Active Principles: N/A

Experimental

PREDNISONE
TABLET
ORAL

-

Active Principles: N/A

Experimental

Truxima 100 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

ATC code: L01FA01 - RITUXIMAB

Active Principles: N/A

Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

ATC code: L01FX34 - ODRONEXTAMAB

Active Principles: N/A

Orphan

Experimental

DOXORUBICIN HYDROCHLORIDE
SOLUTION FOR INJECTION
INTRAVENOUS

-

Active Principles: N/A

Experimental

VINCRISTINE SULFATE
INJECTION
INJECTION

-

Active Principles: N/A

Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

ATC code: L01FX34 - ODRONEXTAMAB

Active Principles: N/A

Orphan

Experimental

CYCLOPHOSPHAMIDE
SOLUTION FOR INJECTION/INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

Truxima 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS

ATC code: L01FA01 - RITUXIMAB
Active Principles: N/A

Experimental

No results