Estudio clínico de MK-4716 en personas con ciertos tumores sólidos (MK-4716-001)

Estado	Tipo de Participantes	Rangos de Edad
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase I , Fase II	179
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	NO

Información

Identificador
2025-522495-84-00 (CTIS)

Cod. Protocolo
MK-4716-001

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

Enfermedad investigada
Cáncer - Tumores sólidos: NSCLC de 1L y todos los demás tumores sólidos avanzados o metastásicos con alteraciones de KRAS (mutación de KRAS o amplificación de KRAS)

Título Científico
A Phase 1, Open-Label, Multicenter Study to Assess Safety, Tolerability, Pharmacokinetics, and Efficacy of MK-4716 as Monotherapy and as Part of Combination Therapy in Participants with KRAS-Altered Advanced or Metastatic Solid Tumors

Justificación

No aportado

Objetivo Principal

1. To determine the safety and tolerability of MK 4716 administered as monotherapy and as part of combination therapy

Variables de Evaluación Primaria

Number of Participants Who Experience One or More Dose-Limiting Toxicities (DLT)
Number of Participants Who Experience an Adverse Event (AE)
Number of Participants Who Discontinue Study Intervention Due to an AE

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate PK of MK 4716 administered as monotherapy and as part of combination therapy

Variables de Evaluación Secundaria

Area Under the Concentration-Time Curve (AUC) of MK-4716
Maximum Plasma Concentration (Cmax) of MK-4716
Trough Plasma Concentration (Ctrough) of MK-4716
Half-Life (t1/2) of MK-4716

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subset of arm MK-4716 Dose Escalation and subset of arm MK-4716 + Cetuximab: Has a confirmed diagnosis of locally advanced unresectable or metastatic solid tumor
Subset of arm MK-4716 Dose Escalation and subset of arm MK-4716 + Cetuximab: Must demonstrate presence of Kirsten rat sarcoma viral oncogene homolog (KRAS) alteration

Subset of arm MK-4716 Dose Escalation and subset of arm MK-4716 + Cetuximab: Has received at least 1 prior line of systemic therapy for locally advanced unresectable or metastatic disease
Arm MK-4716 + Pembrolizumab: Has a confirmed diagnosis of metastatic non-small cell lung cancer
Arm MK-4716 + Pembrolizumab: Must demonstrate presence of KRAS alteration
Arm MK-4716 + Pembrolizumab: Must be untreated
Has measurable disease
Has the ability to swallow and retain oral medication

Criterios de Exclusión

Arm MK-4716 + Pembrolizumab: Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy (in dosing exceeding 10 mg daily of prednisone equivalent) or any other form of immunosuppressive therapy within 7 days prior to the first dose of study intervention
History of stem cell/solid organ transplant
Has not adequately recovered from major surgery or has ongoing surgical complications
Arm MK-4716 + Pembrolizumab: Has received any prior immunotherapy and was discontinued from that treatment
Arm MK-4716 + Pembrolizumab: Has active autoimmune disease that has required systemic treatment in the past 2 years. Hormonal supplementation (eg, thyroxine, insulin, or physiologic corticosteroid) is allowed.
History of human immunodeficiency virus infection
Has a known additional malignancy that is progressing or has required active treatment within the past 2 years
Has a known active central nervous system metastases and/or carcinomatous meningitis
History of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease
Has active infection requiring systemic therapy
Has Hepatitis B or Hepatitis C virus infection

Calendario

(Última actualización: 18/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
23/12/2025	14/01/2026	30/01/2026	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

Marie Will

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitari de Bellvitge

Feixa Llarga, s/n - Antiguo Módulo Banco de Santander 08907 Hospitalet de Llobregat

mcruz@idibell.cat

Centros

Activo (14/01/2026)

Hospital Clinic De Barcelona

Barcelona

BARCELONA

Medical Oncology

Activo (02/02/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Medical Oncology

Activo (15/01/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Medical Oncology

Medicamentos

KEYTRUDA 25 mg/mL concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

Código ATC: L01FF02 - PEMBROLIZUMAB
Principios Activos: N/A

Experimental

MK-4716
TABLET
OTHER USE

-
Principios Activos: N/A

Experimental

-
-
INTRAVENOUS INFUSION

Código ATC: L01FE01 - CETUXIMAB
Principios Activos: N/A

Experimental

MK-4716
TABLET
OTHER USE

-
Principios Activos: N/A

Experimental

MK-4716
TABLET
OTHER USE

-
Principios Activos: N/A

Experimental

Sin resultados

A Clinical study of MK-4716 in people with certain solid tumors (MK-4716-001)

State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	179
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	NO

Information

Identifier
2025-522495-84-00 (CTIS)

Protocol Code
MK-4716-001

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

Investigated Disease
Cancer Solid Tumors : 1L NSCLC and all other advanced or metastatic solid tumors with KRAS alterations (KRAS mutation or KRAS amplification)

Scientific Title
A Phase 1, Open-Label, Multicenter Study to Assess Safety, Tolerability, Pharmacokinetics, and Efficacy of MK-4716 as Monotherapy and as Part of Combination Therapy in Participants with KRAS-Altered Advanced or Metastatic Solid Tumors

Rationale

Not provided

Main Objective

1. To determine the safety and tolerability of MK 4716 administered as monotherapy and as part of combination therapy

Primary Endpoints

Number of Participants Who Experience One or More Dose-Limiting Toxicities (DLT)
Number of Participants Who Experience an Adverse Event (AE)
Number of Participants Who Discontinue Study Intervention Due to an AE

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate PK of MK 4716 administered as monotherapy and as part of combination therapy

Secondary Endpoints

Area Under the Concentration-Time Curve (AUC) of MK-4716
Maximum Plasma Concentration (Cmax) of MK-4716
Trough Plasma Concentration (Ctrough) of MK-4716
Half-Life (t1/2) of MK-4716

Temporary moments of secondary assessment

Not provided

Inclusion criteria

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Has the ability to swallow and retain oral medication

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Has active infection requiring systemic therapy
Has Hepatitis B or Hepatitis C virus infection

Calendar

(Last Update: 18/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
23/12/2025	14/01/2026	30/01/2026	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

Marie Will

+19087404000

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Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

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Active (15/01/2026)

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

Medical Oncology

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KEYTRUDA 25 mg/mL concentrate for solution for infusion.
SOLUTION FOR INFUSION
INTRAVENOUS INFUSION

ATC code: L01FF02 - PEMBROLIZUMAB
Active Principles: N/A

Experimental

MK-4716
TABLET
OTHER USE

-
Active Principles: N/A

Experimental

-
-
INTRAVENOUS INFUSION

ATC code: L01FE01 - CETUXIMAB
Active Principles: N/A

Experimental

MK-4716
TABLET
OTHER USE

-
Active Principles: N/A

Experimental

MK-4716
TABLET
OTHER USE

-
Active Principles: N/A

Experimental

No results