A Study in TKI-naive Patients With Advanced ALK-Positive NSCLC (ALKAZAR)

Estado	**Tipo de Participantes**	**Rangos de Edad**
Reclutando	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	159
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia	NO

Información

Identificador
2024-517553-26-00 (CTIS)

Cod. Protocolo
NVL-655-04

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

Enfermedad investigada
Advanced ALK-positive non-small cell lung cancer (NSCLC)

Título Científico
A Phase 3 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 Compared to Alectinib in First-Line Treatment of Patients With ALK-Positive Advanced Non-Small Cell Lung Cancer (ALKAZAR)

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of NVL-655 compared to alectinib in patients with treatment-naïve ALK-positive advanced NSCLC

Variables de Evaluación Primaria

Progression-free survival (PFS)

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess additional measures of efficacy of NVL-655 compared to alectinib in patients with treatment-naïve ALK-positive advanced NSCLC
To evaluate the safety and tolerability of NVL-655 compared to alectinib
To evaluate and compare patient-reported measures of health-related quality of life (QoL), lung cancer symptoms, patient functioning, and side effects of treatment

Variables de Evaluación Secundaria

1) - Overall survival (OS) - Progression-free survival (PFS) per investigator assessment - Time to intracranial progression per blinded independent central review (BICR) - Intracranial objective response rate (IC-ORR) - Intracranial duration of response (IC-DOR) - Objective response rate (ORR) - Duration of response (DOR) - Time to intracranial progression, IC-ORR, IC-DOR, ORR, and DOR
2) Incidence and severity of treatment-emergent adverse events (TEAEs) and changes in clinically relevant laboratory parameters
3) Changes in patient-reported outcomes (PROs)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Patients must meet all of the following criteria to be eligible to enroll in the study: 1. Histologically or cytologically confirmed locally advanced (not amenable for multimodality treatment) or metastatic Non-small Cell Lung Cancer (NSCLC) 2. Documented Anaplastic Lymphoma Kinase (ALK) rearrangement via testing of tissue or blood 3. No prior systemic anticancer treatment for NSCLC (adjuvant/neoadjuvant chemotherapy allowed if 12 months prior to randomization; prior ALK tyrosine kinase inhibitor [TKI] such as alectinib is not allowed in any setting) 4. Measurable disease (1 or more target lesions per Response Evaluation Criteria in Solid Tumors [RECIST] 1.1) 5. Pretreatment tumor tissue (archived or a fresh biopsy)

Criterios de Exclusión

1. Patients cancer has a known oncogenic driver alteration other than ALK. 2. Known allergy/hypersensitivity to excipients of NVL-655 or alectinib. 3. Major surgery within 4 weeks prior to randomization 4. Ongoing or recent radiotherapy as per protocol-specified timeframes prior to randomization 5. Uncontrolled clinically relevant infection requiring systemic therapy 6. Known active tuberculosis, known active Hepatitis B or C 7. QT corrected for heart rate by Fridericias formula (QTcF) > 470 msec on repeated assessments 8. Clinically significant cardiovascular disease 9. Brain metastases associated with progressive neurological symptoms or requiring increasing doses of corticosteroids to control CNS disease 10. Active malignancy requiring therapy within 2 years prior to randomization

Calendario

(Última actualización: 05/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
05/06/2025	26/11/2025	10/12/2025	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

Nuvalent Inc. United States

1 Broadway Floor 14th

Contact Person

Medical

18573577000

medical@nuvalent.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Autonómico de Galicia

C/ San Lázaro, s/n 15781 Santiago de Compostela

ceic@sergas.es

881546425

Centros

Activo (26/11/2025)

Complexo Hospitalario Universitario A Coruna

A Coruna

CORUÑA

Oncología Médica

Activo (17/02/2026)

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

Oncología Médica

Activo (26/11/2025)

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Oncología Médica

Activo (20/02/2026)

Hospital Universitario Regional De Malaga

Malaga

MÁLAGA

Oncología Médica

Activo (26/12/2025)

Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Oncología Médica

Activo (03/12/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Oncología Médica

Activo (04/03/2026)

Institut Catala D´oncologia

Girona

GERONA

Oncología Médica

Activo (04/03/2026)

Institut Catala D´oncologia

Badalona

BARCELONA

Oncología Médica

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

BARCELONA

Oncología Médica

Activo (27/11/2025)

Micancer Center S.L.P.

Barcelona

BARCELONA

Oncología Médica

Activo (10/12/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Oncología Médica

Medicamentos

Alecensa 150 mg hard capsules
CAPSULE, HARD
ORAL

Código ATC: L01ED03 - ALECTINIB
Principios Activos: N/A

Experimental

NVL-655
TABLET
ORAL

-
Principios Activos: N/A

Experimental

NVL-655
TABLET
ORAL

-
Principios Activos: N/A

Experimental

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Código ATC: L01ED03 - ALECTINIB
Principios Activos: N/A

Experimental

Sin resultados

A Study in TKI-naive Patients With Advanced ALK-Positive NSCLC (ALKAZAR)

State	Type of participants	Age Ranges
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	159
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness	NO

Information

Identifier
2024-517553-26-00 (CTIS)

Protocol Code
NVL-655-04

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

Investigated Disease
Advanced ALK-positive non-small cell lung cancer (NSCLC)

Scientific Title
A Phase 3 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 Compared to Alectinib in First-Line Treatment of Patients With ALK-Positive Advanced Non-Small Cell Lung Cancer (ALKAZAR)

Rationale

Not provided

Main Objective

To evaluate the efficacy of NVL-655 compared to alectinib in patients with treatment-naïve ALK-positive advanced NSCLC

Primary Endpoints

Progression-free survival (PFS)

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess additional measures of efficacy of NVL-655 compared to alectinib in patients with treatment-naïve ALK-positive advanced NSCLC
To evaluate the safety and tolerability of NVL-655 compared to alectinib
To evaluate and compare patient-reported measures of health-related quality of life (QoL), lung cancer symptoms, patient functioning, and side effects of treatment

Secondary Endpoints

1) - Overall survival (OS) - Progression-free survival (PFS) per investigator assessment - Time to intracranial progression per blinded independent central review (BICR) - Intracranial objective response rate (IC-ORR) - Intracranial duration of response (IC-DOR) - Objective response rate (ORR) - Duration of response (DOR) - Time to intracranial progression, IC-ORR, IC-DOR, ORR, and DOR
2) Incidence and severity of treatment-emergent adverse events (TEAEs) and changes in clinically relevant laboratory parameters
3) Changes in patient-reported outcomes (PROs)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Patients must meet all of the following criteria to be eligible to enroll in the study: 1. Histologically or cytologically confirmed locally advanced (not amenable for multimodality treatment) or metastatic Non-small Cell Lung Cancer (NSCLC) 2. Documented Anaplastic Lymphoma Kinase (ALK) rearrangement via testing of tissue or blood 3. No prior systemic anticancer treatment for NSCLC (adjuvant/neoadjuvant chemotherapy allowed if 12 months prior to randomization; prior ALK tyrosine kinase inhibitor [TKI] such as alectinib is not allowed in any setting) 4. Measurable disease (1 or more target lesions per Response Evaluation Criteria in Solid Tumors [RECIST] 1.1) 5. Pretreatment tumor tissue (archived or a fresh biopsy)

Exclusion criteria

1. Patients cancer has a known oncogenic driver alteration other than ALK. 2. Known allergy/hypersensitivity to excipients of NVL-655 or alectinib. 3. Major surgery within 4 weeks prior to randomization 4. Ongoing or recent radiotherapy as per protocol-specified timeframes prior to randomization 5. Uncontrolled clinically relevant infection requiring systemic therapy 6. Known active tuberculosis, known active Hepatitis B or C 7. QT corrected for heart rate by Fridericias formula (QTcF) > 470 msec on repeated assessments 8. Clinically significant cardiovascular disease 9. Brain metastases associated with progressive neurological symptoms or requiring increasing doses of corticosteroids to control CNS disease 10. Active malignancy requiring therapy within 2 years prior to randomization

Calendar

(Last Update: 05/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
05/06/2025	26/11/2025	10/12/2025	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

Nuvalent Inc. United States

1 Broadway Floor 14th

Contact Person

Medical

18573577000

medical@nuvalent.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Autonómico de Galicia

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Sites

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Hospital Universitario Virgen De La Macarena

Sevilla

SEVILLA

Oncología Médica

Active (03/12/2025)

Hospital Universitario 12 De Octubre

Madrid

MADRID

Oncología Médica

Active (04/03/2026)

Institut Catala D´oncologia

Girona

GERONA

Oncología Médica

Active (04/03/2026)

Institut Catala D´oncologia

Badalona

BARCELONA

Oncología Médica

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

Institut Catala D´oncologia

L'hospitalet De Llobregat

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Active (27/11/2025)

Micancer Center S.L.P.

Barcelona

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Active (10/12/2025)

University Hospital Virgen Del Rocio S.L.

Sevilla

SEVILLA

Oncología Médica

Medication

Alecensa 150 mg hard capsules
CAPSULE, HARD
ORAL

ATC code: L01ED03 - ALECTINIB
Active Principles: N/A

Experimental

NVL-655
TABLET
ORAL

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Active Principles: N/A

Experimental

NVL-655
TABLET
ORAL

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Active Principles: N/A

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Alecensa 150 mg hard capsules
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ATC code: L01ED03 - ALECTINIB
Active Principles: N/A

Experimental

No results