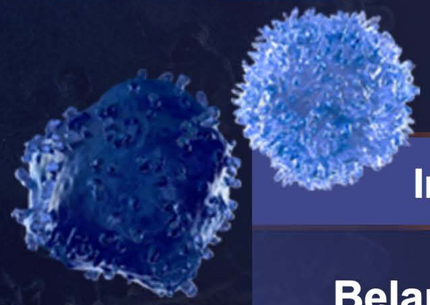


Immuno-Oncology

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

Belantamab mafodotin-blmf is an antibody-drug conjugate (ADC). The antibody component is an afucosylated immunoglobulin 1 (IgG1) directed against B-cell maturation antigen (BCMA), a protein expressed on normal B lymphocytes and multiple myeloma cells. The small molecule component is monomethyl auristatin F (MMAF), a microtubule inhibitor. Upon binding to BCMA, belantamab mafodotin-blmf is internalized followed by release of MMAF via proteolytic cleavage. The released MMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis.

Belantamab mafodotin-blmf had antitumor activity in multiple myeloma cells and mediated killing of tumor cells through MMAF-induced apoptosis, as well as by tumor cell lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

ASCT, autologous stem cell transplant; DVd, daratumumab + bortezomib + dexamethasone; NDMM, newly diagnosed multiple myeloma; Pd, pomalidomide + dexamethasone; Rd, lenalidomide + dexamethasone; RRMM, relapsed/refractory multiple myeloma; Vd, bortezomib + dexamethasone; VRd, bortezomib + lenalidomide + dexamethasone.

*In-license or other partnership with third party.

This information is intended for healthcare professionals only. This piece is designed to foster collaboration with the research community by highlighting study molecules in our GSK oncology pipeline. Compounds are investigational. Inclusion in this piece does not imply regulatory approval for these compounds or indications. For more information on GSK compounds currently in clinical trials, please go to www.clinicaltrials.gov.

References: BLENREP [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2020.

Explore our clinical trials

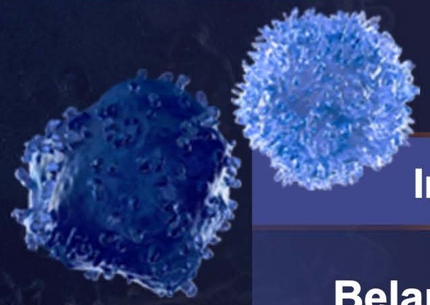
NCT04162210
DREAMM-3: monotherapy vs Pd in RRMM
PHASE III

NCT04246047
DREAMM-7: combination with Vd vs DVd in RRMM
PHASE III

NCT04091126
DREAMM-9: combination with VRd vs VRd alone in NDMM ineligible for ASCT
PHASE III

NCT03848845
DREAMM-4: combination with pembrolizumab in RRMM
PHASE I/II

NCT04126200
DREAMM-5: monotherapy and in
PHASE I/II



Immuno-Oncology

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

Belantamab mafodotin-blmf is an antibody-drug conjugate (ADC). The antibody component is an afucosylated immunoglobulin 1 (IgG1) directed against B-cell maturation antigen (BCMA), a protein expressed on normal B lymphocytes and multiple myeloma cells. The small molecule component is monomethyl auristatin F (MMAF), a microtubule inhibitor. Upon binding to BCMA, belantamab mafodotin-blmf is internalized followed by release of MMAF via proteolytic cleavage. The released MMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis.

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ASCT, autologous stem cell transplant; DVd, daratumumab + bortezomib + dexamethasone; NDMM, newly diagnosed multiple myeloma; Pd, pomalidomide + dexamethasone; Rd, lenalidomide + dexamethasone; RRMM, relapsed/refractory multiple myeloma; Vd, bortezomib + dexamethasone; VRd, bortezomib + lenalidomide + dexamethasone.

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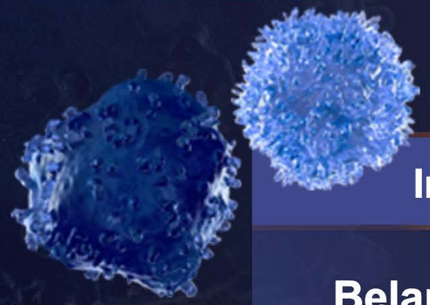
Explore our clinical trials

NCT04126200
DREAMM-5: monotherapy and in combination with GSK3174998 or GSK3359609 in RRMM
PHASE I/II

NCT03544281
DREAMM-6: combination with Rd or with Vd in RRMM
PHASE I/II

NCT04398745
DREAMM-12: monotherapy in patients with RRMM with normal or impaired renal function
PHASE I

NCT04398680
DREAMM-13: monotherapy in patients with RRMM with normal or impaired hepatic function
PHASE I



Immuno-Oncology

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

Belantamab mafodotin-blmf is an antibody-drug conjugate (ADC). The antibody component is an afucosylated immunoglobulin 1 (IgG1) directed against B-cell maturation antigen (BCMA), a protein expressed on normal B lymphocytes and multiple myeloma cells. The small molecule component is monomethyl auristatin F (MMAF), a microtubule inhibitor. Upon binding to BCMA, belantamab mafodotin-blmf is internalized followed by release of MMAF via proteolytic cleavage. The released MMAF intracellularly disrupts the microtubule network, leading to cell cycle arrest and apoptosis.

Belantamab mafodotin-blmf had antitumor activity in multiple myeloma cells and mediated killing of tumor cells through MMAF-induced apoptosis, as well as by tumor cell lysis through antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

ASCT, autologous stem cell transplant; DVd, daratumumab + bortezomib + dexamethasone; NDMM, newly diagnosed multiple myeloma; Pd, pomalidomide + dexamethasone; Rd, lenalidomide + dexamethasone; RRMM, relapsed/refractory multiple myeloma; Vd, bortezomib + dexamethasone; VRd, bortezomib + lenalidomide + dexamethasone.

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Explore our clinical trials

NCT04398745
DREAMM-12: monotherapy in patients with RRMM with normal or impaired renal function
PHASE I

NCT04398680
DREAMM-13: monotherapy in patients with RRMM with normal or impaired hepatic function
PHASE I

NCT03828292
Dose escalation in Japanese patients with RRMM
PHASE I

NCT04177823
Dose escalation in Chinese patients with RRMM
PHASE I

PHASE III (PIVOTAL)

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

DREAMM-3: belantamab mafodotin-blmf monotherapy compared with pomalidomide and dexamethasone in patients with relapsed/refractory multiple myeloma

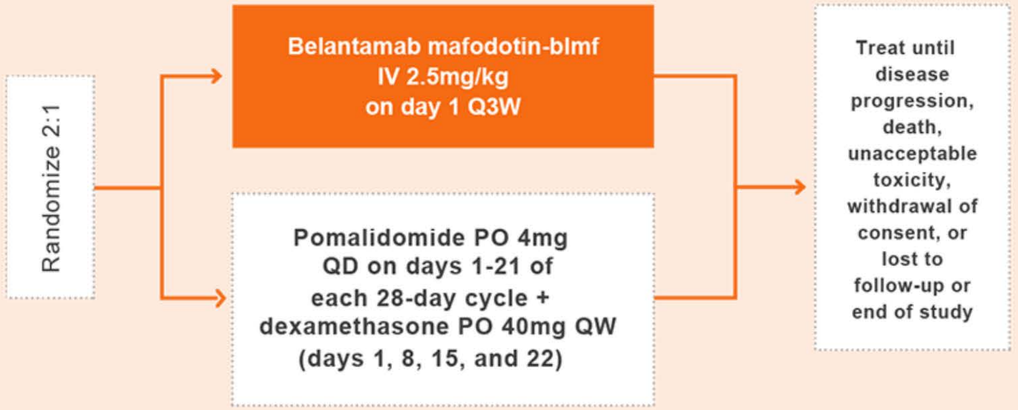
Key inclusion criteria

- Measurable disease
- Histologically or cytologically confirmed diagnosis of MM
- Prior ASCT or considered transplant ineligible
- ≥2 prior lines of MM therapy, including ≥2 consecutve cycles of both lenalidomide and a PI (separately or in combination
- ECOG PS 0-2; adequate organ function

Key exclusion criteria

- Prior anti-BCMA or pomalidomide therapy
- Prior anti-MM mAb treatment within 30 days, or other systemic anti-MM therapy or investigational drug within 14 days or 5 half-lives prior to study drug first dose
- Prior allogeneic stem cell transplant
- Symptomatic amyloidosis, active POEMS syndrome, or plasma cell leukemia
- Concurrent renal condition, mucosal or internal bleeding, unstable liver or biliary disease, or other malignancies
- Unable to tolerate thromboembolic prophylaxis

Phase III, randomized, open-label, multicenter study (N≈380)



Endpoints

Primary:
- PFS

Secondary:
- OS
- ORR
- CBR
- DoR
- TTR
- TTP
- Safety and tolerability
- Ocular findings
- PK
- ADA incidence and titers
- Health-related quality of life
- MRD rate

NCT04162210

Tumor type(s)

Relapsed/refractory multiple myeloma (RRMM)

Study population

Patients with RRMM who have been treated with at least 2 prior lines of therapy, including at least 2 consecutive cycles of both lenalidomide and a PI (separately or in combination)

Primary outcomes

PFS

ADA, anti-drug antibody; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; mAb, monoclonal antibody; MM, multiple myeloma; MRD, minimal residual disease; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; PO, by mouth; POEMS, polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes; Q3W, every 3 weeks; QD, once daily; QW, once weekly; TTP, time to progression; TTR, time to response.

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PHASE III (PIVOTAL)

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

DREAMM-7: belantamab mafodotin-blmf in combination with bortezomib and dexamethasone compared with daratumumab, bortezomib, and dexamethasone in patients with relapsed/refractory multiple myeloma

Key inclusion criteria

- Measurable disease with ≥1 of following:
  - Urine M-protein ≥200mg/day
  - Serum M-protein ≥0.5g/dL
  - FLC level ≥10mg/dL and sFLC ratio <0.26 or >1.65
- ECOG PS 0-2
- Previously treated with ≥1 prior line of MM therapy with documented disease progression during or after most recent therapy

Key exclusion criteria

- Intolerant of daratumumab or refractory to daratumumab or any other anti-CD38 therapy
- Intolerant or refractory to bortezomib
- Prior treatment with anti-BCMA therapy
- Ongoing Grade 2 or higher peripheral neuropathy or neuropathic pain
- Prior allogeneic stem cell transplant
- Corneal epithelial disease

Phase III, open-label, randomized, multicenter study (N=478)

Belantamab mafodotin-blmf + bortezomib + dexamethasone

Daratumumab + bortezomib + dexamethasone

Treat until disease progression, unacceptable toxicity, end of study, or informed consent withdrawal

Endpoints

Primary:
- PFS

Secondary:
- CRR
- ORR
- DoR
- TTR
- TTP
- OS
- PFS2
- MRD
- Safety and tolerability
- Ocular findings
- PK
- Health-related quality of life, PROs
- ADA

NCT04246047

Tumor type(s)
Relapsed/refractory multiple myeloma (RRMM)

Study population
Patients with RRMM who have been treated with at least 1 prior line of MM therapy

Primary outcomes
PFS

ADA, anti-drug antibody; BCMA, B-cell maturation antigen; CD, cluster of differentiation; CRR, complete response rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free light chain; MM, multiple myeloma; MRD, minimal residual disease; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PFS2, progression-free survival on subsequent line of therapy; PK, pharmacokinetics; PRO, patient-reported outcome; sFLC, serum free light chain; TTP, time to progression; TTR, time to response.

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PHASE III (PIVOTAL)

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

DREAMM-9: belantamab mafodotin-blmf in combination with bortezomib, lenalidomide, and dexamethasone in patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation

Key inclusion criteria

- Measurable disease with ≥1 of following:
  - Urine M-protein excretion ≥200mg/day
  - Serum M-protein concentration ≥0.5g/dL
  - FLC level ≥10mg/dL and sFLC ratio <0.26 or >1.65
- ECOG PS 0-2
- Not a candidate for high-dose chemotherapy with ASCT due to frailty and/or significant comorbid condition(s)

Key exclusion criteria

- Prior systemic therapy for MM or SMM
- Patient eligible for HDT with ASCT
- Active liver or biliary disease
- Current corneal epithelial disease except for mild punctate keratopathy

Phase III, open-label, randomized, sequential assignment, two-part study (N=810)

Dose-escalation and cohort-expansion phase

Belantamab mafodotin-blmf
(1.9mg/kg, 1.25mg/kg, 2.5mg/kg, 1.7mg/kg, or 3.4mg/kg)
+
SoC
bortezomib + lenalidomide + dexamethasone (VRd)

→ Dose selection →

Randomized phase III trial

Belantamab mafodotin-blmf
(selected dose)
+
SoC
bortezomib + lenalidomide + dexamethasone (VRd)

SoC
bortezomib + lenalidomide + dexamethasone (VRd)

Endpoints

Primary:
- DLT (Part 1)
- AEs and SAEs (Part 1)
- PFS (Part 2)
- MRD negativity (Part 2)

Secondary:
- RDI (Part 1)
- Cumulative dose (Part 1)
- PK (Part 1)
- ADAs (Part 1 and Part 2)
- AEs and SAEs (Part 2)
- ORR, CRR, OS, DoR, VGPR (Part 2)
- Sustained MRD negativity (Part 2)
- TTP (Part 2)
- Ocular events (Part 2)
- Health-related quality of life, PROs (Part 2)

NCT04091126

Tumor type(s)
Newly diagnosed multiple myeloma (NDMM)

Study population
Patients with NDMM who are ineligible for ASCT

Primary outcomes
Part 1: safety and tolerability
Part 2: negative MRD status, PFS

ADA, anti-drug antibody; AE, adverse event; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CRR, complete response rate; DLT, dose-limiting toxicity; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free light chain; HDT, high-dose therapy; MM, multiple myeloma; MRD, minimal residual disease; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; PRO, patient-reported outcome; RDI, relative dose intensity; SAE, serious adverse event; sFLC, serum free light chain; SMM, smoldering multiple myeloma; SoC, standard of care; TTP, time to progression; VGPR, very good partial response; VRd, bortezomib + lenalidomide + dexamethasone.

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PHASE I/II

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

DREAMM-4: study of belantamab mafodotin-blmf in combination with pembrolizumab in patients with relapsed/refractory multiple myeloma

Key inclusion criteria

- Measurable disease
- Histologically or cytologically confirmed diagnosis of MM
- ECOG PS 0-1
- Undergone stem cell transplant, if eligible
- Received ≥3 prior LoT (including PIs, immunomodulatory agents, and anti-CD38 mAb)

Key exclusion criteria

- Prior treatment with mAb ≤30 days
- Has received prior therapy with anti–PD-(L)1 or anti–PD-L2 agent, stimulatory or co-inhibitory T-cell receptor–directed agent and was discontinued from that treatment due to ≥grade 3 irAE
- Current corneal epithelial disease except mild punctate keratopathy
- Active liver or biliary disease
- Prior allogeneic tissue/solid organ transplant

Phase I/II non-randomized, single arm, open-label, two-part study (N=40)

Part 1: dose escalation
- Belantamab mafodotin-blmf 2.5–3.4mg/kg dose escalation Q3W + pembrolizumab 200mg Q3W to establish RP2D

Part 2: dose expansion
- Selected RP2D of belantamab-blmf mafodotin dose Q3W + pembrolizumab 200mg Q3W

Endpoints

Primary:
- Part 1:
  - DLTs
  - AEs, change in clinical signs and laboratory parameters
- Part 2:
  - ORR

Secondary:
- Part 1:
  - ORR
  - PK
  - ADA
- Part 2:
  - CBR, DoR, TTR, TTBR, PFS, TTP, OS
  - AEs and SAEs
  - Ocular events
  - PK
  - ADA

NCT03848845

Tumor type(s)

Relapsed/refractory multiple myeloma (RRMM)

Study population

Patients with RRMM who have been treated with at least 3 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody, alone or in combination

Primary outcomes

Part 1: safety and tolerability
Part 2: ORR

ADA, anti-drug antibody; AE, adverse event; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; DLT, dose-limiting toxicity; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; irAE, immune-related adverse event; LoT, lines of therapy; mAb, monoclonal antibody; MM, multiple myeloma; ORR, objective response rate; OS, overall survival; PD-(L)1, programmed cell death (ligand) 1; PD-L2, programmed cell death ligand 2; PFS, progression-free survival; PI, proteasome inhibitor; PK, pharmacokinetics; Q3W, every 3 weeks; RP2D, recommended phase 2 dose; SAE, serious adverse event; TTBR, time to best response; TTP, time to progression; TTR, time to response.

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PHASE I/II

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

DREAMM-5: belantamab mafodotin-blmf alone and in combination with GSK3174998 (OX40 agonist antibody) or GSK3359609 (ICOS agonist IgG4 antibody) in patients with relapsed/refractory multiple myeloma

Key inclusion criteria

- Measurable disease
- Histologically or cytologically confirmed diagnosed multiple myeloma
- ≥3 prior lines of anti-myeloma treatments
- ECOG PS 0-2
- Prior ASCT or considered transplant ineligible

Key exclusion criteria

- Current corneal epithelial disease except mild punctate keratopathy
- Prior therapy with other mAbs ≤30 days, prior radiotherapy ≤2 weeks, and an investigational agent ≤14 days or 5 half-lives of receiving the first dose of study drugs, whichever is shorter
- Active infection requiring antibiotic, antiviral, or antifungal treatment
- Prior allogeneic stem cell transplant

Phase I/II, randomized, open-label study (N=464)

Dose-exploration (DE) phase

Experimental (sub-study 1): starting and escalating doses of belantamab mafodotin-blmf + GSK3174998 (OX40 agonist)

Experimental (sub-study 2): starting and escalating doses of belantamab mafodotin-blmf + GSK3359609 (ICOS agonist)

Cohort-expansion (CE) phase

Active comparator (sub-study 1): belantamab mafodotin-blmf monotherapy

Experimental (sub-study 1): RP2D of belantamab mafodotin-blmf + GSK3174998 (OX40 agonist)

Active comparator (sub-study 2): belantamab mafodotin-blmf monotherapy

Experimental (sub-study 2): RP2D of belantamab mafodotin-blmf + GSK3359609 (ICOS agonist)

Endpoints

Primary:
- DE phase: DLT and safety and tolerability
- CE phase: ORR

Secondary:
- DE phase: ORR, ADAs, AESI, PK, corneal events
- CE phase: CBR, PFS, DoR, TTR, OS, PK, AEs and SAEs, AESI, ocular events, ADAs

NCT04126200

Tumor type(s)

Relapsed/refractory multiple myeloma (RRMM)

Study population

Patients with RRMM who have been treated with at least 3 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody

Primary outcomes

Dose-escalation phase: safety and tolerability
Cohort-expansion phase: ORR

ADA, anti-drug antibody; AE, adverse event; AESI, adverse events of special interest; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; DLT, dose-limiting toxicity; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ICOS, inducible T-cell costimulator; IgG4, immunoglobulin G4; mAb, monoclonal antibody; ORR, objective response rate; OS, overall survival; OX40, tumor necrosis factor receptor superfamily, member 4; PFS, progression-free survival; PK, pharmacokinetics; RP2D, recommended phase 2 dose; SAE, serious adverse event; TTR, time to response.

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PHASE I/II

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

DREAMM-6: study of belantamab mafodotin-blmf in combination with lenalidomide and dexamethasone or with bortezomib and dexamethasone in patients with relapsed/refractory multiple myeloma

Key inclusion criteria

- Prior ASCT or considered transplant ineligible
- Progressed on ≥1 prior line of MM therapy
- Measurable disease with ≥1 of following:
  - Urine M-protein excretion ≥200mg/day
  - Serum M-protein concentration ≥0.5g/dL
  - FLC level ≥10mg/dL and sFLC ratio <0.26 or >1.65
- ECOG PS 0-1 for arm A; ECOG PS 0-2 for arm B

Key exclusion criteria

- Prior treatment with a mAb ≤30 days
- Prior allogeneic stem cell transplant
- Active liver or biliary disease
- Current corneal disease except for mild punctate keratopathy

Phase I/II open-label, non-randomized, two-arm, two-part study (N=123)

Part 1: dose escalation

- Arm A: belantamab mafodotin-blmf 1.9mg/kg + lenalidomide/ dexamethasone (28 day cycle); dose escalation from 1.9mg/kg to 2.5mg/kg and further to 3.4mg/kg, if tolerated
- Arm B: belantamab mafodotin-blmf 2.5mg/kg + bortezomib/ dexamethasone (21 day cycle); dose escalation to 3.4mg/kg, if tolerated (if not tolerated, lower dose to 1.9mg/kg)

Part 2: dose expansion

- Arms A and B: further evaluate the safety and preliminary clinical activity of up to 3 dose levels and up to 2 dosing schedules (on day 1 or split dose on days 1 and 8 every 3 or 4 weeks; 2 dose levels in Arm B)

Endpoints

Primary:
- Safety and tolerability
- ORR

Secondary:
- PK
- ADAs
- AESI (including corneal events)
- Health-related quality of life

NCT03544281

Tumor type(s)
Relapsed/refractory multiple myeloma (RRMM)

Study population
Patients with RRMM

Primary outcomes
Part 1: safety and tolerability
Part 2: safety and tolerability, ORR

ADA, anti-drug antibody; AESI, adverse event of special interest; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; FLC, free light chain; mAb, monoclonal antibody; MM, multiple myeloma; ORR, objective response rate; PK, pharmacokinetics; sFLC, serum free light chain.

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Back

PHASE I

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

DREAMM-12: a pharmacokinetics and safety study of belantamab mafodotin-blmf in patients with relapsed/refractory multiple myeloma with normal or varying degrees of impaired renal function

Key inclusion criteria

- Histologically or cytologically confirmed diagnosis of MM
- Undergone ASCT if >100 days prior to study and no active infections
- Failed ≥2 prior lines of antimyeloma treatments
- Measurable disease
- ECOG PS 0-2
- Group 1: EGFR ≥90 mL/min/1.73m^2
- Group 2: EGFR 15-29mL/min/1.73m^2
- Group 3 (not on dialysis): EGFR <15 mL/min/1.73m^2
- Group 4 (on dialysis): EGFR <15 mL/min/1.73m^2

Key exclusion criteria

- Active plasma cell leukemia
- Symptomatic amyloidosis, active POEMS syndrome
- Prior allogeneic stem cell transplant
- Prior treatment with a mAb within 30 days
- Systemic active infection requiring treatment
- Any major surgery within 4 weeks

Phase I, open-label, parallel assignment study (N=40)

Experimental part 1: patients with normal renal function
Belantamab mafodotin-blmf 2.5mg/kg IV on day 1 of every 21-day cycle

Experimental part 1: patients with severe renal impairment
Belantamab mafodotin-blmf 2.5mg/kg IV on day 1 of every 21-day cycle

Experimental part 2: patients with ESRD (not on dialysis)
Belantamab mafodotin-blmf 2.5mg/kg or 1.9mg/kg (or other lower adjusted dose) IV on day 1 of every 21-day cycle

Experimental part 2: patients with ESRD (on hemodialysis)
Belantamab mafodotin-blmf 2.5mg/kg or 1.9mg/kg (or other lower adjusted dose) IV on day 1 of every 21-day cycle

Treat until disease progression, unacceptable toxicity, death, withdrawal of consent, or end of study

Endpoints

Primary:
– PK

Secondary:
– AEs and SAEs
– Vital signs

NCT04398745

Tumor type(s)

Relapsed/refractory multiple myeloma (RRMM)

Study population

Patients with RRMM who have normal or varying degrees of impaired renal function

Primary outcomes

PK

AE, adverse event; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; IV, intravenous; mAb, monoclonal antibody; MM, multiple myeloma; PK, pharmacokinetics; POEMS, polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes; SAE, serious adverse event.

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Back

PHASE I

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

DREAMM-13: a pharmacokinetics and safety study of belantamab mafodotin-blmf in patients with relapsed/refractory multiple myeloma with normal or varying degrees of impaired hepatic function

Key inclusion criteria

- Histologically or cytologically confirmed diagnosis of MM
- Undergone ASCT if >100 days prior to study and no active infections
- Failed ≥2 prior lines of antimyeloma treatments
- Measurable disease
- ECOG PS 0-2

Key exclusion criteria

- Active plasma cell leukemia
- Symptomatic amyloidosis, active POEMS syndrome
- Treatment with an investigational drug within 14 days
- Systemic active infection requiring treatment
- Prior allogeneic stem cell transplant
- Any major surgery within 4 weeks

Phase I, open-label, parallel assignment study (N=40)

Experimental part 1: patients with normal hepatic function
Belantamab mafodotin-blmf 2.5mg/kg IV on day 1 of every 21-day cycle

Experimental part 1: patients with moderate hepatic impairment
Belantamab mafodotin-blmf 2.5mg/kg IV on day 1 of every 21-day cycle

Experimental part 2: patients with severe hepatic impairment
Belantamab mafodotin-blmf 2.5mg/kg or 1.9mg/kg (or other lower adjusted dose) IV on day 1 of every 21-day cycle

Treat until disease progression, unacceptable toxicity, death, withdrawal of consent, or end of study

Endpoints

Primary:
- PK

Secondary:
- AEs and SAEs
- Vital signs

NCT04398680

Tumor type(s)

Relapsed/refractory multiple myeloma (RRMM)

Study population

Patients with RRMM who have normal or varying degrees of impaired hepatic function

Primary outcomes

PK

AE, adverse event; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; PK, pharmacokinetics; POEMS, polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes; SAE, serious adverse event.

*In-license or other partnership with third party.

Back

PHASE I

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

Dose-escalation study of belantamab mafodotin-blmf in Japanese patients with relapsed/refractory multiple myeloma

Key inclusion criteria

- Measurable disease
- Histologically or cytologically confirmed diagnosis of MM
- Prior ASCT >100 days prior to enrollment or considered transplant ineligible
- Pretreated with ≥2 regimens of ≥3 classes of anti-MM therapies
- ECOG PS of 0-2; adequate organ system function

Key exclusion criteria

- Systemic antitumor therapy ≤14 days or plasmapheresis ≤7 days prior to the first dose
- Prior allogeneic stem cell transplant
- Current unstable liver or biliary disease
- Symptomatic amyloidosis, active polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes (POEMS) syndrome, or active plasma cell leukemia
- Current corneal epithelial disease except mild punctate keratopathy

Phase I, open-label, single-group assignment study (N=14)

Experimental: Japanese patients with RRMM
- Escalating doses of belantamab mafodotin-blmf 2.5mg/kg or 3.4mg/kg IV Q3W

Endpoints

Primary:
- DLTs
- AEs and SAEs
- Ocular events
- ECOG scores

Secondary:
- PK
- ADAs
- ORR
- CBR

NCT03828292

Tumor type(s)
Relapsed/refractory multiple myeloma (RRMM)

Study population
Japanese patients with RRMM

Primary outcomes
Safety and tolerability

ADA, anti-drug antibody; AE, adverse event; ASCT, autologous stem cell transplant; BCMA, B-cell maturation antigen; CBR, clinical benefit rate; DLT, dose-limiting toxicity; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; MM, multiple myeloma; ORR, objective response rate; PK, pharmacokinetics; Q3W, every 3 weeks; SAE, serious adverse event.

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PHASE I

Belantamab mafodotin-blmf | Anti-BCMA antibody-drug conjugate*

Dose-escalation study of belantamab mafodotin-blmf in Chinese patients with relapsed/refractory multiple myeloma

Key inclusion criteria

- Measurable disease with ≥1 of following:
  - Urine M-protein ≥200mg/day
  - Serum M-protein ≥0.5g/dL
  - FLC level ≥10mg/dL and sFLC ratio <0.26 or >1.65
- ECOG PS 0-2
- Have undergone stem cell transplant or transplant considered not feasible
- Failed ≥2 prior LoT, containing alkylating agent, immunomodulatory agent, and PI; failed response to CD38 antibody allowed

Key exclusion criteria

- Systemic antitumor therapy ≤14 days, or plasmapheresis ≤7 days prior to the first dose
- Prior allogeneic stem cell transplant
- Current unstable liver or biliary disease
- Symptomatic amyloidosis, active polyneuropathy, organomegaly, endocrinopathy, myeloma protein, and skin changes (POEMS) syndrome, or active plasma cell leukemia
- Current corneal epithelial disease except mild punctate keratopathy

Phase I, open-label, dose-escalation study (N=12)

- Belantamab mafodotin-blmf 3.4mg/kg Q3W
- Belantamab mafodotin-blmf 2.5mg/kg Q3W

→ Treat until disease progression, unacceptable toxicity, end of study, or informed consent withdrawal

Endpoints

Primary:
- AEs and SAEs
- DLTs

Secondary:
- Safety and tolerability
- PK
- ADAs
- ORR
- Ocular events

NCT04177823

Tumor type(s)
Relapsed/refractory multiple myeloma (RRMM)

Study population
Chinese patients with RRMM

Primary outcomes
Safety and tolerability

ADA, anti-drug antibody; AE, adverse event; BCMA, B-cell maturation antigen; CD, cluster of differentiation; DLT, dose-limiting toxicity; ECOG PS, Eastern cooperative oncology group performance status; FLC, free light chain; LoT, lines of therapy; ORR, objective response rate; PI, proteasome inhibitor; PK, pharmacokinetics; Q3W, every 3 weeks; SAE, serious adverse event; sFLC, serum free light chain.

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