Extended Access of Momelotinib for Subjects with Myelofibrosis

Estado	**Tipo de Participantes**	**Rangos de Edad**
Fin Reclutamiento	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	150
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	tratamiento, seguridad, eficacia	NO

Información

Identificador
2023-508018-41-00 (CTIS)

Cod. Protocolo
SRA-MMB-4365/219627

Transicionado 2017-004350-42

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

Enfermedad investigada
Primary Myelofibrosis (PMF), Post-polycythemia Vera or Post-essential Thrombocythemia Myelofibrosis (Post-PV/ET MF)

Título Científico
Extended Access of Momelotinib for Subjects with Primary Myelofibrosis (PMF) or Post-polycythemia Vera or Post-essential Thrombocythemia Myelofibrosis (Post-PV/ETMF)

Justificación

No aportado

Objetivo Principal

"To provide extended access to momelotinib and assess long-term safety in 4 cohorts of subjects who are currently receiving treatment with MMB and have not experienced progression of disease:
- Cohort 1: Study GS-US-352-0101, subjects with PMF or post-PV/ET MF
- Cohort 2: Study GS-US-352-1214, subjects with PMF or post-PV/ET MF
- Cohort 3: Study GS-US-352-1154, subjects with PMF or post-PV/ET MF
- Cohort 4: Study SRA-MMB-301, subjects with PMF or post PV/ET MF"

Variables de Evaluación Primaria

Safety: Incidence, severity, seriousness, and causal relationship of AEs, as defined by CTCAE Version 4.03

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To assess overall survival (OS) and leukemia-free survival (LFS) in all subjects

Variables de Evaluación Secundaria

Efficacy: overall survival (OS) and leukemia-free survival (LFS)

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

For subjects continuing MMB treatment: - Currently enrolled in Studies GS-US-352-0101, GS-US-352-1214, GS-US-352-1154, or SRA-MMB-301
For subjects continuing MMB treatment: - Able to comprehend and willing to sign the informed consent form

Criterios de Exclusión

Known hypersensitivity to MMB, its metabolites, or formulation excipient

Calendario

(Última actualización: 27/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
12/06/2018	31/07/2018	22/08/2018	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
06/10/2021	No aportado	No aportado	No aportado	No aportado

Promotor

Glaxosmithkline Research & Development Limited United Kingdom

G S K House980 Great West Road

Contact Person

EU GSK Clinical Trials Call Center

+442089904466

GSKClinicalSupportHD@gsk.com

Monetary support: N/A

Tipo de promotor: Comercial

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CEIm Hospital Universitario Puerta de Hierro de Majadahonda

C/ Joaquin Rodrigo, 2 Majadahonda 28222 Madrid

secreceic.hpth@salud.madrid.org

911917479-911917662

Centros

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

CEIM Hospital Universitari Germans Trias I Pujol

Badalona

BARCELONA

Department of Haematology

Activo (21/12/2018)

CLÍNICA QUIRÓN ZARAGOZA S.A.

Zaragoza

ZARAGOZA

Hematologia

Activo (06/12/2018)

CLINICA UNIVERSIDAD DE NAVARRA

Pamplona/Iruña

NAVARRA

Hematologia

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

Clinica Universidad De Navarra

Pamplona

NAVARRA

Department of Haematology

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

Complejo Hospitalario QuirónSalud

Zaragoza

ZARAGOZA

Department of Haematology

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

Hospital Universitari Vall D Hebron

Barcelona

BARCELONA

Department of Haematology

Activo (15/08/2018)

HOSPITAL UNIVERSITARI VALL D'HEBRON

Barcelona

BARCELONA

Hematologia

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

Hospital Universitario Puerta De Hierro De Majadahonda

Majadahonda

MADRID

Department of Haematology

Activo (10/08/2018)

HOSPITAL UNIVERSITARIO PUERTA DE HIERRO MAJADAHONDA

Majadahonda

MADRID

Hematologia

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Department of Medicine and Medical Specialties

Cerrado (17/04/2019)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematologia

Medicamentos

PRD11032121
TABLET
ORAL USE

-

Principios Activos: N/A

Huérfano Experimental

PRD11032087
TABLET
ORAL USE

-

Principios Activos: N/A

Huérfano Experimental

PRD11032047
TABLET
ORAL USE

-

Principios Activos: N/A

Huérfano Experimental

Sin resultados

Extended Access of Momelotinib for Subjects with Myelofibrosis

State	Type of participants	Age Ranges
End of recruitment	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	150
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	treatment, safety, effectiveness	NO

Information

Identifier
2023-508018-41-00 (CTIS)

Protocol Code
SRA-MMB-4365/219627

Transitioned 2017-004350-42

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

Investigated Disease
Primary Myelofibrosis (PMF), Post-polycythemia Vera or Post-essential Thrombocythemia Myelofibrosis (Post-PV/ET MF)

Scientific Title
Extended Access of Momelotinib for Subjects with Primary Myelofibrosis (PMF) or Post-polycythemia Vera or Post-essential Thrombocythemia Myelofibrosis (Post-PV/ETMF)

Rationale

Not provided

Main Objective

"To provide extended access to momelotinib and assess long-term safety in 4 cohorts of subjects who are currently receiving treatment with MMB and have not experienced progression of disease:
- Cohort 1: Study GS-US-352-0101, subjects with PMF or post-PV/ET MF
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- Cohort 4: Study SRA-MMB-301, subjects with PMF or post PV/ET MF"

Primary Endpoints

Safety: Incidence, severity, seriousness, and causal relationship of AEs, as defined by CTCAE Version 4.03

Temporary moments of secondary assessment

Not provided

Secondary Objective

To assess overall survival (OS) and leukemia-free survival (LFS) in all subjects

Secondary Endpoints

Efficacy: overall survival (OS) and leukemia-free survival (LFS)

Temporary moments of secondary assessment

Not provided

Inclusion criteria

For subjects continuing MMB treatment: - Currently enrolled in Studies GS-US-352-0101, GS-US-352-1214, GS-US-352-1154, or SRA-MMB-301
For subjects continuing MMB treatment: - Able to comprehend and willing to sign the informed consent form

Exclusion criteria

Known hypersensitivity to MMB, its metabolites, or formulation excipient

Calendar

(Last Update: 27/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
12/06/2018	31/07/2018	22/08/2018	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
06/10/2021	Not aported	Not aported	Not aported	Not aported

Sponsor

Glaxosmithkline Research & Development Limited United Kingdom

G S K House980 Great West Road

Contact Person

EU GSK Clinical Trials Call Center

+442089904466

GSKClinicalSupportHD@gsk.com

Monetary support: N/A

Sponsor type: Commercial

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Sites

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

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NAVARRA

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

Clinica Universidad De Navarra

Pamplona

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Department of Haematology

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

Complejo Hospitalario QuirónSalud

Zaragoza

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

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Majadahonda

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Hematologia

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

Hospital Universitario Ramon Y Cajal

Madrid

MADRID

Department of Medicine and Medical Specialties

Closed (17/04/2019)

HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

Madrid

MADRID

Hematologia

Medication

PRD11032121
TABLET
ORAL USE

-

Active Principles: N/A

Orphan Experimental

PRD11032087
TABLET
ORAL USE

-

Active Principles: N/A

Orphan Experimental

PRD11032047
TABLET
ORAL USE

-

Active Principles: N/A

Orphan Experimental

No results