# 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)
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
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Part 2: Progression free survival (PFS) as assessed by ICR
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Part 2: CR30 as assessed by local investigator
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Part 2: PFS as assessed by local investigator
Part 2: EFS as assessed by local investigator
Part 2: Overall Survival (OS)
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Part 2: BOR as assessed by ICR
Part 2: Duration of response (DOR) assessed by ICR
Part 2: DOR as assessed by local investigator
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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
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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)
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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
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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**

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

**ceic@tauli.cat**

**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