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

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	785
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica	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 zilovertamab 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 zilovertamab vedotin plus R-CHP with R-CHOP with respect to CR rate at EOT per Lugano response criteria as assessed by BICR.
To compare zilovertamab vedotin plus R-CHP with R-CHOP with respect to OS.
To evaluate EFS with zilovertamab vedotin plus R-CHP versus R-CHOP per Lugano response criteria as assessed by BICR.
To evaluate the duration of CR with zilovertamab vedotin plus R-CHP versus R-CHOP.
To evaluate the safety and tolerability of zilovertamab vedotin plus R-CHP.
To evaluate change from baseline in HRQoL and symptoms for zilovertamab 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 Kaposis sarcoma and/or Multicentric Castlemans Disease. Has ongoing corticosteroid therapy

Calendario

(Última actualización: 26/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
11/02/2025	19/03/2025	28/04/2025	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

Merck Sharp & Dohme LLC United States

126 East Lincoln AvenueP. O. Box 2000

Contact Person

Tor Sauter

+14846899806

christopher.sauter@merck.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Clínico San Carlos

C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

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

Zilovertamab 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	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	785
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness, pharmacokinetics, pharmacodynamics	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 zilovertamab 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 zilovertamab vedotin plus R-CHP with R-CHOP with respect to CR rate at EOT per Lugano response criteria as assessed by BICR.
To compare zilovertamab vedotin plus R-CHP with R-CHOP with respect to OS.
To evaluate EFS with zilovertamab vedotin plus R-CHP versus R-CHOP per Lugano response criteria as assessed by BICR.
To evaluate the duration of CR with zilovertamab vedotin plus R-CHP versus R-CHOP.
To evaluate the safety and tolerability of zilovertamab vedotin plus R-CHP.
To evaluate change from baseline in HRQoL and symptoms for zilovertamab vedotin plus R-CHP versus R-CHOP using the FACT-Lym and FACT/GOG-NTX

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)
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

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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.

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 Kaposis sarcoma and/or Multicentric Castlemans Disease. Has ongoing corticosteroid therapy

Calendar

(Last Update: 26/08/2026)

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

Merck Sharp & Dohme LLC United States

126 East Lincoln AvenueP. O. Box 2000

Contact Person

Tor Sauter

+14846899806

christopher.sauter@merck.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Clínico San Carlos

C/ Doctor Martín Lagos, s/n - Ciudad Universitaria 28040 Madrid

ceic.hcsc@salud.madrid.org

917044160

Sites

Active (09/04/2025)

Complejo Hospitalario Universitario Insular Materno Infantil

Las Palmas De Gran Canaria

LAS PALMAS

Oncology

Active (19/03/2025)

Hospital Del Mar

Barcelona

BARCELONA

Hematology

Active (03/04/2025)

Hospital General Universitario Dr. Balmis

Alicante

ALICANTE

Hematology

Active (02/06/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Hematology

Active (11/06/2026)

Hospital Universitario De Cabuenes

Gijon

ASTURIAS

Hematology

Active (25/08/2026)

Hospital Universitario De Cruces

Barakaldo

VIZCAYA/BIZKAIA

Hematology

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

[redacted]
-
-
OTHER USE

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

Experimental

[redacted]
-
-
OTHER USE

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

Experimental

[redacted]
-
-
INTRAVENOUS

ATC code: L01CA02 - VINCRISTINA
Active Principles: N/A

Experimental

[redacted]
-
-
INTRAVENOUS

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

Experimental

[redacted]
-
-
INTRAVENOUS

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

Experimental

[redacted]
-
-
OTHER USE

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

Experimental

[redacted]
Zilovertamab vedotin
SOLUTION FOR INFUSION
INTRAVENOUS

-

Active Principles: N/A

Experimental

[redacted]
-
-
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