A Study of an experimental drug, MK-2140 in combination with standard of care chemotherapy in participants with Diffuse Large B-Cell Lymphoma (DLBCL)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	23
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, dosis, farmacogenética, farmacogenómica	NO

Información

Identificador
2022-501380-40-00 (CTIS)

Cod. Protocolo
MK-2140-007

Transicionado 2021-005861-41

Área terapéutica
Enfermedades [C] - Cáncer [C04]|

Enfermedad investigada
Diffuse large B-cell lymphoma (DLBCL)

Título Científico
A Multicenter, Open-label, Phase 2 Dose Escalation and Confirmation, and Efficacy Expansion Study of Zilovertamab Vedotin (MK-2140) in Combination with R-CHP in Participants with DLBCL (waveLINE)

Justificación

No aportado

Objetivo Principal

1. To evaluate the safety and tolerability and to establish a RP2D of zilovertamab vedotin when used in combination with R-CHP.
2. To evaluate zilovertamab vedotin at the RP2D in combination with R-CHP with respect to complete response rate per Lugano response as assessed by the investigator.

Variables de Evaluación Primaria

Number of Participants Who Experienced Dose-limiting Toxicities (DLTs) in Cycle 1
Number of Participants Who Experienced At Least One Adverse Event (AE)
Number of Participants Who Discontinued Study Treatment Due to an Adverse Event (AE)
Complete Response Rate (CRR) per Lugano Response Criteria

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate zilovertamab vedotin at the RP2D in combination with R-CHP with respect to ORR per Lugano response criteria as assessed by the investigator.
To evaluate zilovertamab vedotin at the RP2D in combination with R-CHP with respect to DOR per Lugano response criteria as assessed by the investigator.

Variables de Evaluación Secundaria

Objective Response Rate (ORR) per Lugano Response Criteria
Duration of Response (DOR) per Lugano Response Criteria

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Has histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) by prior biopsy
Has positron emission tomography (PET)-positive disease verified by blinded independent central review (BICR) at screening, defined as 4-5 on the Lugano response criteria 5-point scale
Has received no prior treatment for DLBCL
Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 assessed within 7 days prior to the start of study intervention

Criterios de Exclusión

Has a history of transformation of indolent disease to DLBCL Has ongoing corticosteroid therapy (exceeding 30 mg daily of prednisone equivalent) Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention Has received a strong inhibitor or inducer of CYP3A4 (including itraconazole, ketoconazole, posaconazole, or voriconazole) within 7 days prior to the start of study intervention or expected requirement for chronic use of a strong CYP3A4 inhibitor until <30 days after the last dose Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 28 days before the first dose of study intervention Has known active central nervous system (CNS) lymphoma Has an active infection requiring systemic therapy Has a known history of human immunodeficiency virus (HIV) infection Has a known active hepatitis C virus infection Has a known active hepatitis B virus infection Has received solid organ transplant at any time Has received a diagnosis of primary mediastinal B-cell lymphoma (PMBCL) Has clinically significant (ie, 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 pericardial effusion or clinically significant pleural effusion Has ongoing Grade >1 peripheral neuropathy Has a demyelinating form of Charcot-Marie-Tooth disease History of a second malignancy unless potentially curative treatment has been completed with no evidence of malignancy for 2 years with the exception of participants who underwent successful definitive resection of basal cell carcinoma of the skin, squamous-cell carcinoma of the skin, or carcinoma in situ, excluding carcinoma in situ of the bladder Has received prior radiotherapy within 28 days of start of study intervention

Calendario

(Última actualización: 28/05/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
20/06/2022	24/08/2022	04/10/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
05/08/2024	No aportado	No aportado	No aportado	No aportado

Promotor

Merck Sharp & Dohme LLC United States

126 East Lincoln Avenue

Contact Person

Puja Patel

+34669118231

laxmi.puja.patel@merck.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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917044160

Centros

Activo (24/08/2022)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Hematología

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Medical Oncology

Activo (09/09/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Hematología

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Medical Oncology

Activo (21/09/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematología

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Medical Oncology

Medicamentos

-
-
INTRAVENOUS

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

Experimental

-
-
ORAL

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

Experimental

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS INFUSION

-
Principios Activos: N/A

Experimental

Zilovertamab vedotin
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS

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

Experimental

Truxima 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

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

Experimental

DOXORUBICIN
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS

Código ATC: L03A - INMUNOESTIMULANTES
Principios Activos: N/A

Experimental

RITUXIMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Principios Activos: N/A

Experimental

-
-
ORAL

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

Experimental

Sin resultados

A Study of an experimental drug, MK-2140 in combination with standard of care chemotherapy in participants with Diffuse Large B-Cell Lymphoma (DLBCL)

State	**Type of participants**	**Age Ranges**
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	23
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, dose, pharmacogenetics, pharmacogenomics	NO

Information

Identifier
2022-501380-40-00 (CTIS)

Protocol Code
MK-2140-007

Transitioned 2021-005861-41

Therapeutic area
Diseases [C] - Cancer [C04]|

Investigated Disease
Diffuse large B-cell lymphoma (DLBCL)

Scientific Title
A Multicenter, Open-label, Phase 2 Dose Escalation and Confirmation, and Efficacy Expansion Study of Zilovertamab Vedotin (MK-2140) in Combination with R-CHP in Participants with DLBCL (waveLINE)

Rationale

Not provided

Main Objective

1. To evaluate the safety and tolerability and to establish a RP2D of zilovertamab vedotin when used in combination with R-CHP.
2. To evaluate zilovertamab vedotin at the RP2D in combination with R-CHP with respect to complete response rate per Lugano response as assessed by the investigator.

Primary Endpoints

Number of Participants Who Experienced Dose-limiting Toxicities (DLTs) in Cycle 1
Number of Participants Who Experienced At Least One Adverse Event (AE)
Number of Participants Who Discontinued Study Treatment Due to an Adverse Event (AE)
Complete Response Rate (CRR) per Lugano Response Criteria

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate zilovertamab vedotin at the RP2D in combination with R-CHP with respect to ORR per Lugano response criteria as assessed by the investigator.
To evaluate zilovertamab vedotin at the RP2D in combination with R-CHP with respect to DOR per Lugano response criteria as assessed by the investigator.

Secondary Endpoints

Objective Response Rate (ORR) per Lugano Response Criteria
Duration of Response (DOR) per Lugano Response Criteria

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Has histologically confirmed diagnosis of diffuse large B-cell lymphoma (DLBCL) by prior biopsy
Has positron emission tomography (PET)-positive disease verified by blinded independent central review (BICR) at screening, defined as 4-5 on the Lugano response criteria 5-point scale
Has received no prior treatment for DLBCL
Has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 assessed within 7 days prior to the start of study intervention

Exclusion criteria

Has a history of transformation of indolent disease to DLBCL Has ongoing corticosteroid therapy (exceeding 30 mg daily of prednisone equivalent) Has received a live or live-attenuated vaccine within 30 days before the first dose of study intervention Has received a strong inhibitor or inducer of CYP3A4 (including itraconazole, ketoconazole, posaconazole, or voriconazole) within 7 days prior to the start of study intervention or expected requirement for chronic use of a strong CYP3A4 inhibitor until <30 days after the last dose Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 28 days before the first dose of study intervention Has known active central nervous system (CNS) lymphoma Has an active infection requiring systemic therapy Has a known history of human immunodeficiency virus (HIV) infection Has a known active hepatitis C virus infection Has a known active hepatitis B virus infection Has received solid organ transplant at any time Has received a diagnosis of primary mediastinal B-cell lymphoma (PMBCL) Has clinically significant (ie, 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 pericardial effusion or clinically significant pleural effusion Has ongoing Grade >1 peripheral neuropathy Has a demyelinating form of Charcot-Marie-Tooth disease History of a second malignancy unless potentially curative treatment has been completed with no evidence of malignancy for 2 years with the exception of participants who underwent successful definitive resection of basal cell carcinoma of the skin, squamous-cell carcinoma of the skin, or carcinoma in situ, excluding carcinoma in situ of the bladder Has received prior radiotherapy within 28 days of start of study intervention

Calendar

(Last Update: 28/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
20/06/2022	24/08/2022	04/10/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
05/08/2024	Not aported	Not aported	Not aported	Not aported

Sponsor

Merck Sharp & Dohme LLC United States

126 East Lincoln Avenue

Contact Person

Puja Patel

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laxmi.puja.patel@merck.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Active (24/08/2022)

HOSPITAL UNIVERSITARIO FUNDACION JIMENEZ DIAZ

Madrid

MADRID

Hematología

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Medical Oncology

Active (09/09/2022)

HOSPITAL UNIVERSITARIO VIRGEN DEL ROCIO

Sevilla

SEVILLA

Hematología

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

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Medical Oncology

Active (21/09/2022)

Institut Catala D'oncologia

Hospitalet de Llobregat, L'

BARCELONA

Hematología

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

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Medical Oncology

Medication

-
-
INTRAVENOUS

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

Experimental

-
-
ORAL

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

Experimental

CYCLOPHOSPHAMIDE
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS INFUSION

-
Active Principles: N/A

Experimental

Zilovertamab vedotin
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

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

Experimental

Truxima 500 mg concentrate for solution for infusion
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

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

Experimental

DOXORUBICIN
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-
Active Principles: N/A

Experimental

-
-
INTRAVENOUS

ATC code: L03A - INMUNOESTIMULANTES
Active Principles: N/A

Experimental

RITUXIMAB
CONCENTRATE FOR SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

-

Active Principles: N/A

Experimental

-
-
ORAL

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

Experimental

No results