

A Phase 1/2 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)

Estado

Reclutando

Tipo de Participantes

No aportado

Rangos de Edad

Mayores de 64 , Adultos (18-64 años)

Género

Ambos

Fases

Fase I , Fase II

Participantes esperados

331

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

No

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

tratamiento, seguridad, eficacia,
farmacocinética, farmacodinámica, dosis

Terapia avanzada

NO

Información

Identificador

2024-514266-39-00 (CTIS)

Cod. Protocolo

NVL-655-01

Transicionado 2022-000122-21

Área terapéutica

Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

Advanced Non-Small Cell Lung Cancer (NSCLC) and Other Solid Tumors with ALK rearrangement or activating ALK mutation

Título Científico

A Phase 1/2 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)

Justificación

No aportado

Objetivo Principal

Phase 1 - To evaluate the overall safety and tolerability of NVL-655

Phase 1 - To determine the RP2D and, if applicable, the MTD of NVL-655 in patients with advanced ALK-positive solid tumors

Phase 2 - To evaluate the efficacy of NVL-655 at the RP2D in patients with advanced ALK-positive NSCLC, including those with ALK resistance mutations, and other solid tumors

Variables de Evaluación Primaria

Phase 1 - Incidence and severity of TEAEs and changes in clinically relevant laboratory parameters

Phase 1 - RP2D and, if applicable, the MTD

Phase 2 - ORR according to RECIST 1.1

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

Phase 1 - To characterize the PK profile of NVL-655

Phase 1 - To evaluate preliminary antitumor activity of NVL-655 in patients with advanced ALK-positive solid tumors

Phase 2 - To assess additional measures of clinical efficacy in patients with ALK-positive NSCLC, including those with ALK resistance mutations, and other solid tumors

Phase 2 - To evaluate the intracranial antitumor activity of NVL-655 at the RP2D in patients with advanced ALK-positive NSCLC and other solid tumors

Phase 2 - To characterize the safety and tolerability of NVL-655 at the RP2D

Phase 2 - To confirm the PK profile of NVL-655 at the RP2D

Phase 2 - To assess treatment-related symptoms and general health status using validated instruments of patient-reported outcomes (PROs) in patients treated with NVL-655

Variables de Evaluación Secundaria

Phase 1 - PK parameters of NVL-655

Phase 1 - ORR according to RECIST 1.1 assessment

Phase 2 - DOR

Phase 2 - IC-ORR

Phase 2 - Incidence and severity of TEAEs and changes in clinically relevant laboratory parameters

Phase 2 - PK parameters of NVL-655

Phase 2 - Changes in PROs

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Age 18 years Phase 2 Cohort 2f only: Age 12 years and weight > 40 kg. Disease criteria: Phase 1: Histologically or cytologically confirmed locally advanced or metastatic solid tumor with a documented ALK rearrangement or activating ALK mutation. Disease criteria: Cohorts 2a, 2b, 2c, 2d, and 2e: Histologically or cytologically confirmed locally advanced or metastatic ALK rearrangement or activating ALK mutation Disease criteria: Cohort 2f: Histologically or cytologically confirmed locally advanced or metastatic solid tumor (including NSCLC not eligible for Cohorts 2a-2e) with a documented ALK rearrangement or activating ALK mutation. Prior anticancer treatment: Phase 1: Must have evaluable disease (target or nontarget) according to RECIST 1.1 Prior anticancer treatment: Phase 2: Must have measurable disease, defined as 1 radiologically measurable target lesion according to RECIST 1.1 Pre-treatment tumor tissue Please refer to the protocol for further criteria

Criterios de Exclusión

Patients cancer has a known oncogenic driver alteration other than ALK
Known allergy/hypersensitivity to excipients of NVL-655
Major surgery within 4 weeks of first dose of study drug
Ongoing or recent anticancer therapy
Ongoing or recent radiation therapy
Please refer to the protocol for further criteria

Calendario

(Última actualización: 30/06/2026)

Autorización 27/07/2022	Inicio de Ensayo 22/11/2022	Inclusión Primer Paciente 29/12/2022	Interrumpido No aportado	Reiniciado No aportado
Fin de reclutamiento No aportado	Fin prematuro (España) No aportado	Fin prematuro (Global) No aportado	Fin del ensayo en España No aportado	Fin del ensayo global No aportado

Promotor

Nuvalent Inc. United States

1 Broadway Floor 14th

Contact Person

Medical

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medical@nuvalent.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

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Centros

Activo (10/07/2023)	CLINICA TRES TORRES Barcelona BARCELONA Oncología - UOMi cancer Center
Activo (20/03/2024)	COMPLEXO HOSPITALARIO UNIVERSITARIO A CORUÑA Coruña, A CORUÑA Oncología médica
No iniciado (---/---/----)	Hospital General Universitario Gregorio Marañon Madrid MADRID Oncology
Activo (11/03/2024)	HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑÓN Madrid MADRID Oncología
Activo (23/11/2022)	HOSPITAL UNIVERSITARI VALL D'HEBRON Barcelona BARCELONA HOSPITAL UNIVERSITARI VALL D'HEBRON#Cod. CNH: 081347#
No iniciado (---/---/----)	Hospital Universitario Hm Sanchinarro Madrid MADRID Oncology
Activo (30/05/2023)	HOSPITAL UNIVERSITARIO 12 DE OCTUBRE Madrid MADRID Oncología médica
No iniciado (---/---/----)	Micancer Center S.L.P. Barcelona BARCELONA Oncology

Medicamentos

NVL-655

TABLET

ORAL

Principios Activos: N/A

Experimental

NVL-655

TABLET

ORAL

Principios Activos: N/A

Experimental

Sin resultados

A Phase 1/2 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)

State

Recruiting

Type of participants

Not provided

Age Ranges

Older than 64 , Adults (18-64 years)

Gender

Both

Phases

Phase I , Phase II

Expected Participants

331

Results

No results

Low level of intervention

No

Rare disease

No

Geographic coverage

Undetermined

Areas of the study

treatment, safety, effectiveness,
pharmacokinetics, pharmacodynamics, dose

Advanced therapy

NO

Information

Identifier

2024-514266-39-00 (CTIS)

Protocol Code

NVL-655-01

Transitioned 2022-000122-21

Therapeutic area

Diseases [C] - Cancer [C04]

Investigated Disease

Advanced Non-Small Cell Lung Cancer (NSCLC) and Other Solid Tumors with ALK rearrangement or activating ALK mutation

Scientific Title

A Phase 1/2 Study of the Selective Anaplastic Lymphoma Kinase (ALK) Inhibitor NVL-655 in Patients with Advanced NSCLC and Other Solid Tumors (ALKOVE-1)

Rationale

Not provided

Main Objective

Phase 1 - To evaluate the overall safety and tolerability of NVL-655

Phase 1 - To determine the RP2D and, if applicable, the MTD of NVL-655 in patients with advanced ALK-positive solid tumors

Phase 2 - To evaluate the efficacy of NVL-655 at the RP2D in patients with advanced ALK-positive NSCLC, including those with ALK resistance mutations, and other solid tumors

Primary Endpoints

Phase 1 - Incidence and severity of TEAEs and changes in clinically relevant laboratory parameters

Phase 1 - RP2D and, if applicable, the MTD

Phase 2 - ORR according to RECIST 1.1

Temporary moments of secondary assessment

Not provided

Secondary Objective

Phase 1 - To characterize the PK profile of NVL-655

Phase 1 - To evaluate preliminary antitumor activity of NVL-655 in patients with advanced ALK-positive solid tumors

Phase 2 - To assess additional measures of clinical efficacy in patients with ALK-positive NSCLC, including those with ALK resistance mutations, and other solid tumors

Phase 2 - To evaluate the intracranial antitumor activity of NVL-655 at the RP2D in patients with advanced ALK-positive NSCLC and other solid tumors

Phase 2 - To characterize the safety and tolerability of NVL-655 at the RP2D

Phase 2 - To confirm the PK profile of NVL-655 at the RP2D

Phase 2 - To assess treatment-related symptoms and general health status using validated instruments of patient-reported outcomes (PROs) in patients treated with NVL-655

Secondary Endpoints

Phase 1 - PK parameters of NVL-655

Phase 1 - ORR according to RECIST 1.1 assessment

Phase 2 - DOR

Phase 2 - IC-ORR

Phase 2 - Incidence and severity of TEAEs and changes in clinically relevant laboratory parameters

Phase 2 - PK parameters of NVL-655

Phase 2 - Changes in PROs

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Age 18 years Phase 2 Cohort 2f only: Age 12 years and weight > 40 kg. Disease criteria: Phase 1: Histologically or cytologically confirmed locally advanced or metastatic solid tumor with a documented ALK rearrangement or activating ALK mutation. Disease criteria: Cohorts 2a, 2b, 2c, 2d, and 2e: Histologically or cytologically confirmed locally advanced or metastatic ALK rearrangement or activating ALK mutation Disease criteria: Cohort 2f: Histologically or cytologically confirmed locally advanced or metastatic solid tumor (including NSCLC not eligible for Cohorts 2a-2e) with a documented ALK rearrangement or activating ALK mutation. Prior anticancer treatment: Phase 1: Must have evaluable disease (target or nontarget) according to RECIST 1.1 Prior anticancer treatment: Phase 2: Must have measurable disease, defined as 1 radiologically measurable target lesion according to RECIST 1.1 Pre-treatment tumor tissue Please refer to the protocol for further criteria

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Ongoing or recent radiation therapy
Please refer to the protocol for further criteria

Calendar

(Last Update: 30/06/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
27/07/2022	22/11/2022	29/12/2022	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

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Monetary support: N/A

Sponsor type: Commercial

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not initialized (---/---/----)	Micancer Center S.L.P. Barcelona BARCELONA Oncology

Medication

NVL-655
TABLET
ORAL

Active Principles: N/A

Experimental

NVL-655
TABLET
ORAL

Active Principles: N/A

Experimental

No results