# A study of belantamab mafodotin compared to a combination of pomalidomide and dexamethasone in participants with relapsed/refractory multiple myeloma

| | | |
|---|---|---|
| **Estado** | **Tipo de Participantes** | **Rangos de Edad** |
| EC Finalizado | Sujetos incapaces de otorgar consentimiento | Mayores de 64 , Adultos (18-64 años) |
| **Género** | **Fases** | **Participantes esperados** |
| Ambos | Fase III | 213 |
| **Resultados** | **Bajo nivel intervención** | **Enfermedad rara** |
| Sin resultados | No | Si |
| **Cobertura geográfica** | **Ámbitos del ensayo** | **Terapia avanzada** |
| Sin determinar | seguridad, eficacia, farmacocinética, farmacogenética | NO |

## Información

### Identificador
2023-508962-14-00 (CTIS)

### Cod. Protocolo
207495

Transicionado 2018-004252-38

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

### Enfermedad investigada
Relapsed/Refractory Multiple Myeloma

### Título Científico
A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Single Agent Belantamab Mafodotin Compared to Pomalidomide plus Low-dose Dexamethasone (pom/dex) in Participants with Relapsed/Refractory Multiple Myeloma (RRMM) (DREAMM 3)

## Justificación

No aportado

## Objetivo Principal

To compare the efficacy with belantamab mafodotin vs pomalidomide plus low dose dexamethasone (pom/dex) in participants with relapsed/refractory multiple myeloma (RRMM)

## Variables de Evaluación Primaria

PFS, defined as the time from the date of randomization until the earliest date of documented disease progression (according to IMWG Response Criteria) or death due to any cause

## Momentos temporales de evaluación primaria

No aportado

## Objetivo Secundario

To compare the overall survival with belantamab mafodotin vs Pom/Dex in participants with RRMM
To compare other markers of efficacy of belantamab mafodotin vs pom/dex in participants with RRMM
To evaluate the safety and tolerability of belantamab mafodotin vs pom/dex in participants with RRMM
To evaluate the pharmacokinetic profile of belantamab mafodotin
To assess anti-drug antibodies (ADAs) against belantamab mafodotin
To evaluate the tolerability of belantamab mafodotin vs pom/dex based on self-reported symptomatic adverse effects
To evaluate and compare changes in symptoms and health-related quality of life (HRQOL) of belantamab mafodotin to pom/dex.
To assess Minimal Residual Disease (MRD) in participants who achieve VGPR or better for belantamab mafodotin vs pom/dex

## Variables de Evaluación Secundaria

OS, defined as the time from randomization until death due to any cause
ORR, defined as the percentage of participants with a confirmed PR or better per IMWG
Clinical benefit rate (CBR), defined as the percentage of participants with a confirmed Minimal response (MR) or better per IMWG
DoR, defined as the time from first documented evidence of PR or better until PD per IMWG or death due To any cause among participants who achieve confirmed PR or better
TTR, defined as the time between the date of randomization and the first documented evidence of response (PR or better) among participants who achieve confirmed PR or better
TTP, defined as the time from the date of randomization until the earliest date of documented PD (per IMWG response Criteria) or death due To PD
Incidence of adverse events (AEs) and changes in laboratory parameters

Ocular findings on ophthalmic exam
Plasma concentrations of belantamab mafodotin, total mAb, and cys-mcMMAF
Incidence and titers of ADAs against belantamab mafodotin
Symptomatic adverse effects as measured by the PRO-CTCAE and OSDI
Health-related QOL as measured by EORTC QLQ-C30, EORTC IL52* and EORTC QLQ-MY20*
MRD negativity rate, defined as; the percentage of participants who are MRD negative by NGS method

## Momentos temporales de evaluación secundaria

No aportado

## Criterios de Inclusión

Capable of giving signed informed consent as described in Appendix 1 which includes compliance with requirements and restrictions listed in the ICF and in the protocol. Participants must be 18 or older, at the time of signing the ICF. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 (Appendix 9). Histologically or cytologically confirmed diagnosis of multiple myeloma (MM) as defined according to International Myeloma Working Group (IMWG), and: a. Has undergone autologous stem cell transplant (SCT), or is considered transplant ineligible, and b. Has received at least 2 prior lines of anti-myeloma treatments, including at least 2 consecutive cycles of both lenalidomide and a proteasome inhibitor (given separately or in combination), AND i) Must have documented disease progression on, or within 60 days of, completion of the last treatment OR ii) Must be non-responsive while on last treatment, where non-responsive is defined as not achieving at least Minimal Response (MR) after 2 complete treatment cycles. In such cases lack of achieving of at least MR must be determined no earlier than at least 4 weeks after the last treatment Has measurable disease with at least one of the following: a. Serum M-protein 0.5 g/dL (5 g/L) b. Urine M-protein 200 mg/24 hours c. Serum free light chain (FLC) assay: Involved FLC level 10 mg/dL ( 100 mg/L) and an abnormal serum FLC ratio (<0.26 or >1.65) Participants with a history of autologous SCT are eligible for study participation provided the following eligibility criteria are met: a. Transplant was >100 days prior to initiating study treatment b. No active infection(s) c. Participant meets the remainder of the protocol eligibility criteria Adequate organ system functions as defined in Table 9 Contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. a. Male Participants: Male participants are eligible if they agree to the following during the Male participants are eligible if they agree to the following during the intervention period and until 6 months* after the last dose of study intervention to allow for clearance of any altered sperm: Refrain from donating sperm PLUS, either: Be abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long term and persistent basis) and agree to remain abstinent OR Must agree to use a male condom throughout study treatment including the 6 month* follow-up period even if they have undergone a successful vasectomy and a female partner to use an additional highly effective contraceptive method with a failure rate of <1% per year as described in Appendix 4 when having sexual intercourse with a pregnant woman or a woman of childbearing potential (WOCBP) who is not currently pregnant. *4 weeks for male participants on Treatment Arm 2 (pom/dex). b. Female Participants: A female participant is eligible to participate if she is not pregnant or breastfeeding, and at least one of the following conditions applies: Is not a WOCBP [Appendix 4] OR Is a WOCBP and agrees to abide by the following: Arm 1 (belantamab mafodotin): Use a contraceptive method that is highly effective (with a failure rate of <1% per year) which includes abstinence, preferably with low user dependency during the intervention period and for 4 months after the last dose of study treatment. Arm 2 (pom/dex): Due to pomalidomide being a thalidomide analogue with risk for embryofetal toxicity and prescribed under a pregnancy prevention/controlled distribution program, WOCBP participants will be eligible if they commit either to abstain continuously from heterosexual sexual intercourse or to use 2 methods of reliable birth control (one method that is highly effective), beginning 4 weeks prior to initiating treatment with pomalidomide, during therapy, during dose interruptions and continuing for at least 4 weeks following discontinuation of pomalidomide treatment. 2 negative pregnancy tests must be obtained prior to initiating therapy. The 1st test should be performed within 10-14 days and the 2nd test within 24 hours prior to prescribing pomalidomide therapy. And agrees not to donate eggs (ova, oocytes) for the purpose of reproduction during this period. Investigator should confirm the

effectiveness of the contraceptive method(s) ahead of the 1st dose of study intervention. Additional requirements for pregnancy testing during and after study intervention are located in Appendix 4. Investigator is responsible for review of medical history, menstrual history, and recent sexual activity to decrease the risk for inclusion of a woman with an early undetected pregnancy. All prior treatment-related toxicities (defined by National Cancer Institute- Common Toxicity Criteria for Adverse Events (NCI-CTCAE), version 5.0, 2017) must be Grade 1 at the time of enrollment, except for alopecia and Grade 2 peripheral neuropathy.

## Criterios de Exclusión

Symptomatic amyloidosis, active POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes); active plasma cell leukemia at the time of screening. History of (non-infectious) pneumonitis that required steroids, or current pneumonitis. Evidence of active mucosal or internal bleeding. Current unstable liver or biliary disease per investigator assessment defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, oesophageal or gastric varices, persistent jaundice, or cirrhosis. NOTE: Stable chronic liver disease (including Gilbert's syndrome or asymptomatic gallstones) or hepatobiliary involvement of malignancy is acceptable if participant otherwise meets entry criteria. Participants with previous or concurrent malignancies other than multiple myeloma are excluded, unless the second malignancy has been considered medically stable for at least 2 years. The participant must not be receiving active therapy, other than hormonal therapy for this disease. NOTE Participants with curatively treated non-melanoma skin cancer are allowed without a 2-year restriction. Evidence of cardiovascular risk including any of the following: a. Evidence of current clinically significant uncontrolled arrhythmias including clinically significant electrocardiogram (ECG) abnormalities including 2nd degree (Mobitz Type II) or 3rd degree atrioventricular block. b. History of myocardial infarction, acute coronary syndromes (including unstable angina), coronary angioplasty, or stenting or bypass grafting within 3 months of Screening. c. Class III or IV heart failure as defined by the New York Heart Association (NYHA) functional classification system (Appendix 10 of the protocol) d. Uncontrolled hypertension. Known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to belantamab mafodotin, pomalidomide, dexamethasone or any of the components of the study intervention. Pregnant or lactating female. Active infection requiring treatment. Known human immunodeficiency virus (HIV), unless the participant can meet all of the following criteria: Established anti-retroviral therapy (ART) for at least 4 weeks and HIV viral load <400 copies/mL CD4+ T-cell (CD4+) counts 350 cells/uL No history of AIDS-defining opportunistic infections within the last 12 months Patients with Hepatitis B will be excluded unless the following criteria can be met (see protocol). Systemic anti-myeloma therapy or use of an investigational drug within <14 days or 5 half-lives, whichever is shorter, before the first dose of study intervention. Positive hepatitis C antibody test result or positive hepatitis C RNA test result at screening or within 3 months prior to first dose of study treatment unless the participant can meet the following criteria (see protocol). Participants unable to tolerate thromboembolic prophylaxis Current corneal epithelial disease except for mild punctate keratopathy Prior treatment with an anti-MM monoclonal antibody within 30 days prior to receiving the first dose of study intervention. Prior BCMA-targeted therapy or prior pomalidomide treatment. Plasmapheresis within 7 days prior to the first dose of study intervention Prior allogeneic stem cell transplant. NOTE Participants who have undergone syngeneic transplant will be allowed only if no history of, or currently active GvHD. Any major surgery within the last 4 weeks. Presence of active renal condition (infection, requirement for dialysis or any other condition that could affect participant's safety). Participants with isolated proteinuria resulting from MM are eligible, provided they fulfil criteria included in Table 9 of the protocol. Any serious and/or unstable pre-existing medical, psychiatric disorder, or other conditions (including lab abnormalities) that could interfere with participant's safety, obtaining informed consent, or compliance with study procedures.

# Calendario

(Última actualización: 16/02/2026)

| Autorización | Inicio de Ensayo | Inclusión Primer Paciente | Interrumpido | Reiniciado |
|---|---|---|---|---|
| 27/03/2020 | 22/06/2020 | 30/06/2020 | No aportado | No aportado |

| Fin de reclutamiento | Fin prematuro (España) | Fin prematuro (Global) | Fin del ensayo en España | Fin del ensayo global |
|---|---|---|---|---|
| 25/03/2022 | No aportado | No aportado | 01/04/2025 | No aportado |

# Promotor

**Glaxosmithkline Research & Development Limited United Kingdom**

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**Contact Person**

EU GSK Clinical Trails Call Center

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**Monetary support: N/A**

**Tipo de promotor: Comercial**

# Ceim

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**915867007**

# Centros

Cerrado (11/02/2026)

**HOSPITAL CLÍNIC DE BARCELONA**

Barcelona

BARCELONA

Cerrado (12/06/2025)

**HOSPITAL QUIRÓNSALUD MADRID**

Pozuelo de Alarcón

MADRID

Cerrado (19/11/2025)

**HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA**

Badalona

BARCELONA

# Medicamentos

### Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Experimental

### Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL USE

Código ATC: L04AX06 - POMALIDOMIDA
Principios Activos: N/A

Experimental

### PRD6002468
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS

-

Principios Activos: N/A

Huérfano

Experimental

### Dexamethason 8 mg GALEN® Tabletten
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

### Dexamethason 8 mg JENAPHARM®
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

### Dexamethasone Tablets BP 2.0mg
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

### Dexamethasone 2mg Tablets
TABLET
ORAL USE

Código ATC: H02AB02 - DEXAMETASONA
Principios Activos: N/A

Experimental

# Sin resultados

# A study of belantamab mafodotin compared to a combination of pomalidomide and dexamethasone in participants with relapsed/refractory multiple myeloma

| State | Type of participants | Age Ranges |
|---|---|---|
| Finished CT | Incapable subjects of giving consent | Older than 64 , Adults (18-64 years) |
| **Gender** | **Phases** | **Expected Participants** |
| Both | Phase III | 213 |
| **Results** | **Low level of intervention** | **Rare disease** |
| No results | No | Yes |
| **Geographic coverage** | **Areas of the study** | **Advanced therapy** |
| Undetermined | safety, effectiveness, pharmacokinetics, pharmacogenetics | NO |

## Information

### Identifier
2023-508962-14-00 (CTIS)

### Protocol Code
207495

Transitioned 2018-004252-38

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

### Investigated Disease
Relapsed/Refractory Multiple Myeloma

### Scientific Title
A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Single Agent Belantamab Mafodotin Compared to Pomalidomide plus Low-dose Dexamethasone (pom/dex) in Participants with Relapsed/Refractory Multiple Myeloma (RRMM) (DREAMM 3)

## Rationale

Not provided

## Main Objective

To compare the efficacy with belantamab mafodotin vs pomalidomide plus low dose dexamethasone (pom/dex) in participants with relapsed/refractory multiple myeloma (RRMM)

## Primary Endpoints

PFS, defined as the time from the date of randomization until the earliest date of documented disease progression (according to IMWG Response Criteria) or death due to any cause

## Temporary moments of secondary assessment

Not provided

## Secondary Objective

To compare the overall survival with belantamab mafodotin vs Pom/Dex in participants with RRMM
To compare other markers of efficacy of belantamab mafodotin vs pom/dex in participants with RRMM
To evaluate the safety and tolerability of belantamab mafodotin vs pom/dex in participants with RRMM
To evaluate the pharmacokinetic profile of belantamab mafodotin
To assess anti-drug antibodies (ADAs) against belantamab mafodotin
To evaluate the tolerability of belantamab mafodotin vs pom/dex based on self-reported symptomatic adverse effects
To evaluate and compare changes in symptoms and health-related quality of life (HRQOL) of belantamab mafodotin to pom/dex.
To assess Minimal Residual Disease (MRD) in participants who achieve VGPR or better for belantamab mafodotin vs pom/dex

## Secondary Endpoints

OS, defined as the time from randomization until death due to any cause
ORR, defined as the percentage of participants with a confirmed PR or better per IMWG
Clinical benefit rate (CBR), defined as the percentage of participants with a confirmed Minimal response (MR) or better per IMWG
DoR, defined as the time from first documented evidence of PR or better until PD per IMWG or death due To any cause among participants who achieve confirmed PR or better
TTR, defined as the time between the date of randomization and the first documented evidence of response (PR or better) among participants who achieve confirmed PR or better
TTP, defined as the time from the date of randomization until the earliest date of documented PD (per IMWG response Criteria) or death due To PD
Incidence of adverse events (AEs) and changes in laboratory parameters

Ocular findings on ophthalmic exam
Plasma concentrations of belantamab mafodotin, total mAb, and cys-mcMMAF
Incidence and titers of ADAs against belantamab mafodotin
Symptomatic adverse effects as measured by the PRO-CTCAE and OSDI
Health-related QOL as measured by EORTC QLQ-C30, EORTC IL52* and EORTC QLQ-MY20*
MRD negativity rate, defined as; the percentage of participants who are MRD negative by NGS method

## Temporary moments of secondary assessment

Not provided

## Inclusion criteria

Capable of giving signed informed consent as described in Appendix 1 which includes compliance with requirements and restrictions listed in the ICF and in the protocol. Participants must be 18 or older, at the time of signing the ICF. Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 (Appendix 9). Histologically or cytologically confirmed diagnosis of multiple myeloma (MM) as defined according to International Myeloma Working Group (IMWG), and: a. Has undergone autologous stem cell transplant (SCT), or is considered transplant ineligible, and b. Has received at least 2 prior lines of anti-myeloma treatments, including at least 2 consecutive cycles of both lenalidomide and a proteasome inhibitor (given separately or in combination), AND i) Must have documented disease progression on, or within 60 days of, completion of the last treatment OR ii) Must be non-responsive while on last treatment, where non-responsive is defined as not achieving at least Minimal Response (MR) after 2 complete treatment cycles. In such cases lack of achieving of at least MR must be determined no earlier than at least 4 weeks after the last treatment Has measurable disease with at least one of the following: a. Serum M-protein 0.5 g/dL (5 g/L) b. Urine M-protein 200 mg/24 hours c. Serum free light chain (FLC) assay: Involved FLC level 10 mg/dL ( 100 mg/L) and an abnormal serum FLC ratio (<0.26 or >1.65) Participants with a history of autologous SCT are eligible for study participation provided the following eligibility criteria are met: a. Transplant was >100 days prior to initiating study treatment b. No active infection(s) c. Participant meets the remainder of the protocol eligibility criteria Adequate organ system functions as defined in Table 9 Contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. a. Male Participants: Male participants are eligible if they agree to the following during the Male participants are eligible if they agree to the following during the intervention period and until 6 months* after the last dose of study intervention to allow for clearance of any altered sperm: Refrain from donating sperm PLUS, either: Be abstinent from heterosexual intercourse as their preferred and usual lifestyle (abstinent on a long term and persistent basis) and agree to remain abstinent OR Must agree to use a male condom throughout study treatment including the 6 month* follow-up period even if they have undergone a successful vasectomy and a female partner to use an additional highly effective contraceptive method with a failure rate of <1% per year as described in Appendix 4 when having sexual intercourse with a pregnant woman or a woman of childbearing potential (WOCBP) who is not currently pregnant. *4 weeks for male participants on Treatment Arm 2 (pom/dex). b. Female Participants: A female participant is eligible to participate if she is not pregnant or breastfeeding, and at least one of the following conditions applies: Is not a WOCBP [Appendix 4] OR Is a WOCBP and agrees to abide by the following: Arm 1 (belantamab mafodotin): Use a contraceptive method that is highly effective (with a failure rate of <1% per year) which includes abstinence, preferably with low user dependency during the intervention period and for 4 months after the last dose of study treatment. Arm 2 (pom/dex): Due to pomalidomide being a thalidomide analogue with risk for embryofetal toxicity and prescribed under a pregnancy prevention/controlled distribution program, WOCBP participants will be eligible if they commit either to abstain continuously from heterosexual sexual intercourse or to use 2 methods of reliable birth control (one method that is highly effective), beginning 4 weeks prior to initiating treatment with pomalidomide, during therapy, during dose interruptions and continuing for at least 4 weeks following discontinuation of pomalidomide treatment. 2 negative pregnancy tests must be obtained prior to initiating therapy. The 1st test should be performed within 10-14 days and the 2nd test within 24 hours prior to prescribing pomalidomide therapy. And agrees not to donate eggs (ova, oocytes) for the purpose of reproduction during this period. Investigator should confirm the

effectiveness of the contraceptive method(s) ahead of the 1st dose of study intervention. Additional requirements for pregnancy testing during and after study intervention are located in Appendix 4. Investigator is responsible for review of medical history, menstrual history, and recent sexual activity to decrease the risk for inclusion of a woman with an early undetected pregnancy. All prior treatment-related toxicities (defined by National Cancer Institute- Common Toxicity Criteria for Adverse Events (NCI-CTCAE), version 5.0, 2017) must be Grade 1 at the time of enrollment, except for alopecia and Grade 2 peripheral neuropathy.

## Exclusion criteria

Symptomatic amyloidosis, active POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes); active plasma cell leukemia at the time of screening. History of (non-infectious) pneumonitis that required steroids, or current pneumonitis. Evidence of active mucosal or internal bleeding. Current unstable liver or biliary disease per investigator assessment defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, oesophageal or gastric varices, persistent jaundice, or cirrhosis. NOTE: Stable chronic liver disease (including Gilbert's syndrome or asymptomatic gallstones) or hepatobiliary involvement of malignancy is acceptable if participant otherwise meets entry criteria. Participants with previous or concurrent malignancies other than multiple myeloma are excluded, unless the second malignancy has been considered medically stable for at least 2 years. The participant must not be receiving active therapy, other than hormonal therapy for this disease. NOTE Participants with curatively treated non-melanoma skin cancer are allowed without a 2-year restriction. Evidence of cardiovascular risk including any of the following: a. Evidence of current clinically significant uncontrolled arrhythmias including clinically significant electrocardiogram (ECG) abnormalities including 2nd degree (Mobitz Type II) or 3rd degree atrioventricular block. b. History of myocardial infarction, acute coronary syndromes (including unstable angina), coronary angioplasty, or stenting or bypass grafting within 3 months of Screening. c. Class III or IV heart failure as defined by the New York Heart Association (NYHA) functional classification system (Appendix 10 of the protocol) d. Uncontrolled hypertension. Known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to belantamab mafodotin, pomalidomide, dexamethasone or any of the components of the study intervention. Pregnant or lactating female. Active infection requiring treatment. Known human immunodeficiency virus (HIV), unless the participant can meet all of the following criteria: Established anti-retroviral therapy (ART) for at least 4 weeks and HIV viral load <400 copies/mL CD4+ T-cell (CD4+) counts 350 cells/uL No history of AIDS-defining opportunistic infections within the last 12 months Patients with Hepatitis B will be excluded unless the following criteria can be met (see protocol). Systemic anti-myeloma therapy or use of an investigational drug within <14 days or 5 half-lives, whichever is shorter, before the first dose of study intervention. Positive hepatitis C antibody test result or positive hepatitis C RNA test result at screening or within 3 months prior to first dose of study treatment unless the participant can meet the following criteria (see protocol). Participants unable to tolerate thromboembolic prophylaxis Current corneal epithelial disease except for mild punctate keratopathy Prior treatment with an anti-MM monoclonal antibody within 30 days prior to receiving the first dose of study intervention. Prior BCMA-targeted therapy or prior pomalidomide treatment. Plasmapheresis within 7 days prior to the first dose of study intervention Prior allogeneic stem cell transplant. NOTE Participants who have undergone syngeneic transplant will be allowed only if no history of, or currently active GvHD. Any major surgery within the last 4 weeks. Presence of active renal condition (infection, requirement for dialysis or any other condition that could affect participant's safety). Participants with isolated proteinuria resulting from MM are eligible, provided they fulfil criteria included in Table 9 of the protocol. Any serious and/or unstable pre-existing medical, psychiatric disorder, or other conditions (including lab abnormalities) that could interfere with participant's safety, obtaining informed consent, or compliance with study procedures.

# Calendar

(Last Update: 16/02/2026)

| Authorization | Start of Trial | First patient inclusion | Halted | Restarted |
|---|---|---|---|---|
| 27/03/2020 | 22/06/2020 | 30/06/2020 | Not aported | Not aported |

| End of recruitment | Premature end (Spain) | Premature End (Global) | Trial end (Spain) | Trial end (Global) |
|---|---|---|---|---|
| 25/03/2022 | Not aported | Not aported | 01/04/2025 | Not aported |

# Sponsor

### Glaxosmithkline Research & Development Limited United Kingdom

**G S K House980 Great West Road**

**Contact Person**

EU GSK Clinical Trails Call Center

**+4402089904466**

**GSKClinicalSupportHD@gsk.com**

**Monetary support: N/A**

**Sponsor type: Commercial**

# Ceim

### CEIm Hospital General Universitario Gregorio Marañón

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**ceim.hgugm@salud.madrid.org**

**915867007**

# Sites

Closed (11/02/2026)

**HOSPITAL CLÍNIC DE BARCELONA**

Barcelona

BARCELONA

Closed (12/06/2025)

**HOSPITAL QUIRÓNSALUD MADRID**

Pozuelo de Alarcón

MADRID

Closed (19/11/2025)

**HOSPITAL UNIVERSITARI GERMANS TRIAS I PUJOL DE BADALONA**

Badalona

BARCELONA

# Medication

### Imnovid 1 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Experimental

### Imnovid 4 mg hard capsules
CAPSULE, HARD
ORAL USE

ATC code: L04AX06 - POMALIDOMIDA
Active Principles: N/A

Experimental

### PRD6002468
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS

-
Active Principles: N/A

Orphan
Experimental

### Dexamethason 8 mg GALEN® Tabletten
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

### Dexamethason 8 mg JENAPHARM®
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

### Dexamethasone Tablets BP 2.0mg
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

### Dexamethasone 2mg Tablets
TABLET
ORAL USE

ATC code: H02AB02 - DEXAMETASONA
Active Principles: N/A

Experimental

# No results