Study to Investigate Alternative Dosing Regimens of Belantamab Mafodotin in Participants with Relapsed or Refractory Multiple Myeloma (DREAMM14)

Estado	**Tipo de Participantes**	**Rangos de Edad**
EC Finalizado	No aportado	Mayores de 64 , Adultos (18-64 años)
Género	**Fases**	**Participantes esperados**
Ambos	Fase II	120
Resultados	**Bajo nivel intervención**	**Enfermedad rara**
Sin resultados	No	Si
Cobertura geográfica	**Ámbitos del ensayo**	**Terapia avanzada**
Sin determinar	seguridad, eficacia, farmacocinética	NO

Información

Identificador
2023-508213-16-00 (CTIS)

Cod. Protocolo
209628

Transicionado 2021-004151-16

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

Enfermedad investigada
Multiple Myeloma

Título Científico
A Phase 2, Randomized, Parallel, Open-Label Study to Investigate the Safety, Efficacy, and Pharmacokinetics of Various Dosing Regimens of Single-Agent Belantamab Mafodotin (GSK2857916) in Participants with Relapsed or Refractory Multiple Myeloma (DREAMM-14)

Justificación

No aportado

Objetivo Principal

To examine the corneal events associated with single-agent belantamab mafodotin using alternative dosing regimens in participants with RRMM in Arms B to D compared to Arm A

Variables de Evaluación Primaria

Incidence rate of Grade 2 corneal events according to the KVA scale

Momentos temporales de evaluación primaria

No aportado

Objetivo Secundario

To further evaluate the corneal safety and tolerability of single-agent belantamab mafodotin in all arms
To evaluate the efficacy of single-agent belantamab mafodotin in all arms
To evaluate the overall safety and tolerability of single-agent belantamab mafodotin in all arms
To assess the pharmacokinetics of single-agent belantamab mafodotin in all arms
To assess anti-drug antibodies against single-agent belantamab mafodotin in all arms

Variables de Evaluación Secundaria

Cumulative event rate of corneal events to Week 16 (KVA scale)
Incidence rate of corneal events by grade (KVA scale)
Exposure-adjusted incidence rate of corneal events by grade (KVA scale)
Median duration of dose delay
Percentage of participants requiring dose reductions, dose delays, and study treatment discontinuation due to corneal events (KVA scale)
Cumulative incidence of corneal events by grade (KVA scale)
Toxicity Index by assessment/visit
Percentage of time on study with corneal events (KVA scale)
Change in BCVA (logMAR)
ORR, defined as the percentage of participants with a confirmed PR or better (i.e., PR, VGPR, CR, and sCR)
Percentage of participants with a confirmed VGPR or better (i.e., VGPR, CR, and sCR)
TTR is defined as the time between the date of randomization and the first documented evidence of response (PR or better), among participants who achieve a response (i.e., confirmed PR or better)
DoR in responders, defined as the time from first documented evidence of PR or better until PD or death due to any cause
TTP, defined as the time from randomization until the earliest date of documented PD or death due to PD

PFS, defined as the time from randomization until the earliest date of documented PD or death due to any cause
OS, defined as the time from randomization until the date of death due to any cause
Instance of AEs (including ocular AEs) (CTCAE Version 5.0) and changes in laboratory parameters
Percentage of participants requiring dose reductions, dose delays, and study treatment discontinuation due to any AEs (CTCAE Version 5.0)
Plasma belantamab mafodotin pharmacokinetic parameters, as data permit
Incidence and titers of ADAs against belantamab mafodotin at each ADA time point

Momentos temporales de evaluación secundaria

No aportado

Criterios de Inclusión

Participant must be 18 years of age inclusive at the time of signing the Informed Consent Form (ICF). Participant meets country-specific inclusion criteria described in Section 10.7, if applicable. Participant has Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. "Participant has a histologically- or cytologically-confirmed diagnosis of myeloma as defined by IMWG criteria [Rajkumar, 2016], and a. Has undergone stem cell transplant or is considered transplant ineligible, and b. Has failed at least 3 prior lines of anti-MM therapies, including an anti?CD38 antibody (e.g., daratumumab) alone or in combination, and is refractory to an immunomodulatory agent (e.g., lenalidomide, pomalidomide)." "Participant has measurable disease with at least one of the following criteria: a. Serum M protein 0.5 g/dL (5 g/L), or b. Urine M protein 200 mg/24h, or c. Serum free light chain (FLC) assay: Involved FLC level 5 mg/dL (50 mg/L) and an abnormal serum FLC ratio (<0.26 or >1.65)." "Participants with a history of autologous stem cell transplant are eligible for study participation provided the following eligibility criteria are met: a. Transplant was >100 days before study enrollment, and b. Participant has no active infection(s), and c. Participant meets the remainder of the eligibility criteria outlined in protocol. " "All prior treatment-related toxicities (defined by the National Cancer Institute Common Terminology Criteria for Adverse Events [NCI-CTCAE] Version 5.0) must be Grade 1 at the time of enrollment, except for alopecia and Grade 2 peripheral neuropathy. " Life expectancy of at least 6 months, in the opinion of the investigator. "Contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. a. Female Participants A female participant is eligible to participate if she is not pregnant or breastfeeding and at least one of the following conditions apply: Is not a woman of childbearing potential (WOCBP) as defined in Section 10.9, or Is a WOCBP and using a contraceptive method that is highly effective (with a failure rate of <1% per year), preferably with low user dependency (as described in Section 10.9) during the treatment period and for at least 4 months after the last dose of study treatment and agrees not to donate eggs (ova, oocytes) for the purpose of reproduction during this period. The investigator should evaluate the effectiveness of the contraceptive method in relationship to the first dose of study treatment. A WOCBP must have a negative highly sensitive serum pregnancy test (as required by local regulations) within 72 hours before the first dose (Cycle 1 Day 1) of study treatment (see Section 8.2.7). Additional requirements for pregnancy testing during and after study treatment are provided in Section 8.2.7 and the Schedule of Activities (SoA) (Section 1.3). The 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. b. Male Participants Contraceptive use by men should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. Male participants are eligible to participate if they agree to the following conditions from the time of first dose of study treatment until 6 months after the last dose of study treatment to allow for clearance of any altered sperm: Refrain from donating sperm, plus either: o 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 o Must agree to use contraception/barrier as follows: Agree to use a male condom, even if they have undergone a successful vasectomy, with female partner use of an additional highly effective contraceptive method with a failure rate of <1% per year as described in Section 10.9, when having sexual intercourse with a WOCBP (including pregnant females). " Participant is capable of giving signed informed consent as described in Section 10.10 which includes compliance with the requirements and restrictions listed in the ICF and

in the protocol.

Criterios de Exclusión

Participant has symptomatic amyloidosis, active POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes), or active plasma cell leukemia at the time of screening. Participant has known human immunodeficiency virus (HIV) infection, unless the participant can meet all of the following criteria: a. Established anti-retroviral therapy (ART) for 4 weeks and HIV viral load <400 copies/mL, and b. CD4+ T cell (CD4+) counts 350 cells/L, and c. No history of acquired immunodeficiency syndrome-defining opportunistic infections within the last 12 months. Participants with hepatitis B virus (HBV) will be excluded unless the criteria in Table 5 can be met. (refer to the protocol section 5.2) Participants with a positive hepatitis C antibody test result or a positive hepatitis C virus (HCV) ribonucleic acid (RNA) test result at screening or 3 months before the first dose of study treatment will be excluded unless the participant can meet the following criteria: a. Negative HCV RNA test result b. Successful antiviral therapy (usually 8 weeks duration), followed by a negative HCV RNA test result after a washout period of 4 weeks. Participant has cirrhosis or current unstable liver or biliary disease per investigator assessment, defined by the presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, or persistent jaundice. Participant has alanine aminotransferase (ALT) >2.5× upper limit of normal (ULN). Participants has total bilirubin >1.5×ULN (isolated total bilirubin >1.5×ULN is acceptable if bilirubin is fractionated and direct bilirubin <35%) Participant has received systemic anti-myeloma therapy within 14 days or 5 half lives, whichever is shorter, before the first dose of study treatment. Participant has received plasmapheresis 7 days before the first dose of study treatment. Participant has received systemic therapy with high dose steroids (equivalent to 60 mg prednisone daily for 4 days) administered to treat MM or non MM disease within 14 days before the first dose of study treatment. Participant has received a prior allogenic stem cell transplant. Participant currently has corneal epithelial disease, except nonconfluent superficial punctate keratitis (SPK). Participant has used an investigational drug 14 days or 5 half lives, whichever is shorter, before the first dose of study treatment or has received therapy with a monoclonal antibody 30 days before the first dose of study treatment, whichever is shorter. Note: Use of monoclonal antibodies for serious conditions unrelated to multiple myeloma, such as COVID, may be permitted after consultation with the GSK Medical Director. Participant has evidence of active mucosal or internal bleeding. Participant has presence of an 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 fulfill adequate organ function inclusion criteria (Exclusion Criteria 24 in protocol). Participant has any serious and/or unstable pre-existing medical condition, psychiatric disorder, or other conditions (including laboratory abnormalities) that could interfere with the participant's safety, obtaining informed consent, or compliance with the study procedures. Participant has malignancies other than the disease under study are excluded, except for any other malignancy from which the participant has been disease-free for >2 years and, in the opinion of the principal investigator and GSK Medical Director, will not affect the evaluation of the effects of the study treatment on the currently targeted malignancy (MM). Participants with curatively treated non-melanoma skin cancer may be enrolled without a 2-year restriction. Participant has evidence of cardiovascular risk including any of the following criteria: a. Evidence of current clinically significant untreated arrhythmias, including clinically significant electrocardiogram (ECG) abnormalities including second degree (Mobitz Type II) or third degree atrioventricular block, or b. History of myocardial infarction, acute coronary syndromes (including unstable angina), coronary angioplasty, or stenting or bypass grafting 3 months before screening, or c. Class III or IV heart failure as defined by the New York Heart Association functional classification system (see Section 10.11). d. Uncontrolled hypertension. Participant is a pregnant or lactating female. Participant has an active infection requiring antibiotic, antiviral, or antifungal therapy.

Calendario

(Última actualización: 19/03/2026)

Autorización	Inicio de Ensayo	Inclusión Primer Paciente	Interrumpido	Reiniciado
22/11/2021	23/03/2022	27/07/2022	No aportado	No aportado

Fin de reclutamiento	Fin prematuro (España)	Fin prematuro (Global)	Fin del ensayo en España	Fin del ensayo global
15/09/2023	No aportado	No aportado	29/01/2025	10/02/2026

Promotor

Glaxosmithkline Research & Development Limited United Kingdom

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Contact Person

EU GSK Clinical Trials Call Center

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GSKClinicalSupportHD@gsk.com

Monetary support: N/A

Tipo de promotor: Comercial

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Centros

Cerrado (26/02/2024)

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València

VALENCIA

Hematología

Cerrado (25/08/2025)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Hematología

Cerrado (02/09/2024)

HOSPITAL GENERAL UNIVERSITARIO DE ALBACETE

Albacete

ALBACETE

Hematología

Cerrado (20/12/2023)

HOSPITAL UNIVERSITARI ARNAU DE VILANOVA DE LLEIDA.

Lleida

LÉRIDA

Hematología

Cerrado (21/11/2024)

HOSPITAL UNIVERSITARI MUTUA DE TERRASSA

Terrassa

BARCELONA

Hematología

Cerrado (28/05/2024)

HOSPITAL UNIVERSITARIO CENTRAL DE ASTURIAS

Oviedo

ASTURIAS

Hematología

Cerrado (06/11/2023)

HOSPITAL UNIVERSITARIO FUNDACION ALCORCON

Alcorcón

MADRID

Hematología

Cerrado (29/01/2025)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Hematología

Cerrado (25/09/2024)

Institut Catala D'oncologia

Girona

GERONA

Hematología

Medicamentos

PRD6002468
POWDER FOR SOLUTION FOR INJECTION
INTRAVENOUS USE

-

Principios Activos: N/A

Experimental

Sin resultados

Study to Investigate Alternative Dosing Regimens of Belantamab Mafodotin in Participants with Relapsed or Refractory Multiple Myeloma (DREAMM14)

State	**Type of participants**	**Age Ranges**
Finished CT	Not provided	Older than 64 , Adults (18-64 years)
Gender	**Phases**	**Expected Participants**
Both	Phase II	120
Results	**Low level of intervention**	**Rare disease**
No results	No	Yes
Geographic coverage	**Areas of the study**	**Advanced therapy**
Undetermined	safety, effectiveness, pharmacokinetics	NO

Information

Identifier
2023-508213-16-00 (CTIS)

Protocol Code
209628

Transitioned 2021-004151-16

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

Investigated Disease
Multiple Myeloma

Scientific Title
A Phase 2, Randomized, Parallel, Open-Label Study to Investigate the Safety, Efficacy, and Pharmacokinetics of Various Dosing Regimens of Single-Agent Belantamab Mafodotin (GSK2857916) in Participants with Relapsed or Refractory Multiple Myeloma (DREAMM-14)

Rationale

Not provided

Main Objective

To examine the corneal events associated with single-agent belantamab mafodotin using alternative dosing regimens in participants with RRMM in Arms B to D compared to Arm A

Primary Endpoints

Incidence rate of Grade 2 corneal events according to the KVA scale

Temporary moments of secondary assessment

Not provided

Secondary Objective

To further evaluate the corneal safety and tolerability of single-agent belantamab mafodotin in all arms
To evaluate the efficacy of single-agent belantamab mafodotin in all arms
To evaluate the overall safety and tolerability of single-agent belantamab mafodotin in all arms
To assess the pharmacokinetics of single-agent belantamab mafodotin in all arms
To assess anti-drug antibodies against single-agent belantamab mafodotin in all arms

Secondary Endpoints

Cumulative event rate of corneal events to Week 16 (KVA scale)
Incidence rate of corneal events by grade (KVA scale)
Exposure-adjusted incidence rate of corneal events by grade (KVA scale)
Median duration of dose delay
Percentage of participants requiring dose reductions, dose delays, and study treatment discontinuation due to corneal events (KVA scale)
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PFS, defined as the time from randomization until the earliest date of documented PD or death due to any cause
OS, defined as the time from randomization until the date of death due to any cause
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Incidence and titers of ADAs against belantamab mafodotin at each ADA time point

Temporary moments of secondary assessment

Not provided

Inclusion criteria

Participant must be 18 years of age inclusive at the time of signing the Informed Consent Form (ICF). Participant meets country-specific inclusion criteria described in Section 10.7, if applicable. Participant has Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2. "Participant has a histologically- or cytologically-confirmed diagnosis of myeloma as defined by IMWG criteria [Rajkumar, 2016], and a. Has undergone stem cell transplant or is considered transplant ineligible, and b. Has failed at least 3 prior lines of anti-MM therapies, including an anti?CD38 antibody (e.g., daratumumab) alone or in combination, and is refractory to an immunomodulatory agent (e.g., lenalidomide, pomalidomide)." "Participant has measurable disease with at least one of the following criteria: a. Serum M protein 0.5 g/dL (5 g/L), or b. Urine M protein 200 mg/24h, or c. Serum free light chain (FLC) assay: Involved FLC level 5 mg/dL (50 mg/L) and an abnormal serum FLC ratio (<0.26 or >1.65)." "Participants with a history of autologous stem cell transplant are eligible for study participation provided the following eligibility criteria are met: a. Transplant was >100 days before study enrollment, and b. Participant has no active infection(s), and c. Participant meets the remainder of the eligibility criteria outlined in protocol. " "All prior treatment-related toxicities (defined by the National Cancer Institute Common Terminology Criteria for Adverse Events [NCI-CTCAE] Version 5.0) must be Grade 1 at the time of enrollment, except for alopecia and Grade 2 peripheral neuropathy. " Life expectancy of at least 6 months, in the opinion of the investigator. "Contraceptive use by men or women should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. a. Female Participants A female participant is eligible to participate if she is not pregnant or breastfeeding and at least one of the following conditions apply: Is not a woman of childbearing potential (WOCBP) as defined in Section 10.9, or Is a WOCBP and using a contraceptive method that is highly effective (with a failure rate of <1% per year), preferably with low user dependency (as described in Section 10.9) during the treatment period and for at least 4 months after the last dose of study treatment and agrees not to donate eggs (ova, oocytes) for the purpose of reproduction during this period. The investigator should evaluate the effectiveness of the contraceptive method in relationship to the first dose of study treatment. A WOCBP must have a negative highly sensitive serum pregnancy test (as required by local regulations) within 72 hours before the first dose (Cycle 1 Day 1) of study treatment (see Section 8.2.7). Additional requirements for pregnancy testing during and after study treatment are provided in Section 8.2.7 and the Schedule of Activities (SoA) (Section 1.3). The 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. b. Male Participants Contraceptive use by men should be consistent with local regulations regarding the methods of contraception for those participating in clinical studies. Male participants are eligible to participate if they agree to the following conditions from the time of first dose of study treatment until 6 months after the last dose of study treatment to allow for clearance of any altered sperm: Refrain from donating sperm, plus either: o 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 o Must agree to use contraception/barrier as follows: Agree to use a male condom, even if they have undergone a successful vasectomy, with female partner use of an additional highly effective contraceptive method with a failure rate of <1% per year as described in Section 10.9, when having sexual intercourse with a WOCBP (including pregnant females). " Participant is capable of giving signed informed consent as described in Section 10.10 which includes compliance with the requirements and restrictions listed in the ICF and

in the protocol.

Exclusion criteria

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Calendar

(Last Update: 19/03/2026)

Authorization	Start of Trial	First patient inclusion	Halted	Restarted
22/11/2021	23/03/2022	27/07/2022	Not aported	Not aported

End of recruitment	Premature end (Spain)	Premature End (Global)	Trial end (Spain)	Trial end (Global)
15/09/2023	Not aported	Not aported	29/01/2025	10/02/2026

Sponsor

Glaxosmithkline Research & Development Limited United Kingdom

G S K House980 Great West Road

Contact Person

EU GSK Clinical Trials Call Center

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GSKClinicalSupportHD@gsk.com

Monetary support: N/A

Sponsor type: Commercial

Ceim

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Sites

Closed (26/02/2024)

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València

VALENCIA

Hematología

Closed (25/08/2025)

HOSPITAL DE LA SANTA CREU I SANT PAU

Barcelona

BARCELONA

Hematología

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HOSPITAL GENERAL UNIVERSITARIO DE ALBACETE

Albacete

ALBACETE

Hematología

Closed (20/12/2023)

HOSPITAL UNIVERSITARI ARNAU DE VILANOVA DE LLEIDA.

Lleida

LÉRIDA

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Hematología

Closed (29/01/2025)

HOSPITAL UNIVERSITARIO REINA SOFIA

Córdoba

CÓRDOBA

Hematología

Closed (25/09/2024)

Institut Catala D'oncologia

Girona

GERONA

Hematología

Medication

PRD6002468

POWDER FOR SOLUTION FOR INJECTION

INTRAVENOUS USE

-

Active Principles: N/A

Experimental

No results