A study to compare how well odronextamab combined with chemotherapy works and how safe it is against rituximab combined with chemotherapy, in patients with previously untreated diffuse large B-cell 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	473
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2022-502785-25-00 (CTIS)

Cod. Protocolo
R1979-ONC-2105

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

Enfermedad investigada
Diffuse Large B-cell Lymphoma

Título Científico
A Phase 3, Open label, Randomized Study Comparing the Efficacy and Safety of Odronextamab (REGN1979), an anti-CD20 × anti-CD3 bispecific antibody, in Combination with CHOP (Odro-CHOP) versus Rituximab in Combination with CHOP (R-CHOP) in Previously Untreated Participants with Diffuse Large B-cell Lymphoma (DLBCL) (OLYMPIA-

3)

Justificación

This is a Phase 3 study and is categorized as a category 2 per EMA guidance.<br/

Objetivo Principal

Study Objectives- Part 1 (Safety Run-in): To assess the safety, tolerability and dose limiting toxicities (DLTs) of odronextamab in combination with CHOP (Odro-CHOP) in participants previously untreated for Diffuse Large B-Cell Lymphoma (DLBCL) with high-risk features or participants with relapsed or refractory DLBCL (Part 1A), and to determine the dose of odronextamab to combine with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) in Part 2. Study Objectives Part 2:
To compare the efficacy of Odro-CHOP with that of rituximab-CHOP (R-CHOP) in participants with previously untreated DLBCL with an (International Prognostic Index) IPI score 3, and subsequently in all participants with an IPI score 2.

Variables de Evaluación Primaria

Part 1: Incidence of dose limiting toxicities (DLTs)
Part 1: Incidence of treatment emergent adverse events (TEAEs)
Part 1: Severity of TEAEs
Part 2: Progression free survival (PFS), assessed by independent central review (ICR)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Part 1: To evaluate the preliminary anti-tumor activity of Odro-CHOP in participants with previously untreated DLBCL with high-risk features or participants with R/R DLBCL.
Part 1: To evaluate the pharmacokinetics (PK) of odronextamab when administered in combination with CHOP
Part 1: To assess the immunogenicity of odronextamab when administered in combination with CHOP
Part 2: To compare therapeutic benefit with Odro-CHOP versus that with R-CHOP assessed by event-free survival (EFS), complete response (CR) and overall survival (OS)
Part 2: To compare supplemental measures of efficacy for Odro-CHOP versus R-CHOP
Part 2: To compare safety and tolerability of Odro-CHOP with R-CHOP
Part 2: To evaluate the PK of odronextamab when administered in combination with CHOP
Part 2: To assess the immunogenicity of odronextamab when administered in combination with CHOP
Part 2: To compare measurable residual disease (MRD) with Odro-CHOP versus R-CHOP
Part 2: To compare the treatment effects on patient reported physical function between Odro-CHOP and R-CHOP
Part 2: To compare the treatment effects of Odro-CHOP versus R-CHOP on patient reported outcomes (PROs) including health-related quality of life, functioning and disease-related symptoms, as measured by European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire 30 (EORTC QLQ-C30),

Functional Assessment of Cancer Therapy - Lymphoma (FACT-LymS), EuroQol-5 Dimension-5 Level Scale (EQ 5D-5L), two global anchors Patient Global Impression of Severity (PGIS) and Patient Global Impression of Change (PGIC), collected during study visits
Part 2: To evaluate the overall impact of treatment toxicity based upon the single item GP5 of the validated Functional Assessment of Cancer Therapy - General [FACT-G questionnaire (I am bothered by side effects of treatment)]

Variables de Evaluación Secundaria

Part 1 & 2: Best Overall response (BOR) as assessed by local investigators
Part 1 & 2: CR as assessed by local investigators
Part 1 & 2: Duration of response (DOR) as assessed by local investigators
Part 1 & 2: Odronextamab concentrations in serum when administered with CHOP
Part 1 & 2: Incidence of anti-drug antibodies (ADA) to odronextamab over the study duration
Part 1 & 2: Titer of ADA to odronextamab over the study duration
Part 1 & 2: Incidence of neutralizing antibodies (NAb) to odronextamab over the study duration
Part 2: Event-free survival (EFS) assessed by ICR
Part 2: Complete response (CR) assessed by ICR
Part 2: Overall survival (OS)
Part 2: PFS assessed by local investigator review
Part 2: EFS assessed by local investigator review
Part 2: BOR assessed by ICR
Part 2: DOR assessed by ICR
Part 2: Incidence of TEAEs
Part 2: Severity of TEAEs
Part 2: Measurable Residual Disease (MRD) status
Part 2: Duration of MRD-negativity
Part 2: Change in physical functioning as measured by EORTC QLQ C30
Part 2: Change in patient reported outcomes, as measured by EORTC QLQ-C30
Part 2: Change in patient reported outcomes, as measured by FACT-LymS
Part 2: Change in patient reported outcomes, as measured by PGIS
Part 2: Change in patient reported outcomes, as measured by PGIC
Part 2: Change in patient reported outcomes, as measured by EQ-5D-5L
Part 2: Change in score of the FACT-G GP5 item

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Previously untreated participants for lymphoma with documented cluster of differentiation 20+ (CD20+) DLBCL, as described in the protocol or R/R DLBCL for whom next available standard of care therapy is not available or deemed ineligible according to investigator (Part 1A only)
Measurable disease with at least one nodal lesion or at least one extranodal lesion, as described in the protocol
Eastern Cooperative Oncology Group (ECOG) performance status 2
Life expectancy 12 months
International Prognostic Index (IPI) of 3 to 5 (part 1 only) and 2 (part 2) for untreated DLBCL only
Adequate hematologic and organ function, as defined in the protocol

Note: Other protocol-defined Inclusion criteria apply

Criterios de Exclusión

Primary central nervous system (CNS) lymphoma or known involvement by non-primary CNS NHL and history or current relevant CNS pathology
Another active malignancy, significant active disease or medical condition, as described in the protocol
Peripheral neuropathy Grade 3
Treatment with any systemic anti-lymphoma therapy , except for participants with R/R DLBCL and participants with DLBCL transformed from an indolent follicular lymphoma after treatment with systemic anti-lymphoma therapy.
Any other therapy or investigational treatment within 28 days or 5 half-lives of the drug, whichever is shorter, prior to the start of study treatment
Recent major surgery, prior organ transplantation, or standard radiotherapy, as described in the protocol
Allergy/hypersensitivity to study drugs, as described in the protocol
Infections such as any active infection (bacterial, viral, fungal, mycobacterial, parasitic or other), active Coronavirus disease (COVID-19) infection, uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV), Cytomegalovirus (CMV) infection, as described in the protocol.
Note: Other protocol-defined Exclusion criteria apply

Calendario

(Última actualización: 23/01/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
11/09/2023	15/02/2024	15/02/2024	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 Affairs

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

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

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematology

Activo (30/05/2024)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematology

Activo (16/05/2024)

Fundacion Instituto Valenciano De Oncologia

Valencia

VALENCIA

Hematology

Activo (18/04/2024)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

Activo (01/02/2024)

Hospital Universitari Mutua Terrassa

Terrassa

BARCELONA

Hematology

Activo (16/05/2024)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Activo (10/03/2025)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Cerrado (21/03/2025)

Hospital Universitario De Toledo Ute

Toledo

TOLEDO

Hematology

Activo (08/01/2024)

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Hematology

Activo (30/04/2024)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Activo (07/02/2024)

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Hematology

Activo (16/02/2024)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Activo (27/03/2024)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Activo (05/02/2024)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Activo (15/02/2024)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

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

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

-

Activo (08/01/2024)

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

Hematology

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

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

Institut Catala D´oncologia

Badalona

BARCELONA

-

Activo (21/03/2024)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Activo (21/03/2024)

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Hematology

Activo (15/01/2024)

University Hospital Son Espases

Palma

BALEARES

Hematology

Activo (16/01/2024)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medicamentos

RITUXIMAB
SOLUTION FOR INFUSION
SOLUTION FOR INFUSION

-
Principios Activos: N/A

Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Huérfano Experimental

VINCRISTINE SULFATE
INJECTION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

DOXORUBICIN HYDROCHLORIDE
SOLUTION FOR INJECTION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

PREDNISOLONE
TABLET
ORAL USE

-
Principios Activos: N/A

Experimental

PREDNISONE
TABLET
ORAL

-
Principios Activos: N/A

Experimental

CYCLOPHOSPHAMIDE MONOHYDRATE
SOLUTION FOR INJECTION
INTRAVENOUS

-
Principios Activos: N/A

Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-
Principios Activos: N/A

Huérfano Experimental

RITUXIMAB
SOLUTION FOR INJECTION
SOLUTION FOR INJECTION

-

Principios Activos: N/A

Experimental

Sin resultados

A study to compare how well odronextamab combined with chemotherapy works and how safe it is against rituximab combined with chemotherapy, in patients with previously untreated diffuse large B-cell lymphoma

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	473
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2022-502785-25-00 (CTIS)

Protocol Code
R1979-ONC-2105

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

Investigated Disease
Diffuse Large B-cell Lymphoma

Scientific Title
A Phase 3, Open label, Randomized Study Comparing the Efficacy and Safety of Odronextamab (REGN1979), an anti-CD20 × anti-CD3 bispecific antibody, in Combination with CHOP (Odro-CHOP) versus Rituximab in Combination with CHOP (R-CHOP) in Previously Untreated Participants with Diffuse Large B-cell Lymphoma (DLBCL) (OLYMPIA-

3)

Rationale

This is a Phase 3 study and is categorized as a category 2 per EMA guidance.<br/

Main Objective

Study Objectives- Part 1 (Safety Run-in): To assess the safety, tolerability and dose limiting toxicities (DLTs) of odronextamab in combination with CHOP (Odro-CHOP) in participants previously untreated for Diffuse Large B-Cell Lymphoma (DLBCL) with high-risk features or participants with relapsed or refractory DLBCL (Part 1A), and to determine the dose of odronextamab to combine with CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone) in Part 2. Study Objectives Part 2:
To compare the efficacy of Odro-CHOP with that of rituximab-CHOP (R-CHOP) in participants with previously untreated DLBCL with an (International Prognostic Index) IPI score 3, and subsequently in all participants with an IPI score 2.

Primary Endpoints

Part 1: Incidence of dose limiting toxicities (DLTs)
Part 1: Incidence of treatment emergent adverse events (TEAEs)
Part 1: Severity of TEAEs
Part 2: Progression free survival (PFS), assessed by independent central review (ICR)

Temporary moments of secondary assessment

Not provided

Secondary Objective

Part 1: To evaluate the preliminary anti-tumor activity of Odro-CHOP in participants with previously untreated DLBCL with high-risk features or participants with R/R DLBCL.
Part 1: To evaluate the pharmacokinetics (PK) of odronextamab when administered in combination with CHOP
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Part 2: To evaluate the PK of odronextamab when administered in combination with CHOP
Part 2: To assess the immunogenicity of odronextamab when administered in combination with CHOP
Part 2: To compare measurable residual disease (MRD) with Odro-CHOP versus R-CHOP
Part 2: To compare the treatment effects on patient reported physical function between Odro-CHOP and R-CHOP
Part 2: To compare the treatment effects of Odro-CHOP versus R-CHOP on patient reported outcomes (PROs) including health-related quality of life, functioning and disease-related symptoms, as measured by European Organization for Research and Treatment of Cancer Quality of Life Core Questionnaire 30 (EORTC QLQ-C30),

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Part 2: To evaluate the overall impact of treatment toxicity based upon the single item GP5 of the validated Functional Assessment of Cancer Therapy - General [FACT-G questionnaire (I am bothered by side effects of treatment)]

Secondary Endpoints

Part 1 & 2: Best Overall response (BOR) as assessed by local investigators
Part 1 & 2: CR as assessed by local investigators
Part 1 & 2: Duration of response (DOR) as assessed by local investigators
Part 1 & 2: Odronextamab concentrations in serum when administered with CHOP
Part 1 & 2: Incidence of anti-drug antibodies (ADA) to odronextamab over the study duration
Part 1 & 2: Titer of ADA to odronextamab over the study duration
Part 1 & 2: Incidence of neutralizing antibodies (NAb) to odronextamab over the study duration
Part 2: Event-free survival (EFS) assessed by ICR
Part 2: Complete response (CR) assessed by ICR
Part 2: Overall survival (OS)
Part 2: PFS assessed by local investigator review
Part 2: EFS assessed by local investigator review
Part 2: BOR assessed by ICR
Part 2: DOR assessed by ICR
Part 2: Incidence of TEAEs
Part 2: Severity of TEAEs
Part 2: Measurable Residual Disease (MRD) status
Part 2: Duration of MRD-negativity
Part 2: Change in physical functioning as measured by EORTC QLQ C30
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Part 2: Change in patient reported outcomes, as measured by FACT-LymS
Part 2: Change in patient reported outcomes, as measured by PGIS
Part 2: Change in patient reported outcomes, as measured by PGIC
Part 2: Change in patient reported outcomes, as measured by EQ-5D-5L
Part 2: Change in score of the FACT-G GP5 item

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Previously untreated participants for lymphoma with documented cluster of differentiation 20+ (CD20+) DLBCL, as described in the protocol or R/R DLBCL for whom next available standard of care therapy is not available or deemed ineligible according to investigator (Part 1A only)
Measurable disease with at least one nodal lesion or at least one extranodal lesion, as described in the protocol
Eastern Cooperative Oncology Group (ECOG) performance status 2
Life expectancy 12 months
International Prognostic Index (IPI) of 3 to 5 (part 1 only) and 2 (part 2) for untreated DLBCL only
Adequate hematologic and organ function, as defined in the protocol

Note: Other protocol-defined Inclusion criteria apply

Exclusion criteria

Primary central nervous system (CNS) lymphoma or known involvement by non-primary CNS NHL and history or current relevant CNS pathology
Another active malignancy, significant active disease or medical condition, as described in the protocol
Peripheral neuropathy Grade 3
Treatment with any systemic anti-lymphoma therapy , except for participants with R/R DLBCL and participants with DLBCL transformed from an indolent follicular lymphoma after treatment with systemic anti-lymphoma therapy.
Any other therapy or investigational treatment within 28 days or 5 half-lives of the drug, whichever is shorter, prior to the start of study treatment
Recent major surgery, prior organ transplantation, or standard radiotherapy, as described in the protocol
Allergy/hypersensitivity to study drugs, as described in the protocol
Infections such as any active infection (bacterial, viral, fungal, mycobacterial, parasitic or other), active Coronavirus disease (COVID-19) infection, uncontrolled infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV), Cytomegalovirus (CMV) infection, as described in the protocol.
Note: Other protocol-defined Exclusion criteria apply

Calendar

(Last Update: 23/01/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
11/09/2023	15/02/2024	15/02/2024	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 Affairs

00353818882469

medical.information_EU@regeneron.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Parc Tauli

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

ceic@tauli.cat

937458454-937458451

Sites

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

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Hematology

Active (30/05/2024)

Complexo Hospitalario Universitario De Santiago

Santiago De Compostela

CORUÑA

Hematology

Active (16/05/2024)

Fundacion Instituto Valenciano De Oncologia

Valencia

VALENCIA

Hematology

Active (18/04/2024)

Hospital De La Santa Creu I Sant Pau

Barcelona

BARCELONA

Hematology

Active (01/02/2024)

Hospital Universitari Mutua Terrassa

Terrassa

BARCELONA

Hematology

Active (16/05/2024)

Hospital Universitario Central De Asturias

Oviedo

ASTURIAS

Hematology

Active (10/03/2025)

Hospital Universitario De Navarra

Pamplona

NAVARRA

Hematology

Closed (21/03/2025)

Hospital Universitario De Toledo Ute

Toledo

TOLEDO

Hematology

Active (08/01/2024)

Hospital Universitario Dr Peset Aleixandre

Valencia

VALENCIA

Hematology

Active (30/04/2024)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Hematology

Active (07/02/2024)

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Hematology

Active (16/02/2024)

Hospital Universitario Infanta Leonor

Madrid

MADRID

Hematology

Active (27/03/2024)

Hospital Universitario Marques De Valdecilla

Santander

CANTABRIA

Hematology

Active (05/02/2024)

Hospital Universitario Quironsalud Madrid

Pozuelo De Alarcon

MADRID

Hematology

Active (15/02/2024)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Hematology

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

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

-

Active (08/01/2024)

Hospital Universitario Virgen De Las Nieves

Granada

GRANADA

Hematology

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

Hematology

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

Institut Catala D´oncologia

Badalona

BARCELONA

-

Active (21/03/2024)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Active (21/03/2024)

Parc Tauli Hospital Universitari

Sabadell

BARCELONA

Hematology

Active (15/01/2024)

University Hospital Son Espases

Palma

BALEARES

Hematology

Active (16/01/2024)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Hematology

Medication

RITUXIMAB
SOLUTION FOR INFUSION
SOLUTION FOR INFUSION

-

Active Principles: N/A

Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Orphan

Experimental

VINCRISTINE SULFATE
INJECTION
INTRAVENOUS

-

Active Principles: N/A

Experimental

DOXORUBICIN HYDROCHLORIDE
SOLUTION FOR INJECTION
INTRAVENOUS

-

Active Principles: N/A

Experimental

PREDNISOLONE
TABLET
ORAL USE

-

Active Principles: N/A

Experimental

PREDNISONE
TABLET
ORAL

-

Active Principles: N/A

Experimental

CYCLOPHOSPHAMIDE MONOHYDRATE
SOLUTION FOR INJECTION
INTRAVENOUS

-

Active Principles: N/A

Experimental

Odronextamab
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Orphan

Experimental

RITUXIMAB
SOLUTION FOR INJECTION
SOLUTION FOR INJECTION

-

Active Principles: N/A

Experimental

No results