Advances in the role of BCMA-targeting agents in multiple myeloma: An update from the European Hematology Association 2021 Virtual Congress

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Overview

BCMA-targeting therapies in multiple myeloma:

- PART 1: CAR T-cell therapies
- PART 2: antibody–drug conjugates
- PART 3: bispecific antibodies

BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor.

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BCMA-targeting CAR T-cell therapies in relapsed/refractory multiple myeloma

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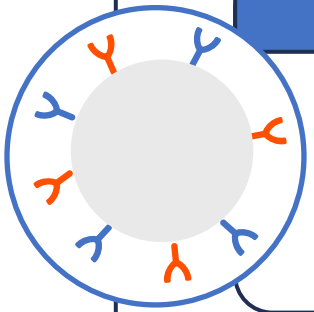
BCMA-targeting CAR T-cell therapies

Idecabtagene vicleucel[1,2]

Approved in USA and Canada
Phase II KarMMa trial
NCT03361748

Approved for use in patients with RRMM, who have received ≥4 prior regimens (≥3 in Canada), including PI, immunomodulatory agent and anti-CD38 mAb (Canada: and refractory to last regimen)



In development[3,4]

Ciltacabtagene autoleucel
Orvacabtagene autoleucel
P-BCMA-101
CT053

BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CD, cluster of differentiation; mAb, monoclonal antibodies; PI, proteasome inhibitor; RRMM, relapsed/refractory multiple myeloma.

1. FDA. Idecabtagene vicleucel Prescribing Information. 2021. Available at: www.fda.gov/media/147055/download (accessed 16 June 2021);
2. Bristol Myers Squibb. 2021. Available at: www.bms.com/ca/en/media/press-release-listing/2021-05-31-press-release.html (accessed 16 June 2021);
3. Sanchez L, et al. *Ther Adv Hematol*. 2021;12:1–16; 4.Yu B, et al. *J Hematol Oncol*. 2020;13:1–24.

Ide-cel in RRMM: Updated KarMMa results

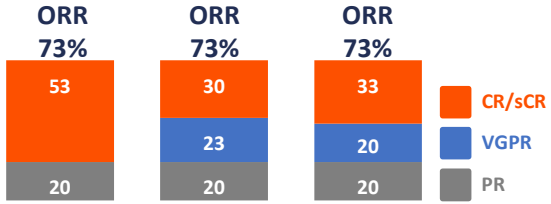
Oriol A, et al.

Evaluate longer-term efficacy and safety of ide-cel in patients with RRMM who have received ≥3 prior regimens, including an immunomodulatory agent, PI and anti-CD38 antibody

140 patients enrolled
128 patients treated with ide-cel

Median follow-up of 24.8 months at data cut-off (21 December 2020)

Efficacy endpoints



mPFS
8.6 mo

mDOR
10.9 mo

Median OS was:

- 24.8 months among all patients
- 22.0 months and 25.2 months in patients who received 3 and ≥4 prior lines of therapy, respectively
- >20 months in those aged ≥65 years, with extramedullary disease and triple refractory

- Safety profile of ide-cel was consistent with previous reports across all groups
- Similar rates of infections and secondary primary malignancy, and no unexpected gene therapy-related toxicities were observed

- **Updated results from the KarMMa trial continue to demonstrate deep, durable responses with ide-cel in heavily pretreated patients with RRMM**
- **The favourable clinical benefit–risk profile regardless of the number of prior lines of therapy supports its role as a treatment option for heavily pretreated patients**

CAR, chimeric antigen receptor; CD38, cluster of differentiation 38; CR, complete response; ide-cel; idecabtagene vicleucel; mDOR, median duration of response; mo, months; mPFS, median progression-free survival; ORR, overall response rate; OS, overall survival; PI, proteasome inhibitor; PR, partial response; RRMM, relapsed/refractory multiple myeloma; sCR, stringent complete response; VGPR, very good partial response.

Oriol A, et al. Poster EP1009. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03361748.

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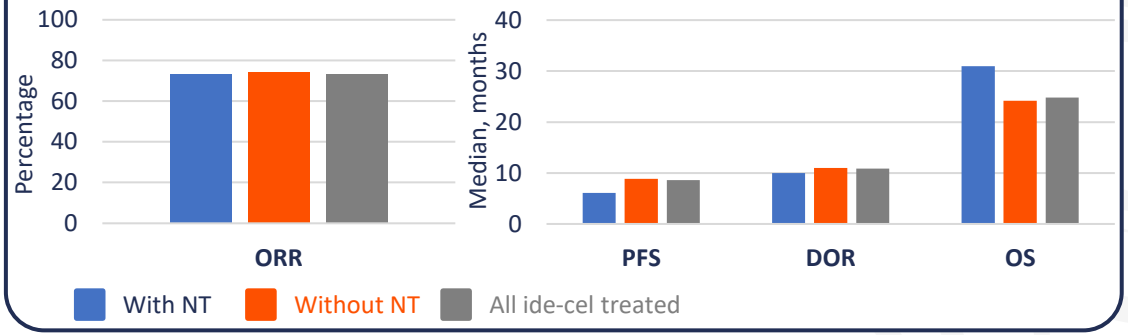
Characteristics of neurotoxicity associated with ide-cel in KarMMa

Manier S, et al.

To characterize neurotoxicity events in patients treated with ide-cel in the KarMMa trial and their association with patient and disease characteristics, patient management and outcomes

- 128 treated patients
- Neurotoxicity reported in **18%** (78% grade 1/2; no grade 4/5)
- Median time to first onset: **2 days**
- Median duration: **2.5–8.5 days**
- All neurotoxicity events occurred in the proximity of CRS events

Impact of neurotoxicity on outcomes



- **Neurotoxicity was mostly grade 1/2, occurred early and was generally short in duration**
- **All neurotoxicity was proximal to CRS**
- **Patients experiencing neurotoxicity achieved frequent and deep responses**

CRS, cytokine release syndrome; ide-cel, idecabtagene vicleucel; DOR, duration of response; OS, overall survival; PFS, progression-free survival; NT, neurotoxicity; ORR, overall response rate.

Manier S, et al. Poster EP984. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03361748.

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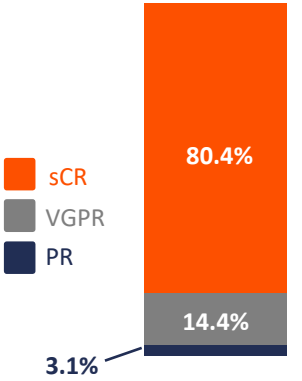
Cilta-cel in RRMM: Updated CARTITUDE-1 results

Usmani SZ, et al.

To present longer follow-up data (median: 18 months) from CARTITUDE-1, a trial of cilta-cel in patients with RRMM previously treated with an immunomodulatory agent, PI and anti-CD38 antibody

N=97
ORR: 97.9%



Response rates were comparable (range 95–100%) across different subgroups, e.g.:

- Number of lines of prior therapy
- Refractoriness
- Extramedullary plasmacytomas
- Cytogenetic risk

MRD negativity at 10^{-5}

91.8% of MRD-evaluable patients
57.7% of all patients

18-month PFS: **66.0%**

18-month OS: **80.9%**

- No new safety signals at 18 months' follow-up
- New patient management strategies have been implemented in the CARTITUDE programme to prevent and reduce the incidence of neurotoxicity

→ Enhanced bridging therapy to reduce tumour burden

→ Early and aggressive treatment of CRS and ICANS

→ Handwriting assessments and extended monitoring

At a longer median follow-up of 18 months, a single infusion of cilta-cel yielded early, deep and durable responses in heavily pretreated patients with RRMM, with no new safety signals

CD38, cluster of differentiation 38; cilta-cel, ciltacabtagene autoleucel; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; MRD, minimal residual disease; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; PR, partial response; RRMM, relapsed/refractory multiple myeloma; sCR, stringent complete response; VGPR, very good partial response.

Usmani SZ, et al. EP964. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03548207.

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Cilta-cel in progressive MM: Initial results from CARTITUDE-2

Agha M, et al.

To present initial data from Cohort A of the CARTITUDE-2 trial exploring cilta-cel in patients with progressive MM after 1–3 prior lines of therapy

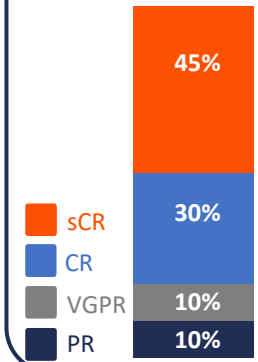
N=20

- Prior therapy includes a PI and an immunomodulatory agent
- Lenalidomide refractory
- No prior exposure to BCMA-targeting agents

All patient with MRD-evaluable samples at the 10^{-5} threshold (n=4) were MRD-negative at data cut-off

Efficacy

ORR: 95%



- Median time to first response: **1 month**
- Responses deepened over time

Safety

- Incidence of CRS was **85%**
- CRS mostly **grade 2** (55%)
- Median time to onset of CRS: **7 days**
- No cases of movement or neurocognitive TEAEs

A single cilta-cel infusion led to early and deep responses with a manageable safety profile in patients with MM who had received 1–3 prior lines of therapy and were lenalidomide refractory

BCMA, B-cell maturation antigen; cilta-cel, ciltacabtagene autoleucel; CR, complete response; CRS, cytokine release syndrome; MM, multiple myeloma; MRD, minimum residual disease; ORR, overall response rate; PI, proteasome inhibitor; PR, partial response, sCR, stringent complete response; TEAE, treatment-emergent adverse event; VGPR, very good partial response.

Agha M, et al. S190. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT04133636.

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Neurologic AEs in patients treated with cilta-cel in CARTITUDE-2

Einsele H, et al.

To describe patient management strategies for neurologic AEs in CARTITUDE-2

Patient management strategies for neurologic AEs

More effective bridging therapy to reduce tumour burden

Early and aggressive treatment of CRS and ICANS

Handwriting assessments and extended monitoring

As of 4 January 2021, 20 patients in Cohort A had received cilta-cel (median follow-up: 5.8 months)

Neurotoxicities occurred in 4 patients (20%)

Neurotoxicities	Grade 1/2	Grade ≥3
ICANS, n (%)	3 (15)	0
Other neurotoxicities, n (%)	1 (5)	0

- **Median time to onset of symptoms: 8 days**
- **Median duration: 2 days**

None of the patients from Cohort A in CARTITUDE-2 experienced other neurotoxicities characterized by a cluster of movement and neurocognitive TEAEs, as seen in CARTITUDE-1

Successful new patient management strategies have been implemented in the CARTITUDE programme to prevent and reduce the incidence of neurotoxicity

AE, adverse event; cilta-cel, ciltacabtagene autoleucel; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; TEAEs, treatment-emergent adverse events.

Einsele H, et al. EP1003. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT04133636.

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Anakinra prophylaxis with orva-cel treatment in the EVOLVE trial

Costa LJ, et al.

Explore the role of prophylactic anakinra on reducing the incidence of ≥ grade 2 CRS after orva-cel treatment at a dose level of 600x10^6 CAR+ T-cells

CRS is mediated in part by IL-1
Anakinra is an IL-1 receptor antagonist

≥3 prior therapies:
- **ASCT**
- **Immunomodulatory drug, PI**
- **Anti-CD38 antibody**

Refractory to last line of therapy

Anakinra prophylaxis
n=14
Median follow-up:
5.9 months

No anakinra prophylaxis
n=19
Median follow-up:
11.8 months

Potentially important differences between the groups were noted

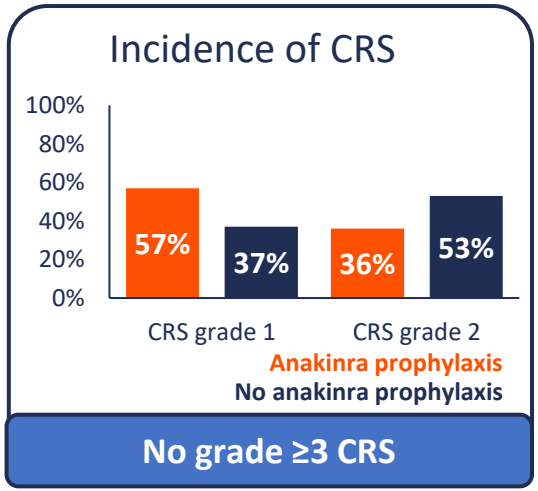
	Anakinra	No anakinra
Measurable disease: Serum M-protein only, n (%)	8 (57)	7 (37)
Measurable disease: Serum FLC only, n (%)	1 (7)	5 (26)
Extramedullary plasmacytomas, n (%)	4 (29)	2 (11)
LDH > ULN, n (%)	3 (21)	0

ASCT, autologous stem-cell transplantation; CAR, chimeric antigen receptor; CD38, cluster of differentiation 38; CRS, cytokine release syndrome; FLC, free light chains; IL-1, interleukin-1; LDH, lactate dehydrogenase; orva-cel, orvacabtagene vicleucel; PI, proteasome inhibitor; ULN, upper limit of normal.

Costa L, et al. EP747. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03430011.

Anakinra prophylaxis with orva-cel treatment in the EVOLVE trial

Costa LJ, et al.



No grade ≥3 CRS

Incidence of NEs was numerically higher in patients receiving anakinra prophylaxis

Incidence of MAS/HLH and infections were similar in both groups

Tocilizumab and steroid use was numerically lower with anakinra prophylaxis

- Reduced levels of GM-CSF and TNF-α in the anakinra prophylaxis group
- Anakinra prophylaxis did not negatively impact orva-cel pharmacokinetics or persistence
- ORR was 100% in both arms, with a CRR of 21% in the anakinra prophylaxis group and 63% in the no prophylaxis group

- **The incidence of grade ≥2 CRS was lower in patients receiving anakinra prophylaxis**
- **Anakinra has no negative impact on orva-cel pharmacokinetics or persistence, but there was a numerically lower CRR in the prophylaxis group (may be accounted for by differences in patient/disease characteristics)**

CRR, complete response rate; CRS, cytokine release syndrome; GM-CSF, granulocyte-macrophage colony-stimulating factor; HLH, haemophagocytic lymphohistiocytosis; MAS, macrophage activation syndrome; NE, neurological events; ORR, overall response rate; orva-cel, orvacabtagene vicleucel; TNF-α, tumour necrosis factor α.

Costa L, et al. EP747. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03430011.

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Summary

- Updated results from the KarMMa trial continue to demonstrate deep, durable responses with a single infusion of ide-cel in heavily pretreated, triple-class exposed patients with RRMM
- A single cilta-cel infusion led to early and deep responses with manageable safety in patients with heavily pretreated MM (CARTITUDE-1) and after 1–3 prior lines of therapy (CARTITUDE-2)
- Neurologic toxicity is common with CAR T-cell therapy, but was generally manageable in patients with MM following treatment with both ide-cel and cilta-cel
- The incidence of grade ≥2 CRS was lower in patients treated with orva-cel when they received anakinra prophylaxis

CAR, chimeric antigen receptor; cilta-cel, ciltacabtagene autoleucel; CRS, cytokine release syndrome; ide-cel, idecabtagene vicleucel; MM, multiple myeloma; orva-cel, orvacabtagene vicleucel; RRMM, relapsed/refractory multiple myeloma.

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BCMA-targeting antibody–drug conjugates in relapsed/refractory multiple myeloma

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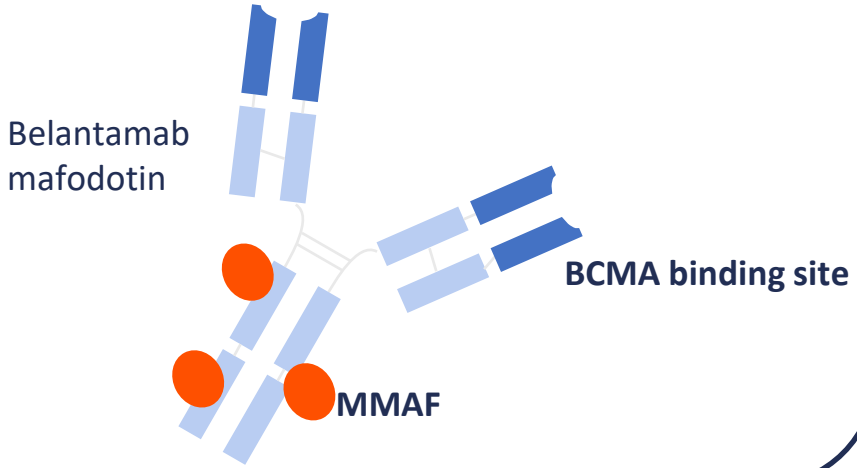
Antibody–drug conjugates in RRMM

Monoclonal antibodies attached to biologically active drugs by chemical linkers[1]



FDA and EMA approved

- Belantamab mafodotin[2,3]

In clinical development:[1]

- CC-99712

BCMA, B-cell maturation antigen; EMA, European Medicines Agency; FDA, US Food and Drug Administration; MMAF, microtubule-disrupting agent monomethyl auristatin-F; RRMM, relapsed/refractory multiple myeloma.

1. Martino M, Paviglianiti A. *Expert Opin Biol Ther*. 2021:doi: 10.1080/14712598.2021.1872540 [Online ahead of print];
2. US FDA. Belantamab mafodotin Prescribing Information. Available at: www.accessdata.fda.gov/drugsatfda_docs/label/2020/761158s000lbl.pdf (accessed 29 April 2021);
3. EMA. Belantamab mafodotin. Available at: www.ema.europa.eu/en/documents/overview/blenrep-epar-medicine-overview_en.pdf (accessed 30 April 2021).

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Characterizing ocular AEs with belantamab mafodotin ≥12 months: Post hoc analysis of DREAMM-2

Lonial S, et al.

To characterize the safety profile of belantamab mafodotin in patients treated for ≥12 months, in a post hoc analysis of the 2.5 mg/kg Q3W arm of the phase II DREAMM-2 study at 13-month follow-up

2.5 mg/kg cohort n=97

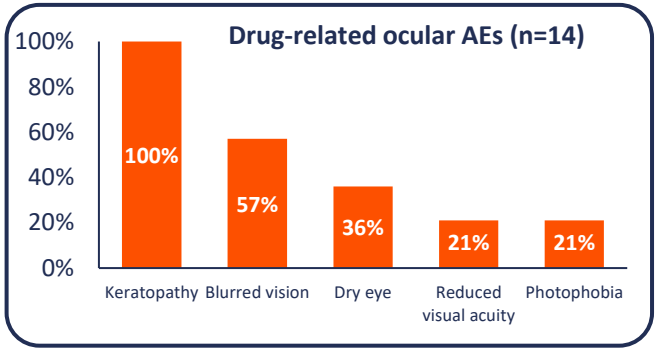
≥12 months' treatment n=14

Eye exams were conducted at baseline and prior to each dose, including a corneal exam and in assessment of BCVA change

All patients required ≥2 dose delays:

- **Mean dose delays: 3.6**
- **Dose delays >63 days: 73%**

Long delays did not appear to negatively impact clinical response



- Dose reduction occurred as a result of keratopathy (71%) and blurred vision (7%)
- Dose delays most commonly occurred as a result of keratopathy (93%) and blurred vision (21%)

- **Patients and clinicians should expect dose delays related to ocular events with belantamab mafodotin**
- **Dose modification was effective in managing ocular symptoms and decreasing findings at eye examinations, allowing patients to stay on therapy**
- **Safety with belantamab mafodotin will be characterized further**

AE, adverse event; BCVA, best corrected visual acuity; Q3W, every 3 weeks.

Lonial S, et al. EP1026. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03525678.

Relationship between corneal exam findings, BCVA and ocular symptoms in patients with RRMM in DREAMM-2

Terpos E, et al.

Post hoc investigation of relationships between corneal exam findings, BCVA changes and patient-reported ocular symptoms (OSDI) to explore dosing guided by BCVA changes rather than corneal exams

Belantamab mafodotin 2.5 mg/kg, n=97

Corneal examinations for keratopathy and BCVA performed by ophthalmologists at baseline and prior to each dose of belantamab mafodotin

Ocular symptoms and OSDI questionnaire evaluations reported by patients

Concordance of surrogate measures with keratopathy (773 evaluations)

Grade 3–4 keratopathy and grade 0–1 BCVA change	**12.5%**
Grade 3–4 keratopathy and grade 0–1 BCVA change + no ocular symptoms	**7.5%**
Grade 3–4 keratopathy and OSDI no item 'most of the time'	**5.0%**

- Grade 3–4 keratopathy rarely observed with grade 0–1 BCVA change and no ocular symptoms
- Grade 3–4 keratopathy rarely observed when symptoms reported less than most of the time by OSDI

BCVA changes, ocular symptoms and the OSDI questionnaire should be further investigated as surrogates for corneal alterations to reduce the burden on patients and healthcare professionals

BCVA, best corrected visual acuity; OSDI, Ocular Surface Disease Index; RRMM, relapsed/refractory multiple myeloma.

Terpos E, et al. EP1001. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03525678.

Real-world data for belantamab mafodotin in RRMM

Shragai T, et al.

To assess the safety and efficacy of belantamab mafodotin for RRMM in an expanded-access compassionate care programme in a multisite real-world setting

n=67 with RRMM

9 Israeli centres

Apr 2019 – Feb 2021

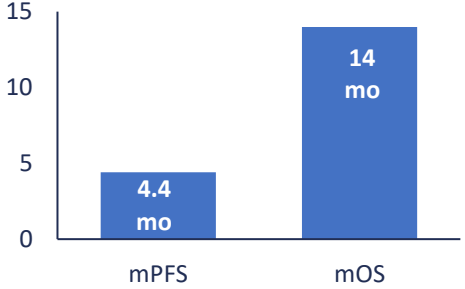
Received ≥2 doses of belantamab mafodotin

47% high-risk cytogenetics including t(4;14), t(14;16), t(14;20), del17p and +1q

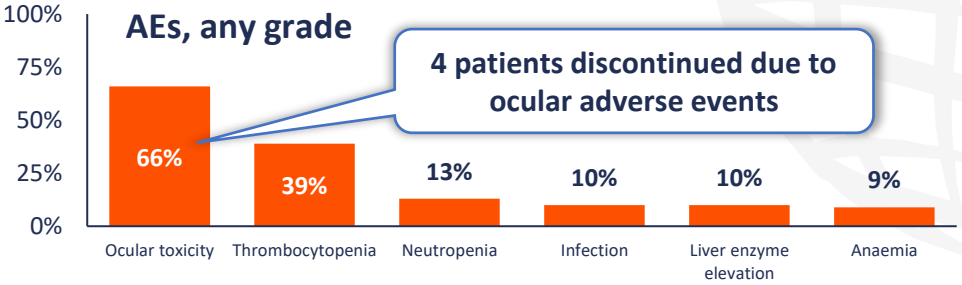
Median 4 cycles

ORR 54%: 6% CR, 23% VGPR, 25% PR

Primary endpoint: **PFS**
Median follow-up: 16.1 mo



Belantamab mafodotin showed significant anti-myeloma activity in heavily pretreated patients with RRMM in a real-world setting with a manageable safety profile



4 patients discontinued due to ocular adverse events

AE, adverse event; CR, complete response; mo, months; mOS, median overall survival; mPFS, median progression-free survival; ORR, overall response rate; PR, partial response; RRMM, relapsed/refractory multiple myeloma; VGPR, very good partial response.

Shragai T, et al. EP1023. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03525678.

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DREAMM-5 platform trial: Belantamab mafodotin combinations

Richardson P, et al.

The primary objectives of this multi-arm study are to identify the RP2D (DE phase) and ORR (CE phase) of belantamab mafodotin combinations

Phase I DE phase: RP2D

N≤10 per sub-study

Belantamab mafodotin +

1: GSK3174998 (OX40 agonist antibody)
2: Feladilimab (ICOS agonist)
3: Nirogacestat (gamma-secretase inhibitor)
4: Dostarlimab, PD-1 antagonist antibody)
5: Isatuximab (anti-CD38 antibody)

Analysis of sub-study safety, PK, biomarker and efficacy data to proceed to CE

Phase II CE phase: ORR, safety and tolerability

N≥35 per cohort

Selected sub-studies with shared belantamab mafodotin monotherapy control arm

Key inclusion criteria

- Age ≥18 years
- Histologically/cytologically confirmed MM (IMWG criteria)
- Measurable disease (serum and/or urine M-protein and/or serum free light chain levels)
- ECOG PS 0–2
- ≥3 prior lines of therapy including immunomodulatory agent, PI and an anti-CD38 mAb
- Acceptable haematologic function

DE phase consists of multiple dosing cohorts with belantamab mafodotin combinations to determine whether the combination should move forward at the RP2D to the CE phase

CD38, cluster of differentiation 38; CE, cohort-expansion; DE, dose-exploration; ECOG PS, Eastern Cooperative Oncology Group performance status; ICOS, inducible T-cell costimulatory; IMWG, International Myeloma Working Group; mAb, monoclonal antibody; MM, multiple myeloma; ORR, objective response rate; PD-1, programmed death-1; PI, proteasome inhibitor; PK, pharmacokinetics; RP2D, recommended phase 2 dose.

Richardson P, et al. PB1698. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03525678.

Summary

- Belantamab mafodotin is currently the only approved BCMA-targeting antibody–drug conjugate for patients with RRMM
- Ocular-related adverse events are common in treatment with belantamab mafodotin and dose modification was effective in managing ocular symptoms
- Belantamab mafodotin shows significant anti-myeloma activity in heavily pretreated patients with RRMM in a real-world setting with a manageable safety profile
- Belantamab mafodotin may be combined with other agents in an earlier setting to further enhance the benefit–risk profile

BCMA, B-cell maturation agent; RRMM, relapsed/refractory multiple myeloma.

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BCMA-targeting bispecific antibodies in relapsed/refractory multiple myeloma

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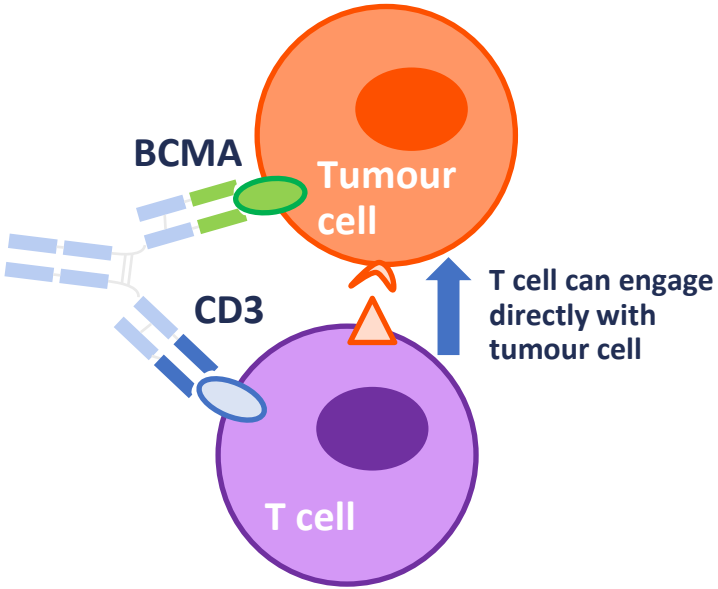
Bispecific antibodies in RRMM

Bispecific antibodies are designed to have affinities for two different epitopes which allows for either monovalent or bivalent binding to two targets



In clinical development:

- **Teclistamab**
- **Elranatamab**
- AMG 701
- REGN5458
- TNB-383B
- CC-93269

BCMA, B cell maturation antigen; CD3, cluster of differentiation 3; RRMM, relapsed/refractory multiple myeloma.
Sanchez L, et al. *Ther Adv Hematol*. 2021;12:1–16.

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Phase I study of elranatamab in RRMM: MAGNETISMM-1

Costello C, et al.

To define the RP2D and characterize the efficacy and safety of subcutaneous elranatamab (BCMA x CD3 bispecific antibody) in patients with RRMM

- Median age 63 years (40% ≥65 y)
- Median 8 prior therapies
- 87% triple-refractory
- 23% had prior BCMA-directed ADC or CAR T-cell therapy

N=30

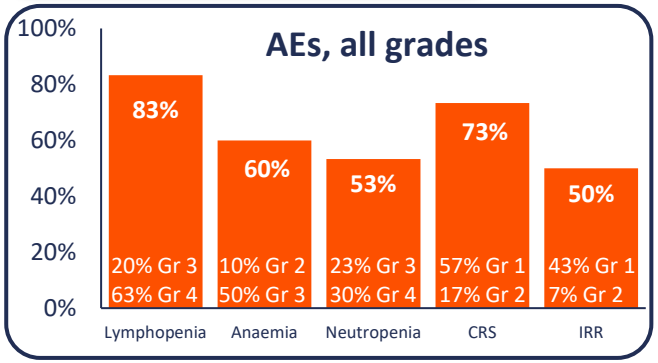
80 µg/kg n=6	360 µg/kg n=4
130 µg/kg n=4	600 µg/kg n=6
215 µg/kg n=4	1,000 µg/kg n=6

ORR 70% at ≥215 µg/kg

- sCR n=5
- CR n=1
- VGPR n=7
- PR n=1

ORR 83.3% at RP2D

RP2D 1,000 µg/kg qw SC



- Elranatamab demonstrated a manageable safety profile and wide therapeutic index with no dose-limiting toxicities
- Premedication/step-up dosing will be explored to mitigate CRS
- Doses ≥215 µg/kg SC achieved ORR of 75%

AE, adverse event; ADC, antibody–drug conjugate; BCMA, B-cell maturation antigen; CAR, chimeric antigen receptor; CD3, cluster of differentiation 3; CR, complete response; CRS, cytokine release syndrome; Gr, grade; IRR, infusion-related reaction; ORR, overall response rate; PR, partial response; qw, weekly; RP2D, recommended phase 2 dose; RRMM, relapsed/refractory multiple myeloma; SC, subcutaneous; sCR, stringent CR; VGPR, very good partial response; y, years.

Costello C, et al. S192. Presented at: European Hematology Association 2021 Virtual Congress, 9–17 June 2021. Clinicaltrials.gov identifier: NCT03269136.

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Phase I study of teclistamab in RRMM: updated results

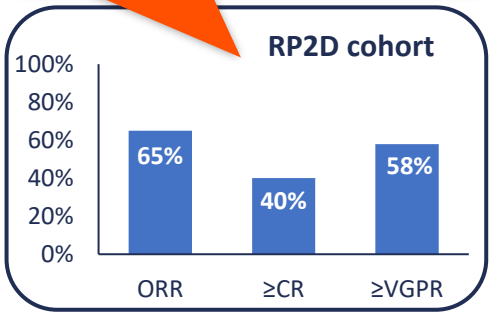
van de Donk N, et al.

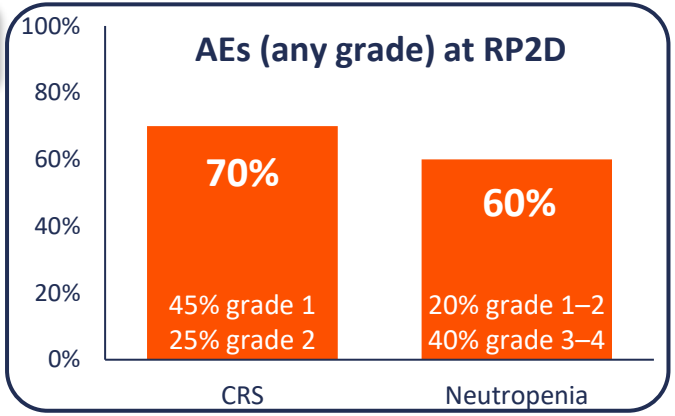
To identify the RP2D of the BCMA x CD3 bispecific antibody teclistamab in patients with multiple myeloma who are relapsed/refractory to standard therapies, including immunomodulatory drugs and proteasome inhibitors

N=157
IV n=84
SC n=73

40 patients at RP2D of weekly SC 1,500 µg/kg teclistamab with 60 and 300 µg/kg step-up doses
- 83% triple-refractory and 83% refractory to last line

Median follow-up 6.1 mo
mDOR not reached at RP2D





- **Teclistamab at the RP2D of 1,500 µg/kg qw SC was well tolerated with encouraging efficacy; durable, deepening responses and delayed low-grade CRS were observed**
- **Future studies will investigate teclistamab in earlier lines of therapy, and in combinations**

AE, adverse event; BCMA, B-cell maturation antigen; CD3, cluster of differentiation 3; CR, complete response; CRS, cytokine release syndrome; IV, intravenous; mDOR, median duration of response; mo, months; ORR, overall response rate; qw, weekly; RP2D, recommended phase 2 dose; RRMM, relapsed/refractory multiple myeloma; SC, subcutaneous; VGPR, very good partial response.

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Summary

- Elranatamab demonstrated a manageable safety profile and wide therapeutic index
- Teclistamab was well tolerated and demonstrated encouraging efficacy with durable, deepening responses
- Other BCMA-targeting bispecific antibodies are under investigation

BCMA, B-cell maturation antigen.

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