A Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib versus Adjuvant Platinum-Based Chemotherapy in Patients with Completely Resected Stage Ib (tumors 4 cm) to Stage IIIa Anaplastic Lymphoma Kinase-Positive Non-Small Cell Lung Cancer

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase III	202
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	No
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-506861-76-00 (CTIS)

Cod. Protocolo
BO40336

Transicionado 2017-004331-37

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

Enfermedad investigada
Completely resected, Stage Ib (tumors 4 cm) to Stage IIIa, Anaplastic Lymphoma Kinase (ALK)-Positive Non-Small Cell Lung Cancer (NSCLC)

Título Científico
A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus

Adjuvant Platinum-Based Chemotherapy in Patients with Completely Resected Stage Ib (Tumors 4 Cm) to Stage IIIa Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer

Justificación

No aportado

Objetivo Principal

To evaluate the efficacy of alectinib compared with platinum-based chemotherapy in patients with completely resected Stage Ib (tumors 4 cm) to Stage IIIa, ALK-positive NSCLC based on investigator assessed disease-free survival

Variables de Evaluación Primaria

1. Disease-free survival per investigators assessment

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate the efficacy of alectinib compared with platinum-based chemotherapy in patients with completely resected Stage Ib (tumors 4 cm) to Stage IIIa, ALK-positive NSCLC based on overall survival
To evaluate the safety and tolerability of alectinib compared with platinum-based chemotherapy in patients with completely resected Stage Ib (tumors 4 cm) to Stage IIIa, ALK-positive NSCLC
For alectinib arm only To characterize the pharmacokinetics (PK) of alectinib and its major metabolite(s) in patients with completely resected Stage Ib (tumors4 cm) to Stage IIIa, ALK-positive NSCLC
For alectinib arm only At Japanese sites only: To characterize the pharmacokinetics of alectinib and its major metabolite(s) in Japanese patients

Variables de Evaluación Secundaria

1. Overall survival
2. Incidence of adverse events, with severity determined through use of National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0
3. Incidence of abnormal laboratory findings
4. Changes in vital signs and electrocardiograms
5. Plasma concentrations of alectinib and its major metabolite(s) at specified timepoints for alectinib

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Complete resection of histologically-confirmed Stage Ib (tumor 4 cm) to Stage IIIa (T2-3 N0, T1-3 N1, T1-3 N2, T4 N0-1) NSCLC as per UICC/AJCC, 7th edition, with negative margins, at 4-12 weeks before enrollment
Documented ALK-positive disease according to an FDA-approved and CE-marked test
Eligible to receive a platinum-based chemotherapy regimen according to the local labels or guidelines
Eastern Cooperative Oncology Group Performance Status of Grade 0 or 1
Adequate hematologic and renal function
Willingness and ability to comply with scheduled visits, treatment plans, laboratory tests, and other study procedures

Criterios de Exclusión

Pregnant or breastfeeding, or intending to become pregnant during the study and for at least 5 weeks after the last dose of alectinib or according to local labels or guidelines for chemotherapy
Prior adjuvant radiotherapy for NSCLC Prior exposure to systemic anti-cancer therapy and ALK inhibitors
Stage IIIA N2 patients that, in the investigator's opinion, should receive post-operative radiotherapy treatment are excluded from the study
Known sensitivity to any component of study drug to which the patient may be randomized. This includes, but is not limited to, patients with galactose intolerance, a congenital lactase deficiency or glucose-galactose malabsorption.
Significant liver disease or impaired liver transaminase enzymes levels, symptomatic bradycardia, any GI disorder that may affect absorption of oral medications, such as malabsorption syndrome or status post-major bowel resection, HIV positivity

Calendario

(Última actualización: 04/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
11/05/2018	09/08/2018	11/12/2018	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
29/10/2021	No aportado	No aportado	No aportado	No aportado

Promotor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Universitario Puerta de Hierro de Majadahonda

C/ Joaquin Rodrigo, 2 Majadahonda 28222 Madrid

secreceic.hpth@salud.madrid.org

911917479-911917662

Centros

Cerrado (08/02/2022)

COMPLEJO HOSPITALARIO REGIONAL DE MÁLAGA

Málaga

Servicio de Oncologia

Activo (03/09/2018)

COMPLEJO HOSPITALARIO REGIONAL VIRGEN DEL ROCÍO

Sevilla

SEVILLA

Servicio de Oncologia

Cerrado (21/02/2022)

COMPLEJO UNIVERSITARIO DE SAN CARLOS (*)

Madrid

MADRID

Servicio de Oncologia

Activo (09/08/2018)

COMPLEJO UNIVERSITARIO LA PAZ

Madrid

MADRID

Servicio de Oncologia

Cerrado (10/02/2022)

COMPLEXO HOSPITALARIO UNIVERSITARIO A CORUÑA

Coruña, A

Servicio de Oncologia

Activo (21/08/2018)

HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA

Valencia

VALENCIA

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

Hospital De La Santa Creu I Sant Pau

Barcelona

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Oncología

Activo (09/08/2018)

Hospital de la Santa Creu i Sant Pau

Barcelona

BARCELONA

Servicio de Oncologia

Activo (18/10/2018)

Hospital Universitari Germans Trias i Pujol de Badalona

Badalona

BARCELONA

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Cerrado (03/02/2022)

HOSPITAL UNIVERSITARI I POLITÈCNIC LA FE

Valencia

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Cerrado (14/03/2022)

Hospital Universitari Quirón Dexeus

Barcelona

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Activo (14/09/2018)

Hospital Universitari Vall d'Hebron

Barcelona

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Cerrado (28/03/2022)

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Donostia/San Sebastián

GUIPÚZCOA

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Cerrado (25/02/2022)

HOSPITAL UNIVERSITARIO MADRID SANCHINARRO

Madrid

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Cerrado (27/02/2022)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Servicio de Oncologia

Cerrado (18/02/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Oncologia

Medicamentos

Alecensa 150 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Carboplatin ACTAVIS 10 mg/ml concentrat pentru soluie perfuzabil
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01XA02 - CARBOPLATINO
Principios Activos: N/A

Experimental

ALIMTA 500 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01BA04 - PEMETREXED
Principios Activos: N/A

Experimental

Gemcitabin-GRY 1000 mg Pulver zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01BC05 - GEMCITABINA
Principios Activos: N/A

Experimental

Carboplatin-GRY® 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
INJECTION
IV INFUSION

Código ATC: L01XA02 - CARBOPLATINO
Principios Activos: N/A

Experimental

Alecensa 150 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

VINORELBINE
CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

-
Principios Activos: N/A

Experimental

Cisplatin NeoCorp 1 mg/ml - Konzentrat zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

Código ATC: L01XA01 - CISPLATINO
Principios Activos: N/A

Experimental

Sin resultados

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State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase III	202
Results	**Low level of intervention**	**Rare disease**
No results	No	No
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-506861-76-00 (CTIS)

Protocol Code
BO40336

Transitioned 2017-004331-37

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

Investigated Disease
Completely resected, Stage Ib (tumors 4 cm) to Stage IIIa, Anaplastic Lymphoma Kinase (ALK)-Positive Non-Small Cell Lung Cancer (NSCLC)

Scientific Title
A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus

Adjuvant Platinum-Based Chemotherapy in Patients with Completely Resected Stage Ib (Tumors 4 Cm) to Stage IIIa Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer

Rationale

Not provided

Main Objective

To evaluate the efficacy of alectinib compared with platinum-based chemotherapy in patients with completely resected Stage Ib (tumors 4 cm) to Stage IIIa, ALK-positive NSCLC based on investigator assessed disease-free survival

Primary Endpoints

1. Disease-free survival per investigators assessment

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate the efficacy of alectinib compared with platinum-based chemotherapy in patients with completely resected Stage Ib (tumors 4 cm) to Stage IIIa, ALK-positive NSCLC based on overall survival
To evaluate the safety and tolerability of alectinib compared with platinum-based chemotherapy in patients with completely resected Stage Ib (tumors 4 cm) to Stage IIIa, ALK-positive NSCLC
For alectinib arm only To characterize the pharmacokinetics (PK) of alectinib and its major metabolite(s) in patients with completely resected Stage Ib (tumors4 cm) to Stage IIIa, ALK-positive NSCLC
For alectinib arm only At Japanese sites only: To characterize the pharmacokinetics of alectinib and its major metabolite(s) in Japanese patients

Secondary Endpoints

1. Overall survival
2. Incidence of adverse events, with severity determined through use of National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0
3. Incidence of abnormal laboratory findings
4. Changes in vital signs and electrocardiograms
5. Plasma concentrations of alectinib and its major metabolite(s) at specified timepoints for alectinib

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Complete resection of histologically-confirmed Stage Ib (tumor 4 cm) to Stage IIIa (T2-3 N0, T1-3 N1, T1-3 N2, T4 N0-1) NSCLC as per UICC/AJCC, 7th edition, with negative margins, at 4-12 weeks before enrollment
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Prior adjuvant radiotherapy for NSCLC Prior exposure to systemic anti-cancer therapy and ALK inhibitors
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Known sensitivity to any component of study drug to which the patient may be randomized. This includes, but is not limited to, patients with galactose intolerance, a congenital lactase deficiency or glucose-galactose malabsorption.
Significant liver disease or impaired liver transaminase enzymes levels, symptomatic bradycardia, any GI disorder that may affect absorption of oral medications, such as malabsorption syndrome or status post-major bowel resection, HIV positivity

Calendar

(Last Update: 04/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
11/05/2018	09/08/2018	11/12/2018	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
29/10/2021	Not aported	Not aported	Not aported	Not aported

Sponsor

F. Hoffmann-La Roche AG Switzerland

Grenzacherstrasse 124

Contact Person

Trial Information System - TISL

41616881111

global.eudract@roche.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Closed (08/02/2022)

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Closed (27/02/2022)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Servicio de Oncologia

Closed (18/02/2022)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Servicio de Oncologia

Medication

Alecensa 150 mg hard capsules
CAPSULE, HARD
ORAL

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

Experimental

Carboplatin ACTAVIS 10 mg/ml concentrat pentru soluie perfuzabil
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01XA02 - CARBOPLATINO
Active Principles: N/A

Experimental

ALIMTA 500 mg powder for concentrate for solution for infusion
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01BA04 - PEMETREXED
Active Principles: N/A

Experimental

Gemcitabin-GRY 1000 mg Pulver zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01BC05 - GEMCITABINA
Active Principles: N/A

Experimental

Carboplatin-GRY® 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
INJECTION
IV INFUSION

ATC code: L01XA02 - CARBOPLATINO
Active Principles: N/A

Experimental

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CAPSULE, HARD
ORAL

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

Experimental

VINORELBINE
CONCENTRATE FOR SOLUTION FOR INFUSION
IV INFUSION

-
Active Principles: N/A

Experimental

Cisplatin NeoCorp 1 mg/ml - Konzentrat zur Herstellung einer Infusionslösung
SOLUTION FOR INFUSION
IV INFUSION

ATC code: L01XA01 - CISPLATINO
Active Principles: N/A

Experimental

No results