

Study to allow access to dabrafenib and/or trametinib for subjects that are benefiting from dabrafenib and/or trametinib treatment in a Novartis or GSK sponsored study.

Estado

Reclutando

Tipo de Participantes

Sujetos incapaces de otorgar consentimiento

Rangos de Edad

Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años)

Género

Ambos

Fases

Fase IV

Participantes esperados

82

Resultados

Sin resultados

Bajo nivel intervención

No

Enfermedad rara

Si

Cobertura geográfica

Sin determinar

Ámbitos del ensayo

seguridad

Terapia avanzada

NO

Información

Identificador

2023-509318-13-00 (CTIS)

Cod. Protocolo

CDRB436X2X02B

Transicionado 2017-001987-39

Área terapéutica

Enfermedades [C] - Cáncer [C04]

Enfermedad investigada

Multiple indications

Título Científico

An open label, multi-center roll-over study to assess long-term safety in patients who are ongoing or have completed a prior global Novartis or GSK sponsored Tafenlar (dabrafenib) and/or Mekinist (trametinib) study and are judged by

the investigator to benefit from continued treatment.

Justificación

No aportado

Objetivo Principal

The primary objective is to evaluate long-term safety as assessed by occurrence of AEs/SAEs.

Variables de Evaluación Primaria

Frequency and severity of AEs/SAEs.

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To evaluate clinical benefit as assessed by the Investigator.

Variables de Evaluación Secundaria

Proportion of subjects with clinical benefit as assessed by the Investigator at scheduled visits.

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Subject is currently receiving treatment with dabrafenib and/or trametinib monotherapy or combination within a Novartis or former GSK sponsored study which has fulfilled the requirements for the primary objective.

In the opinion of the Investigator would benefit from continued treatment.

Subject has demonstrated compliance, as assessed by the Investigator, within the parent study protocol requirement(s).

Willingness and ability to comply with scheduled visits, treatment plans and any other study procedures.

Written informed consent obtained prior to enrolling in the roll-over study and receiving study medication. If consent

cannot be expressed in writing, it must be formally documented and witnessed, ideally via an independent trusted witness.

Does not require treatment with prohibited concomitant medications.

Criterios de Exclusión

Subject has been previously permanently discontinued from study treatment in the parent protocol.

Subjects indication is commercially available and reimbursed in the local country.

Subject currently has unresolved toxicities for which dabrafenib and/or trametinib dosing has been interrupted in the parent study. If the patient, in the opinion of the investigator and as per parent protocol, can resume treatment then the patient will be allowed to enroll in CDRB436X2X02B study.

Female subjects who are lactating, unless they are willing discontinue nursing prior to first dose of study treatment, and willing to refrain from nursing throughout the treatment period and for 4 months following the last dose of study treatment.

Women of childbearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception whilst taking study treatment and for 16 weeks after stopping treatment with trametinib (for trametinib monotherapy trials); 2 weeks after stopping treatment with dabrafenib (for dabrafenib monotherapy trials); 16 weeks after stopping treatment with trametinib or 2 weeks after stopping treatment with dabrafenib, whichever is longer (for trials of dabrafenib in combination with trametinib).

Sexually active males unwilling to use a condom during intercourse whilst taking study treatment and for: 16 weeks after stopping study treatment with dabrafenib in combination with trametinib 2 weeks after stopping study treatment with dabrafenib monotherapy 16 weeks after stopping study treatment with trametinib monotherapy A condom is required for all sexually active male participants to prevent them from fathering a child AND to prevent delivery of study treatment via seminal fluid to their partner. In addition, male participants must not donate sperm for the time period specified above.

Calendario

(Última actualización: 13/05/2026)

Autorización 18/12/2017	Inicio de Ensayo 11/01/2018	Inclusión Primer Paciente 17/01/2018	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

Novartis Pharma AG Switzerland

Lichtstrasse 35

Contact Person

Novartis Pharma Arzneimittel GmbH

+499112730

legal.representative@novartis.com

Monetary support: N/A

Tipo de promotor: Comercial

Ceim

CEIm Hospital Fundación Jiménez Díaz

Avda. Reyes Católicos, 2 - 5ª Ascensores 4-5 28040 Madrid

ceic@fjd.es

915443720

Centros

No iniciado (---/---/----)	Hospital General Universitario Gregorio Marañón Madrid MADRID #3105:Oncología Hematológica
No iniciado (---/---/----)	Hospital Infantil Universitario Niño Jesús Madrid MADRID #3104:Oncología Hematológica
No iniciado (---/---/----)	Hospital Universitari Vall D Hebron Barcelona BARCELONA #3100:Oncología Médica
Activo (08/01/2018)	Hospital Universitari Vall d'Hebron Barcelona BARCELONA Vall d' Hebron Institute of Oncology (VHIO)
Activo (08/01/2018)	HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ Madrid MADRID
No iniciado (---/---/----)	Hospital Universitario Fundación Jiménez Díaz Madrid MADRID #3101:Oncología Médica
No iniciado (---/---/----)	Hospital Universitario Hm Sanchinarro Madrid MADRID #3102:Oncología Médica
Activo (08/01/2018)	HOSPITAL UNIVERSITARIO MADRID SANCHINARRO Madrid MADRID

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

#3106:Onco Hematología

Activo (01/06/2021)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medicamentos

DRB436

CAPSULE, HARD
ORAL USE

-

Principios Activos: N/A

Huérfano

Experimental

DRB436

DISPERSIBLE TABLET
ORAL USE

-

Principios Activos: N/A

Huérfano

Experimental

Mekinist 2 mg film-coated tablets

FILM-COATED TABLET
ORAL USE

Código ATC: L01EE01 - TRAMETINIB

Principios Activos: N/A

Huérfano

Experimental

DRB436

CAPSULE, HARD
ORAL USE

-

Principios Activos: N/A

Huérfano

Experimental

TMT212

POWDER FOR ORAL SOLUTION
ORAL USE

Código ATC: L01EE01 - TRAMETINIB

Principios Activos: N/A

Huérfano

Experimental

TMT212

FILM-COATED TABLET
ORAL USE

Código ATC: L01EE01 - TRAMETINIB

Principios Activos: N/A

Huérfano

Experimental

TMT212

FILM-COATED TABLET
ORAL USE

Código ATC: L01EE01 - TRAMETINIB

Principios Activos: N/A

Huérfano

Experimental

Mekinist 0.5 mg film-coated tablets

FILM-COATED TABLET
ORAL USE

Código ATC: L01EE01 - TRAMETINIB

Principios Activos: N/A

Huérfano

Experimental

Sin resultados

Study to allow access to dabrafenib and/or trametinib for subjects that are benefiting from dabrafenib and/or trametinib treatment in a Novartis or GSK sponsored study.

State	Type of participants	Age Ranges
Recruiting	Incapable subjects of giving consent	Less than 18 , Older than 64 , Adults (18-64 years) , Teens (12-17 years) , Children (2-11 years)
Gender	Phases	Expected Participants
Both	Phase IV	82
Results	Low level of intervention	Rare disease
No results	No	Yes
Geographic coverage	Areas of the study	Advanced therapy
Undetermined	safety	NO

Information

Identifier

2023-509318-13-00 (CTIS)

Protocol Code

CDRB436X2X02B

Transitioned 2017-001987-39

Therapeutic area

Diseases [C] - Cancer [C04]

Investigated Disease

Multiple indications

Scientific Title

An open label, multi-center roll-over study to assess long-term safety in patients who are ongoing or have completed a prior global Novartis or GSK sponsored Tafinlar (dabrafenib) and/or Mekinist (trametinib) study and are judged by

the investigator to benefit from continued treatment.

Rationale

Not provided

Main Objective

The primary objective is to evaluate long-term safety as assessed by occurrence of AEs/SAEs.

Primary Endpoints

Frequency and severity of AEs/SAEs.

Temporary moments of secondary assessment

Not provided

Secondary Objective

To evaluate clinical benefit as assessed by the Investigator.

Secondary Endpoints

Proportion of subjects with clinical benefit as assessed by the Investigator at scheduled visits.

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Subject is currently receiving treatment with dabrafenib and/or trametinib monotherapy or combination within a Novartis or former GSK sponsored study which has fulfilled the requirements for the primary objective.

In the opinion of the Investigator would benefit from continued treatment.

Subject has demonstrated compliance, as assessed by the Investigator, within the parent study protocol requirement(s).

Willingness and ability to comply with scheduled visits, treatment plans and any other study procedures.

Written informed consent obtained prior to enrolling in the roll-over study and receiving study medication. If consent

cannot be expressed in writing, it must be formally documented and witnessed, ideally via an independent trusted witness.

Does not require treatment with prohibited concomitant medications.

Exclusion criteria

Subject has been previously permanently discontinued from study treatment in the parent protocol.

Subjects indication is commercially available and reimbursed in the local country.

Subject currently has unresolved toxicities for which dabrafenib and/or trametinib dosing has been interrupted in the parent study. If the patient, in the opinion of the investigator and as per parent protocol, can resume treatment then the patient will be allowed to enroll in CDRB436X2X02B study.

Female subjects who are lactating, unless they are willing discontinue nursing prior to first dose of study treatment, and willing to refrain from nursing throughout the treatment period and for 4 months following the last dose of study treatment.

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Calendar

(Last Update: 13/05/2026)

Authorization 18/12/2017	Start of Trial 11/01/2018	First patient inclusion 17/01/2018	Halted Not aported	Restarted Not aported
End of recruitment Not aported	Premature end (Spain) Not aported	Premature End (Global) Not aported	Trial end (Spain) Not aported	Trial end (Global) Not aported

Sponsor

Novartis Pharma AG Switzerland

Lichtstrasse 35

Contact Person

Novartis Pharma Arzneimittel GmbH

+499112730

legal.representative@novartis.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

CEIm Hospital Fundación Jiménez Díaz

Avda. Reyes Católicos, 2 - 5ª Ascensores 4-5 28040 Madrid

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Sites

not initialized (---/---/----)	Hospital General Universitario Gregorio Marañón Madrid MADRID #3105:Onco Hematolog&iacute;a	Hospital Infantil Universitario Nino Jesus Madrid MADRID #3104:Onco Hematolog&iacute;a
not initialized (---/---/----)	Hospital Universitari Vall D Hebron Barcelona BARCELONA #3100:Oncolog&iacute;a m&eacute;dica	Hospital Universitari Vall d'Hebron Barcelona BARCELONA Vall d' Hebron Institute of Oncology (VHIO)
Active (08/01/2018)	HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ Madrid MADRID	Hospital Universitario Fundacion Jimenez Diaz Madrid MADRID #3101:Oncolog&iacute;a m&eacute;dica
not initialized (---/---/----)	Hospital Universitario Hm Sanchinarro Madrid MADRID #3102:Oncolog&iacute;a m&eacute;dica	HOSPITAL UNIVERSITARIO MADRID SANCHINARRO Madrid MADRID

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

#3106:Onco Hematologícuta;a

Active (01/06/2021)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Medication

DRB436

CAPSULE, HARD
ORAL USE

-

Active Principles: N/A

Orphan

Experimental

DRB436

DISPERSIBLE TABLET
ORAL USE

-

Active Principles: N/A

Orphan

Experimental

Mekinist 2 mg film-coated tablets

FILM-COATED TABLET
ORAL USE

ATC code: L01EE01 - TRAMETINIB

Active Principles: N/A

Orphan

Experimental

DRB436

CAPSULE, HARD
ORAL USE

-

Active Principles: N/A

Orphan

Experimental

TMT212

POWDER FOR ORAL SOLUTION
ORAL USE

ATC code: L01EE01 - TRAMETINIB

Active Principles: N/A

Orphan

Experimental

TMT212

FILM-COATED TABLET
ORAL USE

ATC code: L01EE01 - TRAMETINIB

Active Principles: N/A

Orphan

Experimental

TMT212

FILM-COATED TABLET
ORAL USE

ATC code: L01EE01 - TRAMETINIB

Active Principles: N/A

Orphan

Experimental

Mekinist 0.5 mg film-coated tablets

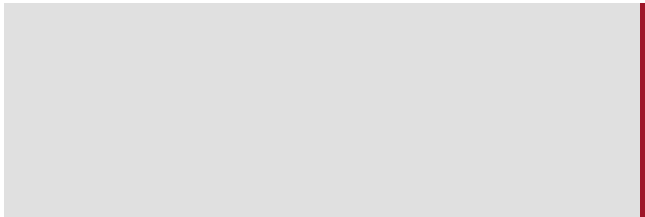
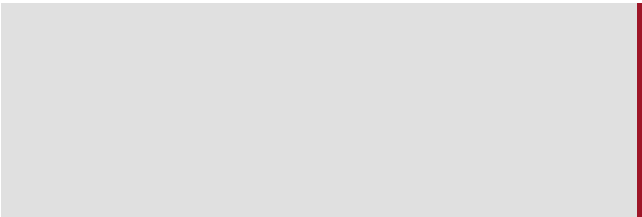
FILM-COATED TABLET
ORAL USE

ATC code: L01EE01 - TRAMETINIB

Active Principles: N/A

Orphan

Experimental



No results