

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
Reclutando

Tipo de Participantes
No aportado

Rangos de Edad
Mayores de 64 , Adultos (18-64 años)

Género
Ambos

Fases
Fase III

Participantes esperados
513

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
No

Cobertura geográfica
Sin determinar

Ámbitos del ensayo
seguridad, eficacia

Terapia avanzada
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 Therapy-General 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: 22/05/2026)

Autorización 24/10/2023	Inicio de Ensayo 01/02/2024	Inclusión Primer Paciente 01/02/2024	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global 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

CEIm Parc Tauli

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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
No iniciado (---/---/----)	Complejo Hospitalario Universitario De Ourense Ourense OURENSE Hematology
Activo (16/05/2024)	Fundacion Instituto Valenciano De Oncologia Valencia VALENCIA Hematology
No iniciado (---/---/----)	Hospital Clinico Universitario De Valencia Valencia VALENCIA Hematology
No iniciado (---/---/----)	Hospital Clinico Universitario Lozano Blesa Zaragoza ZARAGOZA Hematology
No iniciado (---/---/----)	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

Activo (10/05/2024)

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

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

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

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

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

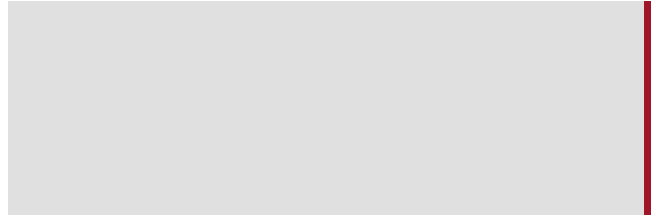
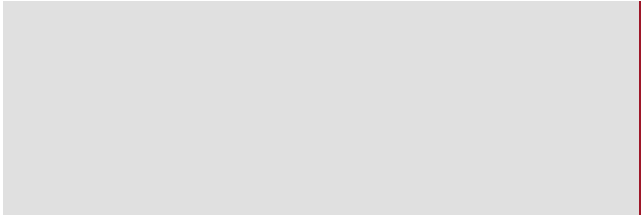
Huérfano

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
Recruiting

Type of participants
Not provided

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

Gender
Both

Phases
Phase III

Expected Participants
513

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
safety, effectiveness

Advanced therapy
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)

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

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

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 Therapy-General 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: 22/05/2026)

Authorization 24/10/2023	Start of Trial 01/02/2024	First patient inclusion 01/02/2024	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) 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

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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
not initialized (---/---/----)	Complejo Hospitalario Universitario De Ourense Ourense OURENSE Hematology
Active (16/05/2024)	Fundacion Instituto Valenciano De Oncologia Valencia VALENCIA Hematology
not initialized (---/---/----)	Hospital Clinico Universitario De Valencia Valencia VALENCIA Hematology
not initialized (---/---/----)	Hospital Clinico Universitario Lozano Blesa Zaragoza ZARAGOZA Hematology
not initialized (---/---/----)	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

Active (10/05/2024)

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

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

Hospital Universitario Lucas 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

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

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

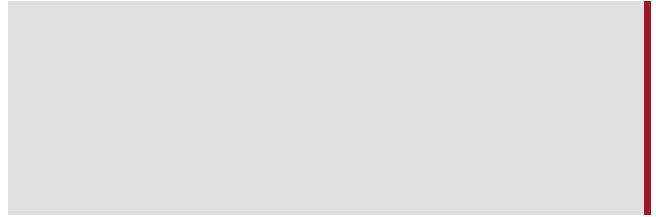
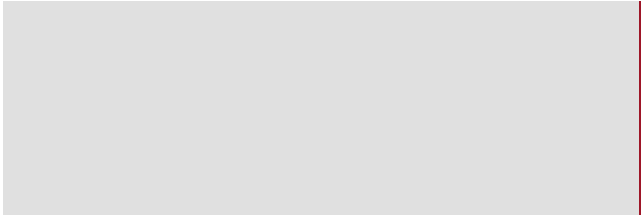
Experimental

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