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	**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	331
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

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	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
27/07/2022	22/11/2022	29/12/2022	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 Hospital Universitari Vall d Hebron

Passeig de la Vall d.Hebron, 119-129 - Edificio Materno-Infantil, planta 13 08035 Barcelona

ceic@vhir.org

934894010

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 Maranon

Madrid

MADRID

Oncology

Activo (11/03/2024)

HOSPITAL GENERAL UNIVERSITARIO GREGORIO MARAÑON

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	**Type of participants**	**Age Ranges**
Recruiting	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase I , Phase II	331
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
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

Exclusion criteria

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Ongoing or recent radiation therapy
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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

medical@nuvalent.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Universitari Vall d Hebron

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Sites

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Coruña, A

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Oncología médica

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

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

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

Oncology

Active (30/05/2023)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Oncología médica

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