

A clinical study of zilovertamab vedotin in people with large B-cell lymphoma (MK-2140-010)

Estado
Reclutando

Tipo de Participantes
No aportado

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

Género
Ambos

Fases
Fase III

Participantes esperados
785

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
No

Cobertura geográfica
Sin determinar

Ámbitos del ensayo
tratamiento, seguridad, eficacia,
farmacocinética, farmacodinámica

Terapia avanzada
NO

Información

Identificador
2024-515566-13-00 (CTIS)

Cod. Protocolo
MK-2140-010

Área terapéutica
Enfermedades [C] - Cáncer [C04]

Enfermedad investigada
Diffuse Large B-Cell Lymphoma (DLBCL)

Título Científico
A Randomized, Open-Label, Multicenter, Phase 3 Study of Zilovertamab Vedotin (MK-2140) in Combination With R-CHP Versus R-CHOP in Participants With Previously Untreated Diffuse Large B-Cell Lymphoma (DLBCL) (waveLINE-010)

Justificación

No aportado

Objetivo Principal

To compare zilovetamab vedotin plus R-CHP with R-CHOP with respect to PFS per Lugano response criteria as assessed by BICR.

Variables de Evaluación Primaria

Progression-free Survival (PFS) per Lugano Response Criteria

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare zilovetamab vedotin plus R-CHP with R-CHOP with respect to CR rate at EOT per Lugano response criteria as assessed by BICR.

To compare zilovetamab vedotin plus R-CHP with R-CHOP with respect to OS.

To evaluate EFS with zilovetamab vedotin plus R-CHP versus R-CHOP per Lugano response criteria as assessed by BICR.

To evaluate the duration of CR with zilovetamab vedotin plus R-CHP versus R-CHOP.

To evaluate the safety and tolerability of zilovetamab vedotin plus R-CHP.

To evaluate change from baseline in HRQoL and symptoms for zilovetamab vedotin plus R-CHP versus R-CHOP using the FACT-Lym and FACT/GOG-NTX

Variables de Evaluación Secundaria

Complete Response (CR) at End of Treatment (EOT) per Lugano Response Criteria

Overall Survival (OS)

Event-free Survival (EFS) per Lugano Response Criteria

Duration of CR

Number of Participants Who Experienced At Least One Adverse Event (AE)

Number of Participants Who Discontinued Study Treatment Due to an Adverse Event (AE)

Change From Baseline in Health-Related Quality Of Life (HRQoL) on Functional Assessment of Cancer Therapy Lymphoma (FACT-Lym) Trial Outcome Index (TOI) Score

Change From Baseline in HRQoL on FACT-Lym Total Score

Change From Baseline in HRQoL on FACT-Lym Physical Wellbeing (PWB) score

Change From Baseline in HRQoL on Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity (FACT/GOG-NTX) Neurotoxicity Subscale Score

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Has histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL), by prior biopsy, according to the WHO classification of neoplasms of the hematopoietic and lymphoid tissues.

Has positron emission tomography (PET) positive disease at screening, defined as 4 to 5 on the Lugano 5-point scale.

Has received no prior treatment for their DLBCL.

Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 assessed within 7 days before randomization.

Has an ejection fraction 45% as determined by either echocardiogram (ECHO) or multigated acquisition (MUGA)

Human immunodeficiency virus (HIV) infected participants must have well controlled HIV on antiretroviral therapy (ART)

Who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy and have undetectable HBV viral load prior to randomization

Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening.

Criterios de Exclusión

Has a history of transformation of indolent disease to DLBCL Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. Administration of killed vaccines is allowed. Known additional malignancy that is progressing or has required active treatment within the past 2 years Known active central nervous system (CNS) lymphoma. Has active autoimmune disease that has required systemic treatment in the past 2 years Has active infection requiring systemic therapy. Has concurrent active HBV (defined as HBsAg positive and detectable HBV DNA) and HCV (defined as anti-HCV antibody positive and detectable HCV ribonucleic acid (RNA)) infection. Has history of allogeneic tissue/solid organ transplant Has received a diagnosis of primary mediastinal B-cell lymphoma (PMBCL) or Grey zone lymphoma Has Ann Arbor Stage I DLBCL Has clinically significant (i.e., active) cardiovascular disease: cerebral vascular accident/stroke (<6 months prior to enrollment), myocardial infarction (<6 months prior to enrollment), unstable angina, congestive heart failure (New York Heart Association Classification Class II), or serious cardiac arrhythmia requiring medication Has clinically significant pericardial or pleural effusion. Has ongoing Grade >1 peripheral neuropathy. Has a demyelinating form of Charcot-Marie-Tooth disease. HIV-infected participants with a history of Kaposi sarcoma and/or Multicentric Castlemans Disease. Has ongoing corticosteroid therapy

Calendario

(Última actualización: 26/08/2026)

Autorización 11/02/2025	Inicio de Ensayo 19/03/2025	Inclusión Primer Paciente 28/04/2025	Interrumpido No aportado	Reiniciado No aportado
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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
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Promotor

Merck Sharp & Dohme LLC United States

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Contact Person

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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917044160

Centros

Activo (09/04/2025)	Complejo Hospitalario Universitario Insular Materno Infantil Las Palmas De Gran Canaria LAS PALMAS Oncology
Activo (19/03/2025)	Hospital Del Mar Barcelona BARCELONA Hematology
Activo (03/04/2025)	Hospital General Universitario Dr. Balmis Alicante ALICANTE Hematology
Activo (02/06/2026)	Hospital General Universitario Gregorio Maranon Madrid MADRID Hematology
Activo (11/06/2026)	Hospital Universitario De Cabuenes Gijon ASTURIAS Hematology
Activo (25/08/2026)	Hospital Universitario De Cruces Barakaldo VIZCAYA/BIZKAIA Hematology
Activo (19/03/2025)	Hospital Universitario La Paz Madrid MADRID Hematology
Cerrado (21/05/2026)	Hospital Universitario Miguel Servet Zaragoza ZARAGOZA Hematology

Activo (14/05/2026)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Activo (19/03/2025)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Activo (01/04/2025)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Oncology

Activo (20/10/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Activo (04/06/2025)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medicamentos

-
-
OTHER USE

Código ATC: H02AB06 - PREDNISOLONA
Principios Activos: N/A
Experimental

-
-
OTHER USE

Código ATC: H02AB07 - PREDNISONA
Principios Activos: N/A
Experimental

-
-
INTRAVENOUS

Código ATC: L01CA02 - VINCRISTINA
Principios Activos: N/A
Experimental

-
-
INTRAVENOUS

Código ATC: L01AA01 - CICLOFOSFAMIDA
Principios Activos: N/A
Experimental

-
-
INTRAVENOUS

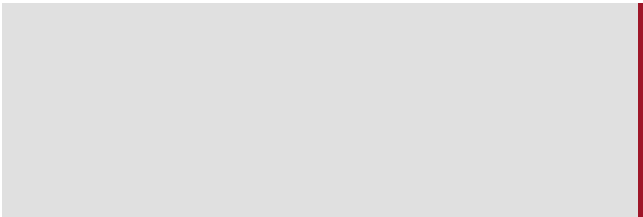
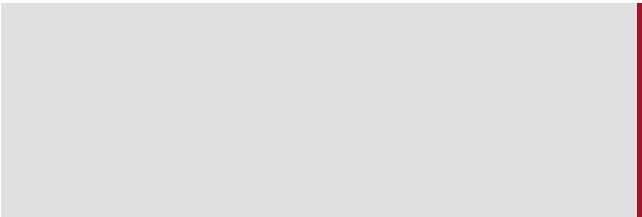
Código ATC: L01FA01 - RITUXIMAB
Principios Activos: N/A
Experimental

-
-
OTHER USE

Código ATC: H02AB04 - METILPREDNISOLONA
Principios Activos: N/A
Experimental

Zilovetamab vedotin
SOLUTION FOR INFUSION
INTRAVENOUS
-
Principios Activos: N/A
Experimental

-
-
INTRAVENOUS
Código ATC: L01DB01 - DOXORUBICINA
Principios Activos: N/A
Experimental



-
-

INTRAVENOUS

Código ATC: L03AA - FACTORES ESTIMULANTES DE COLONIAS
Principios Activos: N/A

Experimental

Sin resultados

A clinical study of zilovertamab vedotin in people with large B-cell lymphoma (MK-2140-010)

State
Recruiting

Type of participants
Not provided

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

Gender
Both

Phases
Phase III

Expected Participants
785

Results
No results

Low level of intervention
No

Rare disease
No

Geographic coverage
Undetermined

Areas of the study
treatment, safety, effectiveness,
pharmacokinetics, pharmacodynamics

Advanced therapy
NO

Information

Identifier
2024-515566-13-00 (CTIS)

Protocol Code
MK-2140-010

Therapeutic area
Diseases [C] - Cancer [C04]

Investigated Disease
Diffuse Large B-Cell Lymphoma (DLBCL)

Scientific Title
A Randomized, Open-Label, Multicenter, Phase 3 Study of Zilovertamab Vedotin (MK-2140) in Combination With R-CHP Versus R-CHOP in Participants With Previously Untreated Diffuse Large B-Cell Lymphoma (DLBCL) (waveLINE-010)

Rationale

Not provided

Main Objective

To compare zilovetamab vedotin plus R-CHP with R-CHOP with respect to PFS per Lugano response criteria as assessed by BICR.

Primary Endpoints

Progression-free Survival (PFS) per Lugano Response Criteria

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare zilovetamab vedotin plus R-CHP with R-CHOP with respect to CR rate at EOT per Lugano response criteria as assessed by BICR.

To compare zilovetamab vedotin plus R-CHP with R-CHOP with respect to OS.

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Secondary Endpoints

Complete Response (CR) at End of Treatment (EOT) per Lugano Response Criteria

Overall Survival (OS)

Event-free Survival (EFS) per Lugano Response Criteria

Duration of CR

Number of Participants Who Experienced At Least One Adverse Event (AE)

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Change From Baseline in HRQoL on Functional Assessment of Cancer Therapy/Gynecologic Oncology Group-Neurotoxicity (FACT/GOG-NTX) Neurotoxicity Subscale Score

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Participants with history of hepatitis C virus (HCV) infection are eligible if HCV viral load is undetectable at screening.

Exclusion criteria

Has a history of transformation of indolent disease to DLBCL Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention. Administration of killed vaccines is allowed. Known additional malignancy that is progressing or has required active treatment within the past 2 years Known active central nervous system (CNS) lymphoma. Has active autoimmune disease that has required systemic treatment in the past 2 years Has active infection requiring systemic therapy. Has concurrent active HBV (defined as HBsAg positive and detectable HBV DNA) and HCV (defined as anti-HCV antibody positive and detectable HCV ribonucleic acid (RNA)) infection. Has history of allogeneic tissue/solid organ transplant Has received a diagnosis of primary mediastinal B-cell lymphoma (PMBCL) or Grey zone lymphoma Has Ann Arbor Stage I DLBCL Has clinically significant (i.e., active) cardiovascular disease: cerebral vascular accident/stroke (<6 months prior to enrollment), myocardial infarction (<6 months prior to enrollment), unstable angina, congestive heart failure (New York Heart Association Classification Class II), or serious cardiac arrhythmia requiring medication Has clinically significant pericardial or pleural effusion. Has ongoing Grade >1 peripheral neuropathy. Has a demyelinating form of Charcot-Marie-Tooth disease. HIV-infected participants with a history of Kaposi sarcoma and/or Multicentric Castlemans Disease. Has ongoing corticosteroid therapy

Calendar

(Last Update: 26/08/2026)

Authorization 11/02/2025	Start of Trial 19/03/2025	First patient inclusion 28/04/2025	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

Merck Sharp & Dohme LLC United States

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Monetary support: N/A

Sponsor type: Commercial

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Sites

Active (09/04/2025)	Complejo Hospitalario Universitario Insular Materno Infantil Las Palmas De Gran Canaria LAS PALMAS Oncology
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Active (19/03/2025)	Hospital Universitario La Paz Madrid MADRID Hematology
Closed (21/05/2026)	Hospital Universitario Miguel Servet Zaragoza ZARAGOZA Hematology

Active (14/05/2026)

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Hematology

Active (19/03/2025)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Hematology

Active (01/04/2025)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Oncology

Active (20/10/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Hematology

Active (04/06/2025)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Hematology

Medication

-
-
OTHER USE

ATC code: H02AB06 - PREDNISOLONA
Active Principles: N/A
Experimental

-
-
OTHER USE

ATC code: H02AB07 - PREDNISONA
Active Principles: N/A
Experimental

-
-
INTRAVENOUS

ATC code: L01CA02 - VINCISTINA
Active Principles: N/A
Experimental

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INTRAVENOUS

ATC code: L01AA01 - CICLOFOSFAMIDA
Active Principles: N/A
Experimental

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INTRAVENOUS

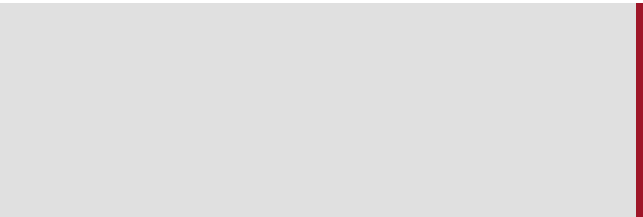
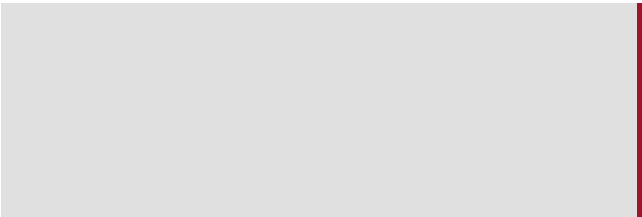
ATC code: L01FA01 - RITUXIMAB
Active Principles: N/A
Experimental

-
-
OTHER USE

ATC code: H02AB04 - METILPREDNISOLONA
Active Principles: N/A
Experimental

Zilovetamab vedotin
SOLUTION FOR INFUSION
INTRAVENOUS
-
Active Principles: N/A
Experimental

-
-
INTRAVENOUS
ATC code: L01DB01 - DOXORUBICINA
Active Principles: N/A
Experimental



-

-

INTRAVENOUS

ATC code: L03AA - FACTORES ESTIMULANTES DE COLONIAS

Active Principles: N/A

Experimental

No results