A clinical trial of V940 with or without MK-3475A in people with non-small cell lung cancer (V940-014)

Estado
Reclutando

Tipo de Participantes
No aportado

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

Género
Ambos

Fases
Fase III

Participantes esperados
608

Resultados
Sin resultados

Bajo nivel intervención
No

Enfermedad rara
No

Cobertura geográfica
Sin determinar

Ámbitos del ensayo
tratamiento, seguridad, eficacia, farmacocinética, farmacodinamica, farmacogenética, farmacogenómica, farmacoeconómica

Terapia avanzada
Terapia génica

Información

Identificador
2025-522643-18-00 (CTIS)

Cod. Protocolo
V940-014

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

Enfermedad investigada
Stage I NSCLC

Título Científico
A Phase 3, Randomized, Placebo-Controlled Study of Adjuvant Intismeran Autogene Plus Subcutaneous Pembrolizumab and Berahyaluronidase Alfa (MK-3475A) or Intismeran Autogene Monotherapy Versus Placebo in

Participants With Completely Resected High-Risk Stage I Non-Small Cell Lung Cancer (INTerpath-014)

Justificación

No aportado

Objetivo Principal

1. To compare intismeran in combination with MK-3475A to placebo with respect to DFS assessed by BICR in nonsquamous NSCLC.

Variables de Evaluación Primaria

Disease-Free Survival (DFS) as assessed by Blinded Independent Central Review (BICR) in participants with nonsquamous non-small cell lung cancer (NSCLC) in Arm A and Arm C

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To compare intismeran in combination with MK-3475A or intismeran monotherapy to placebo with respect to DFS assessed by BICR.
To compare intismeran in combination with MK-3475A or intismeran monotherapy to placebo with respect to DMFS as assessed by BICR.
To compare intismeran in combination with MK-3475A or intismeran monotherapy to placebo with respect to OS.
To evaluate the safety and tolerability of intismeran as monotherapy and in combination with MK-3475A.
To evaluate intismeran in combination with MK-3475A or intismeran monotherapy to placebo with respect to mean change from baseline in global health status/QoL, physical functioning, and role functioning using the EORTC QLQ-C30.

Variables de Evaluación Secundaria

DFS as assessed by BICR
Distant metastasis-free survival (DMFS)
Overall Survival (OS)
Number Participants Who Experience an Adverse Events (AE)
Number of Participants Who Discontinue Study Treatment Due to an AE
Change From Baseline in European Organization for Research and Treatment (EORTC) Quality of Life Questionnaire-Core 30 (QLQ-C30) Combined Global Health Status/Quality of Life (Items 29 & 30) Scale Combined Score
Change From Baseline in Physical Functioning (EORTC QLQ-C30 Items 1-5) Score

Change From Baseline in Role Functioning (EORTC QLQ-C30 Items 6-7) Score

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Has a histological diagnosis of pathological Stage I (tumor 4 cm) non-small cell lung cancer (NSCLC) per American Joint Committee on Cancer (AJCC) 9th Edition with at least 1of the following high-risk pathologic features as assessed locally: tumor size >2cm, visceral pleural invasion, lymphovascular invasion, or high grade histology Has undergone a complete surgical resection of the primary NSCLC Has not received other prior treatment outside of definitive surgery (including but not limited to chemotherapy, immunotherapy, targeted therapy, or radiotherapy) for their current Stage I NSCLC Has provided a tissue sample from recent surgery along with the required blood sample Human immunodeficiency virus (HIV)-infected participants must have well-controlled HIV on antiretroviral therapy (ART) Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks, 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 diagnosis of any 1 of the following: small cell lung cancer (SCLC) or, for mixed tumors, presence of small cell elements, neuroendocrine tumor with large cell components, sarcomatoid carcinoma, or two synchronous primary NSCLCs
Has any clinically significant cardiovascular disease within 12 months before randomization, including a history of coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI), valvular heart disease requiring surgical intervention, New York Heart Association Class III-IV heart failure, unstable angina, myocardial infarction (MI), pulmonary hypertension, cardiovascular accident (CVA), or hemodynamically unstable cardiac arrhythmia
HIV-infected participants with a history of Kaposis sarcoma and/or Multicentric Castlemans Disease
Has known additional malignancy that is progressing or has required active treatment within the past 3 years
Has active autoimmune disease that has required systemic treatment in the past 2 years. Hormonal supplementation (eg, thyroxine, insulin, or physiologic corticosteroid) is allowed.
Has history of (noninfectious) pneumonitis/interstitial lung disease that required steroids or has current pneumonitis/interstitial lung disease
Has active infection requiring systemic therapy other than those permitted in protocol
Has history of stem cell/solid organ transplant
Participants who have not adequately recovered from major surgery or have ongoing surgical complications

Calendario

(Última actualización: 20/08/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
22/06/2026	29/06/2026	03/08/2026	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

Jeffrey Thompson

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Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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917044160

Centros

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

Consorcio Hospital General Universitario De Valencia

Valencia

VALENCIA

Oncology

Activo (17/07/2026)

Hospital Clinico San Carlos

Madrid

MADRID

Medical Oncology

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

Hospital Del Mar

Barcelona

BARCELONA

Medical Oncology

Activo (13/07/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Oncology

Activo (20/08/2026)

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Medical Oncology

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

Hospital Universitario De Badajoz

Badajoz

BADAJOZ

Medical Oncology

Activo (24/07/2026)

Hospital Universitario De Cruces

Barakaldo

VIZCAYA/BIZKAIA

Oncology

Activo (29/06/2026)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Medical Oncology

Activo (28/07/2026)

Hospital Universitario Virgen De La Victoria

Malaga

MÁLAGA

Oncology

Activo (18/08/2026)

Institut Catala D'oncologia

L'hospitalet De Llobregat

BARCELONA

Medical Oncology

Medicamentos

MK-3475A
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Principios Activos: N/A

Experimental

mRNA-4157
DISPERSION FOR INJECTION
INTRAMUSCULAR

-

Principios Activos: N/A

Experimental

Sin resultados

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State	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	608
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, pharmacogenetics, pharmacogenomics, pharmacoeconomic	Gene therapy

Information

Identifier
2025-522643-18-00 (CTIS)

Protocol Code
V940-014

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

Investigated Disease
Stage I NSCLC

Scientific Title
A Phase 3, Randomized, Placebo-Controlled Study of Adjuvant Intismeran Autogene Plus Subcutaneous Pembrolizumab and Berahyaluronidase Alfa (MK-3475A) or Intismeran Autogene Monotherapy Versus Placebo in

Participants With Completely Resected High-Risk Stage I Non-Small Cell Lung Cancer (INTerpath-014)

Rationale

Not provided

Main Objective

1. To compare intismeran in combination with MK-3475A to placebo with respect to DFS assessed by BICR in nonsquamous NSCLC.

Primary Endpoints

Disease-Free Survival (DFS) as assessed by Blinded Independent Central Review (BICR) in participants with nonsquamous non-small cell lung cancer (NSCLC) in Arm A and Arm C

Temporary moments of secondary assessment

Not provided

Secondary Objective

To compare intismeran in combination with MK-3475A or intismeran monotherapy to placebo with respect to DFS assessed by BICR.
To compare intismeran in combination with MK-3475A or intismeran monotherapy to placebo with respect to DMFS as assessed by BICR.
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To evaluate intismeran in combination with MK-3475A or intismeran monotherapy to placebo with respect to mean change from baseline in global health status/QoL, physical functioning, and role functioning using the EORTC QLQ-C30.

Secondary Endpoints

DFS as assessed by BICR
Distant metastasis-free survival (DMFS)
Overall Survival (OS)
Number Participants Who Experience an Adverse Events (AE)
Number of Participants Who Discontinue Study Treatment Due to an AE
Change From Baseline in European Organization for Research and Treatment (EORTC) Quality of Life Questionnaire-Core 30 (QLQ-C30) Combined Global Health Status/Quality of Life (Items 29 & 30) Scale Combined Score
Change From Baseline in Physical Functioning (EORTC QLQ-C30 Items 1-5) Score

Change From Baseline in Role Functioning (EORTC QLQ-C30 Items 6-7) Score

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Has a histological diagnosis of pathological Stage I (tumor 4 cm) non-small cell lung cancer (NSCLC) per American Joint Committee on Cancer (AJCC) 9th Edition with at least 1of the following high-risk pathologic features as assessed locally: tumor size >2cm, visceral pleural invasion, lymphovascular invasion, or high grade histology Has undergone a complete surgical resection of the primary NSCLC Has not received other prior treatment outside of definitive surgery (including but not limited to chemotherapy, immunotherapy, targeted therapy, or radiotherapy) for their current Stage I NSCLC Has provided a tissue sample from recent surgery along with the required blood sample Human immunodeficiency virus (HIV)-infected participants must have well-controlled HIV on antiretroviral therapy (ART) Participants who are hepatitis B surface antigen (HBsAg) positive are eligible if they have received hepatitis B virus (HBV) antiviral therapy for at least 4 weeks, 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 diagnosis of any 1 of the following: small cell lung cancer (SCLC) or, for mixed tumors, presence of small cell elements, neuroendocrine tumor with large cell components, sarcomatoid carcinoma, or two synchronous primary NSCLCs
Has any clinically significant cardiovascular disease within 12 months before randomization, including a history of coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI), valvular heart disease requiring surgical intervention, New York Heart Association Class III-IV heart failure, unstable angina, myocardial infarction (MI), pulmonary hypertension, cardiovascular accident (CVA), or hemodynamically unstable cardiac arrhythmia
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Has active infection requiring systemic therapy other than those permitted in protocol
Has history of stem cell/solid organ transplant
Participants who have not adequately recovered from major surgery or have ongoing surgical complications

Calendar

(Last Update: 20/08/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
22/06/2026	29/06/2026	03/08/2026	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

Jeffrey Thompson

+17325944000

jeffrey.thompson1@merck.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

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

Consorcio Hospital General Universitario De Valencia

Valencia

VALENCIA

Oncology

Active (17/07/2026)

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Active (18/08/2026)

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Medical Oncology

Medication

MK-3475A
SOLUTION FOR INJECTION
SUBCUTANEOUS USE

-

Active Principles: N/A

Experimental

mRNA-4157
DISPERSION FOR INJECTION
INTRAMUSCULAR

-

Active Principles: N/A

Experimental

No results