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	Tipo de Participantes	Rangos de Edad
Reclutando	Sujetos incapaces de otorgar consentimiento	Menores de 18 , Mayores de 64 , Adultos (18-64 años) , Adolescentes (12-17 años) , Niños (2-11 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase IV	82
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad	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 Tafinlar (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	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
18/12/2017	11/01/2018	17/01/2018	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

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 Maranon

Madrid

MADRID

#3105:Onco Hematología

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

#3104:Onco Hematología

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 Fundacion Jimenez Diaz

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.
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.

Calendar

(Last Update: 13/05/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
18/12/2017	11/01/2018	17/01/2018	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

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

ceic@fjd.es

915443720

Sites

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

Hospital General Universitario Gregorio Maranon

Madrid

MADRID

#3105:Onco Hematología

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

Hospital Infantil Universitario Nino Jesus

Madrid

MADRID

#3104:Onco Hematología

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

#3100:Oncología médica

Active (08/01/2018)

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

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

Hospital Universitario Fundacion Jimenez Diaz

Madrid

MADRID

#3101:Oncología médica

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

Hospital Universitario Hm Sanchinarro

Madrid

MADRID

#3102:Oncología médica

Active (08/01/2018)

HOSPITAL UNIVERSITARIO MADRID SANCHINARRO

Madrid

MADRID

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

Hospital Universitario Y Politecnico La Fe

Valencia

VALENCIA

#3106:Onco Hematología

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