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University of Nebraska Medical Center

Bio Ascend™

VIRTUAL CHALLENGING CASE CLINIC:

Multiple Myeloma

Updates from ASCO and EHA

Broadcast on June 16, 2021

2021-2022 Webinar Schedule

3rd Wednesday Every Other Month (12 PM Eastern / 9 AM Pacific)	Topic	Presenter
Wednesday, April 18, 2021	CAR T Cells for MM	Nina Shah, MD
Wednesday, June 16, 2021	Updates from ASCO and EHA	Jonathan Kaufman, MD
Wednesday, August 18, 2021	Agents Targeting BCMA	Noopur Raje, MD
Wednesday, October 20, 2021	Aligning Induction Therapy for Each Patient	Saad Usmani, MD, FACP
Wednesday, December 15, 2021	Updates from ASH	Krina Patel, MD, MSc
Wednesday, February 16, 2022	MM-associated AL Amyloidosis	Shaji Kumar, MD

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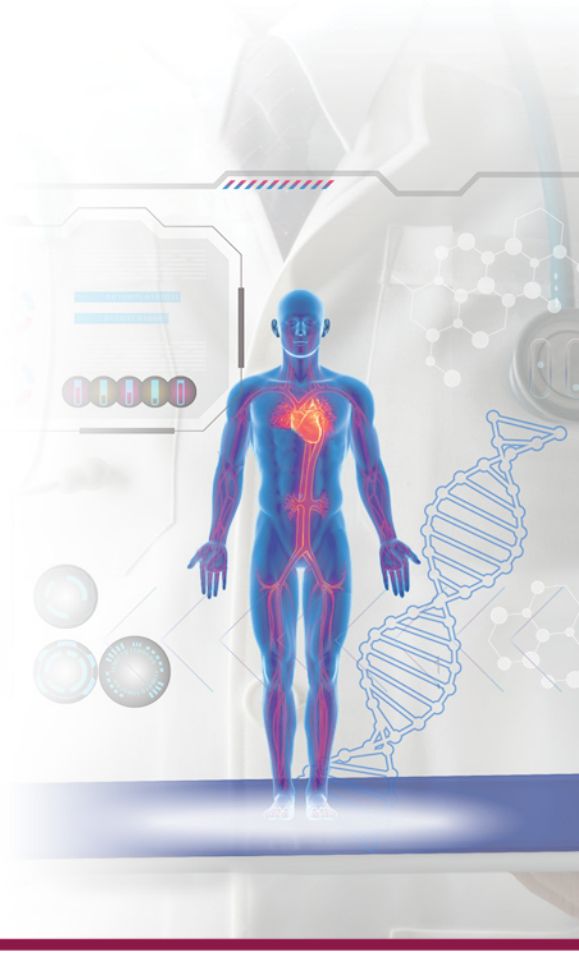
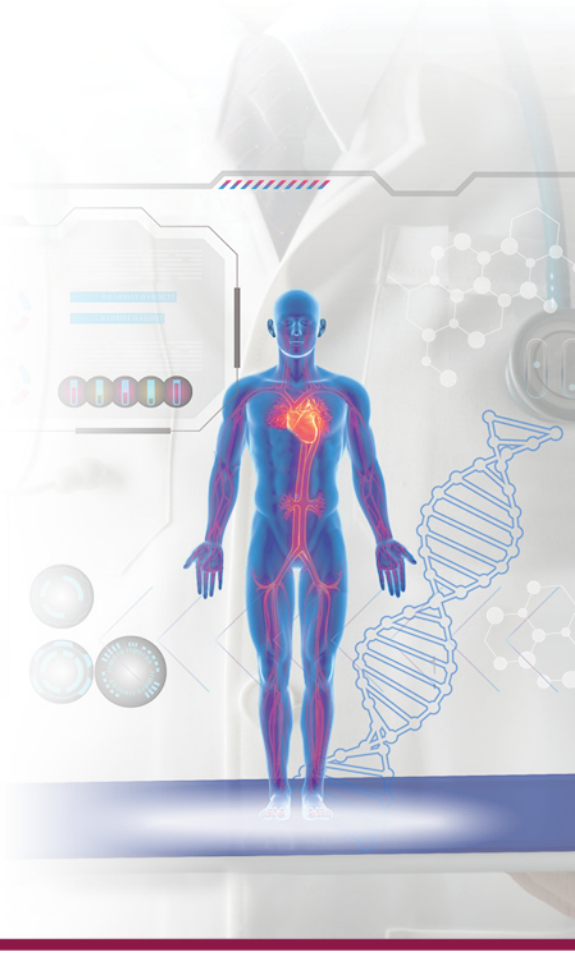


This activity is supported by independent educational grants from Bristol-Myers Squibb and Oncopeptides



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Disclosures

Sagar Lonial, MD, FACP

Consulting Fees: Amgen Inc., Bristol-Myers Squibb Company, Celgene Corporation, GlaxoSmithKline LLC, Janssen Oncology, Karyopharm Therapeutics, Merck & Co., Novartis

Jonathan Kaufman, MD

Consulting Fees: Bristol-Myers Squibb Company, Roche

Contracted Research & Publishing: AbbVie, Amgen Inc., Bristol-Myers Squibb Company, Janssen, Novartis

Planning Committee

The following planning committee members have nothing to disclose:
UNMC: Brenda Ram, CMP, CHCP

Bio Ascend: Patti Bunyasaranand, MS; Dru Dace, PhD; Lucja Grajkowska, PhD; Kraig Steubing

Learning Objectives

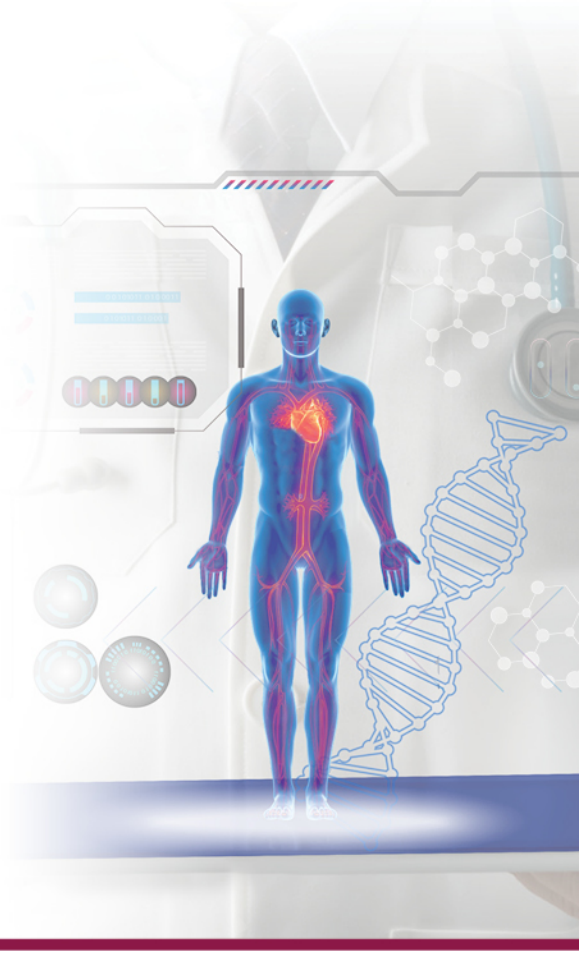
- Evaluate best available evidence regarding the treatment of patients with multiple myeloma
- Assess the implications of emerging clinical trial data regarding multiple myeloma treatment approaches
- Develop strategies to address complicated multiple myeloma cases

Updates from ASCO

NDMM

Dara maintenance or observation after VTd +/- dara and ASCT in patients with NDMM: CASSIOPEIA part 2

Moreau P, et al. ASCO (abstr 8004)



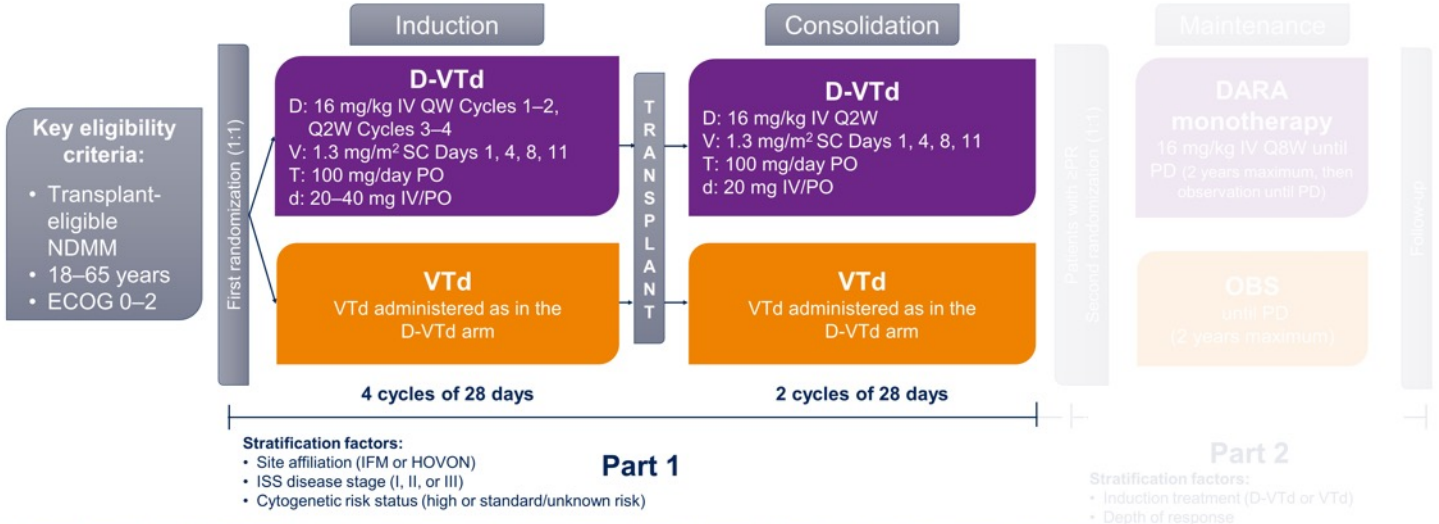
Dara Maintenance vs Observation in Part 2

- **At the time CASSIOPEIA was designed (2015), no maintenance therapy was approved or established as SOC**
- **Current treatment guidelines recommend the use of maintenance therapy to prolong initial response[1-5]**
- **Lenalidomide was approved as maintenance therapy by the EMA and US FDA in early 2017; it remains the only approved maintenance treatment**
  - Lenalidomide improved PFS and OS but was associated with higher rates of discontinuation due to AEs vs placebo/observation in a large meta-analysis[6]
- **Part 2 of CASSIOPEIA compared DARA every 8 weeks (reduced frequency compared with standard long-term dosing frequency of every 4 weeks) vs OBS for a fixed duration of 2 years in patients who achieved ≥PR in Part 1 and underwent second randomization**

1. Engelhardt M, et al. *Haematologica* 2014;99:232-42. 2. Moreau P, et al. *Ann Oncol* 2017;28:iv52-iv61. 3. Cavo M, et al. *Blood* 2011;117:6063-73. 4. Ludwig H, et al. *Blood* 2102;119:3003-15. 5. Sengsayadeth S, et al. *Blood Cancer J* 2017;7:E545. 6. McCarthy PL, et al. *J Clin Oncol* 2017;35:3279-89.
≥PR, partial response or better; AEs, adverse events; DARA, daratumumab; EMA, European Medicines Agency; OBS, observation; OS, overall survival; PFS, progression-free survival; SOC, standard of care; US FDA, United States Food and Drug Administration.

CASSIOPEIA Part 1 Study Design

- Part 1 compared D-VTd vs VTd as induction/consolidation

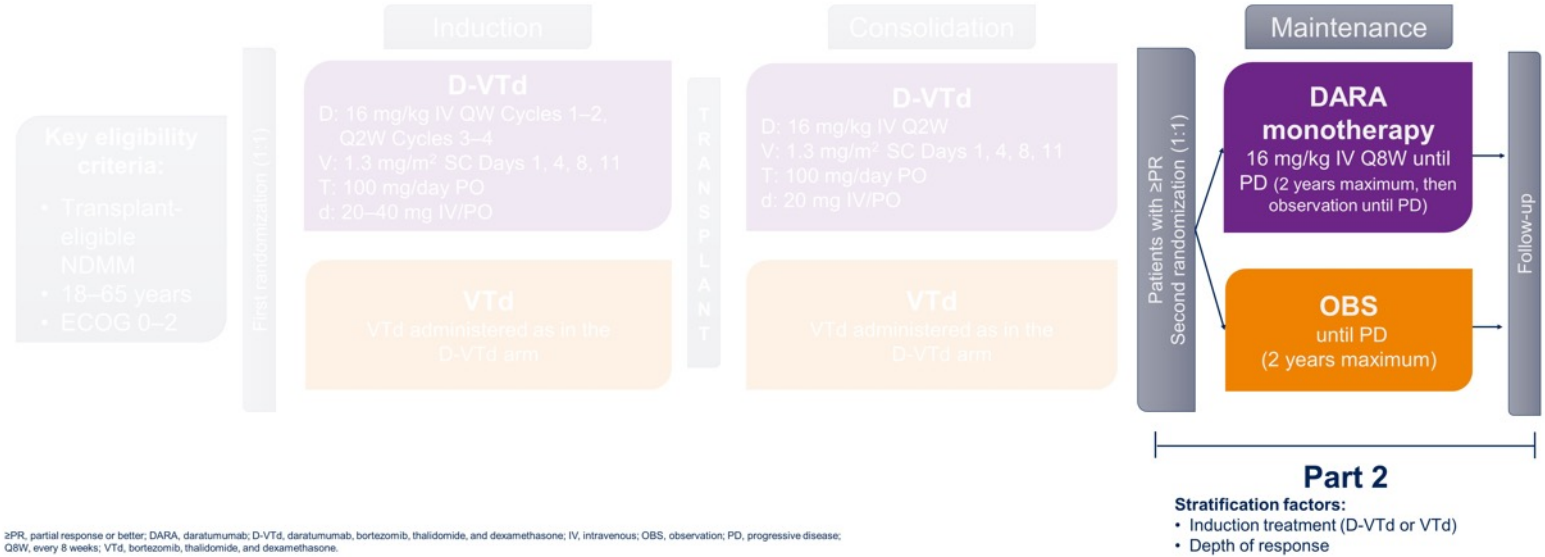


D-VTd, daratumumab, bortezomib, thalidomide, and dexamethasone; ECOG, Eastern Cooperative Oncology Group; IFM, Intergroupe Francophone du Myélome; ISS, International Staging System; HOVON, the Dutch-Belgian Cooperative Trial Group for Hematology-Oncology; IV, intravenous; NDMM, newly diagnosed multiple myeloma; PO, oral; Q2W, every 2 weeks; QW, every week; SC, subcutaneous; VTd, bortezomib, thalidomide, and dexamethasone.

Moreau P, et al. ASCO (abstr 8004)

CASSIOPEIA Part 2 Study Design

- Patients who completed consolidation and achieved ≥PR were re-randomized 1:1 to DARA 16 mg/kg IV every 8 weeks or OBS (no maintenance) for 2 years



≥PR, partial response or better; DARA, daratumumab; D-VTd, daratumumab, bortezomib, thalidomide, and dexamethasone; IV, intravenous; OBS, observation; PD, progressive disease; Q8W, every 8 weeks; VTd, bortezomib, thalidomide, and dexamethasone.

Patient Demographics

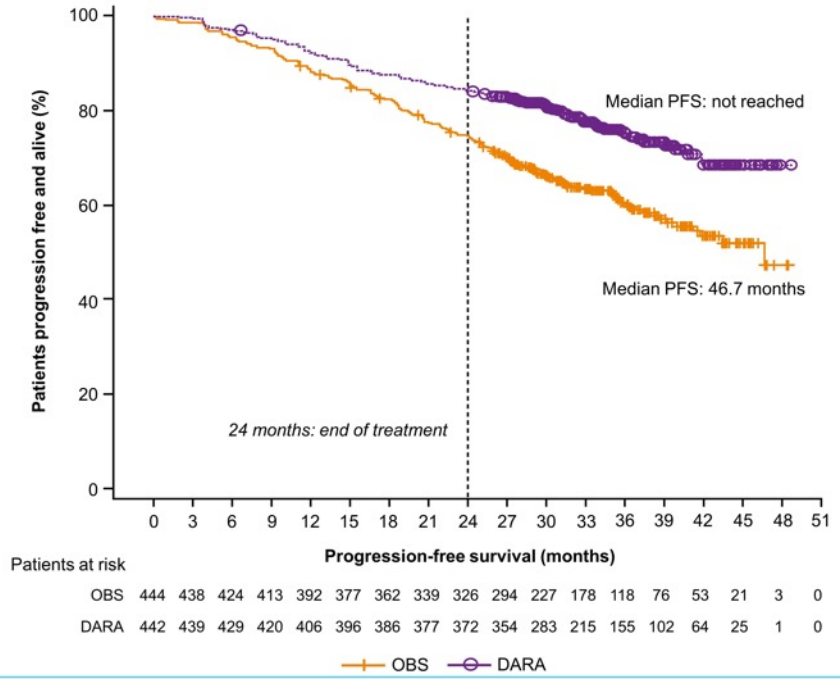
	DARA (n=442)	OBS (n=444)
Median (range) age,* years	59.0 (27–66)	59.0 (36–66)
Male sex,* n (%)	261 (59.0)	254 (57.2)
Baseline ECOG performance status,* n (%)		
0	252 (57.0)	260 (58.6)
1	174 (39.4)	172 (38.7)
≥2	16 (3.6)	12 (2.7)
ISS staging,† n (%)		
I	189 (42.8)	171 (38.5)
II	181 (41.0)	214 (48.2)
III	72 (16.3)	59 (13.3)

	DARA (n=442)	OBS (n=444)
Cytogenetic profile,† n/N (%)		
Standard risk	383/440 (87.0)	374/444 (84.2)
High risk‡	57/440 (13.0)	70/444 (15.8)
Type of induction/consolidation, n (%)		
D-VTd	229 (51.8)	229 (51.6)
VTd	213 (48.2)	215 (48.4)
Depth of response,§ n (%)		
MRD negative, ≥VGPR	337 (76.2)	337 (75.9)
MRD positive, ≥VGPR	68 (15.4)	69 (15.5)
MRD positive, PR	37 (8.4)	38 (8.6)

*Pre-consolidation; †Pre-induction; ‡Patients with del(17p) or t(11;14); § As determined by MRD measured by multiparametric flow cytometry at 10^{-4} and post-consolidation response per investigator assessment used for stratification.
≥VGPR, very good partial response or better; D-VTd, daratumumab, bortezomib, thalidomide, and dexamethasone; DARA, daratumumab; ECOG, Eastern Cooperative Oncology Group; ISS, International Staging System; MRD, minimal residual disease; OBS, observation; PR, partial response; VTd, bortezomib,

PFS from Second Randomization vs Observation

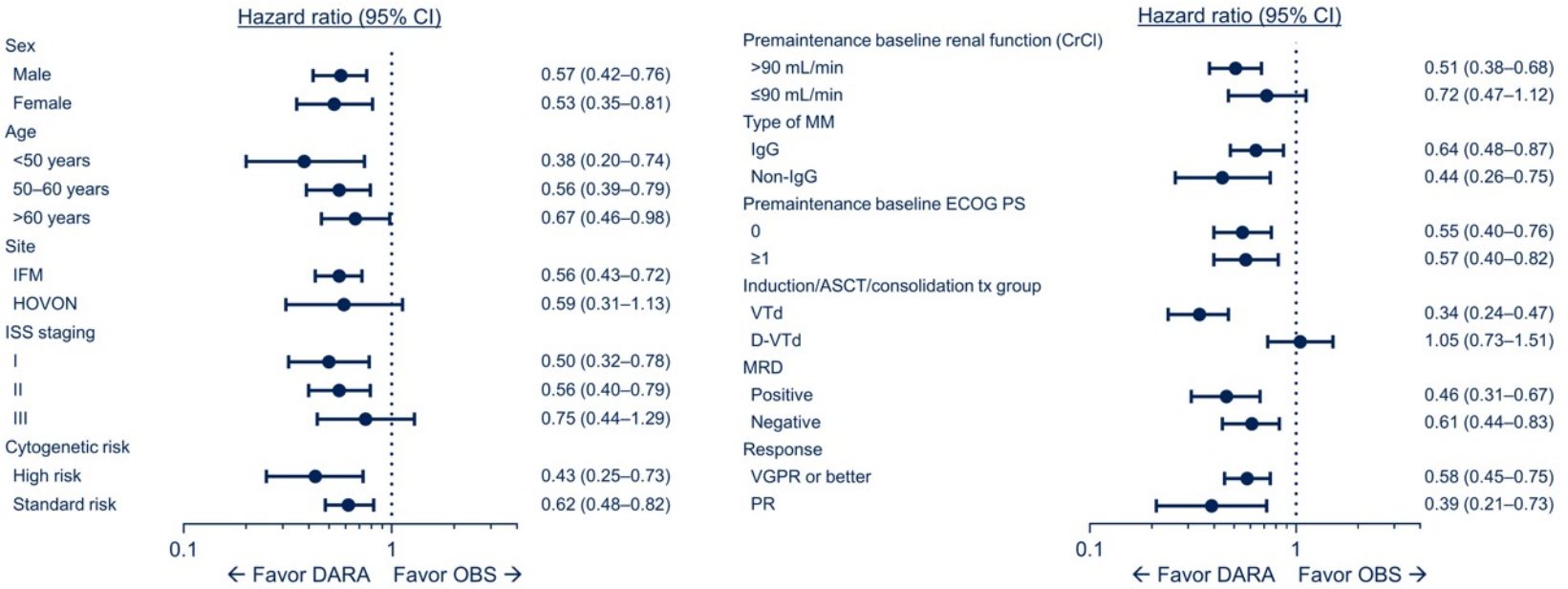
Median follow-up:
35.4 months
from second
randomization



HR 0.53
(95% CI 0.42–0.68)
P<0.0001

CI, confidence interval; DARA, daratumumab; HR, hazard ratio; OBS, observation; PFS, progression-free survival.

PFS Across Prespecified Subgroups



ASCT, autologous stem cell transplant; CI, confidence interval; CrCl, creatinine clearance; D-VTd, daratumumab, bortezomib, thalidomide, and dexamethasone; DARA, daratumumab; ECOG PS, Eastern Cooperative Oncology Group performance status; IFM, Intergroupe Francophone du Myélome; IgG, immunoglobulin G; ISS, International Staging System; HOVON, the Dutch-Belgian Cooperative Trial Group for Hematology-Oncology; MM, multiple myeloma; MRD, minimal residual disease; OBS, observation; PFS, progression-free survival; PR, partial response; tx, treatment; VGPR, very good partial response; VTd, bortezomib, thalidomide, and dexamethasone.

Treatment-Emergent Adverse Events

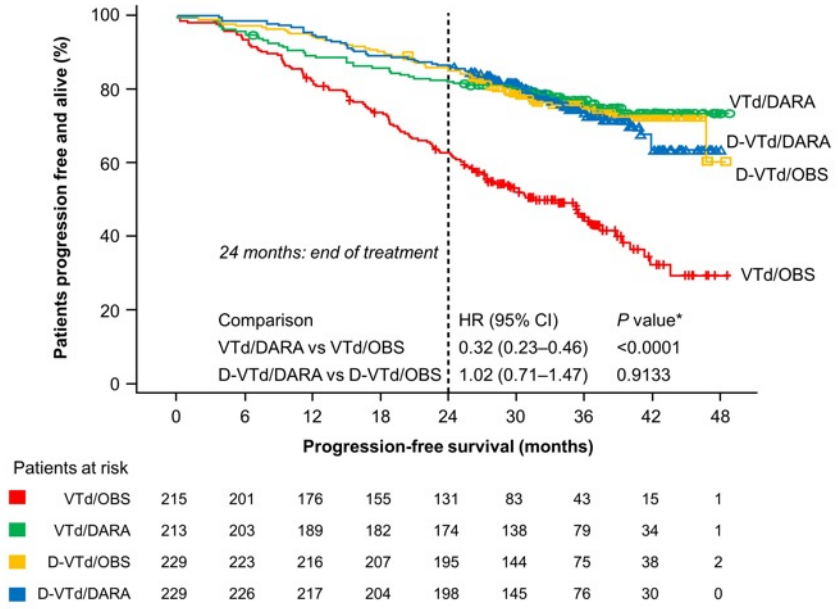
Patients, n (%)	DARA n=440	OBS n=444
Any TEAE	420 (95.5)	394 (88.7)
Any serious TEAE	100 (22.7)	84 (18.9)
Grade ≥3 TEAEs	132 (30.0)	108 (24.3)
Discontinuation of DARA due to TEAE	13 (3.0)	n/a
Fatal AEs	2 (0.5)	0
Neutropenia	9 (2.0)	10 (2.3)
Grade 3	9 (2.0)	10 (2.3)
Grade 4	0	0
Second primary malignancy*	24 (5.5)	12 (2.7)
Hematologic	5 (1.1)	1 (0.2)
Solid tumor	19 (4.3)	11 (2.5)
Infusion-related reactions	115 (54.5)†	n/a
Infections‡	341 (77.5)	284 (64.0)

*Hematologic second primary malignancies were DARA: T-cell lymphoma (2), blastic plasmacytoid dendritic cell neoplasia (1), myelodysplastic syndrome (1), natural killer-cell lymphoblastic lymphoma (1) and OBS: acute myeloid leukemia (1); †Among patients (N=211) who received VTd as induction therapy (ie, no prior DARA exposure). Most (103/115 or 89.6%) were grade 1 or 2; ‡The majority of infections (303 of 341 [88.9%] in the DARA group and 254 of 284 [89.4%] in the OBS group) were grade 1 or 2.
AEs, adverse events; DARA, daratumumab; n/a, not applicable; OBS, observation; TEAE, treatment-emergent AE; VTd, bortezomib, thalidomide, and dexamethasone.

Moreau P, et al. ASCO (abstr 8004)

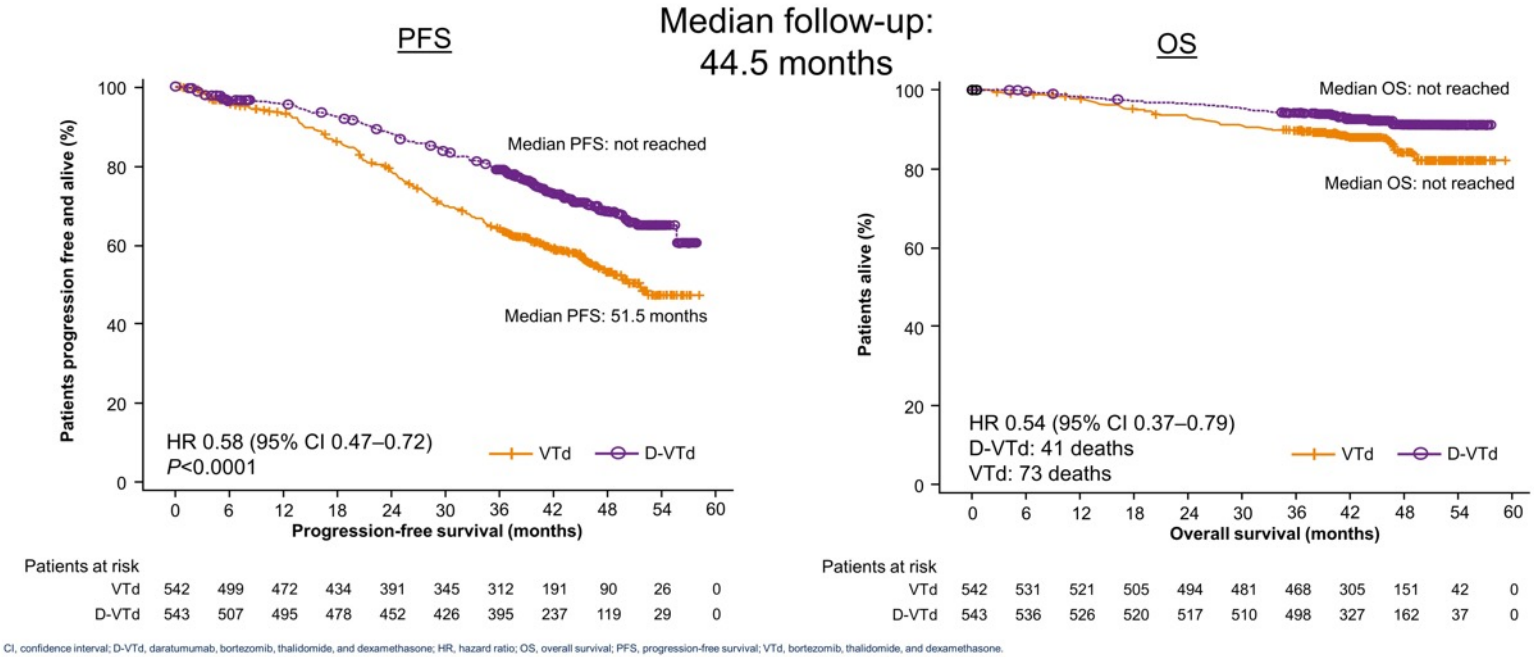
PFS in Patients Treated with VTd Induction/Consolidation

- A prespecified analysis showed significant interaction between maintenance and induction/consolidation therapy
- A PFS benefit was observed for VTd/DARA vs VTd/OBS
- PFS was not different for D-VTd/DARA vs D-VTd/OBS



*Nominal *P* value.
CI, confidence interval; D-VTd, daratumumab, bortezomib, thalidomide, and dexamethasone; DARA, daratumumab; HR, hazard ratio; OBS, observation; PFS, progression-free survival; VTd, bortezomib, thalidomide, and dexamethasone.

Updated Analyses from First Randomization Confirm Benefits of D-VTd vs VTd Induction/Consolidation



CI, confidence interval; D-VTd, daratumumab, bortezomib, thalidomide, and dexamethasone; HR, hazard ratio; OS, overall survival; PFS, progression-free survival; VTd, bortezomib, thalidomide, and dexamethasone.

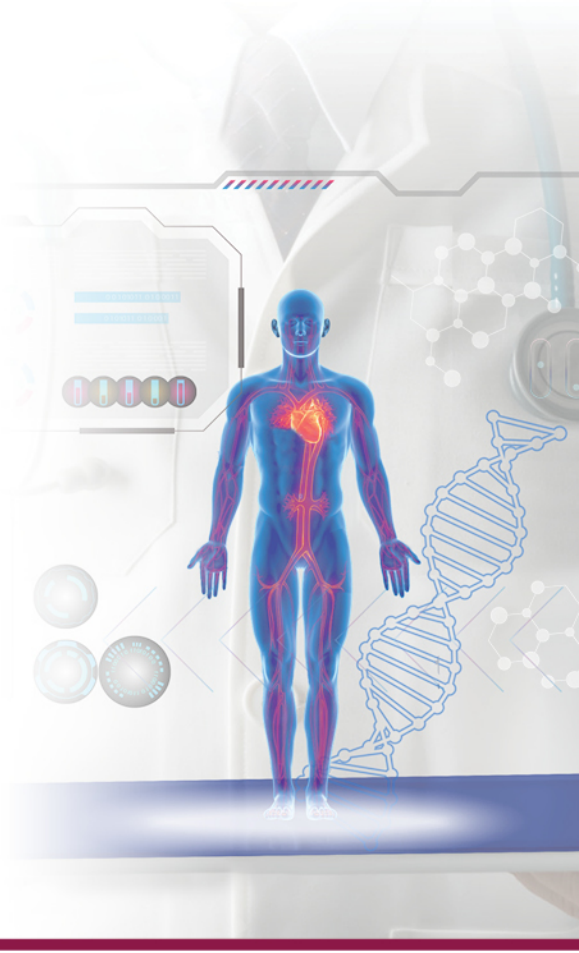
Authors' Conclusions

- **Reduced-frequency DARA maintenance (every 8 weeks) significantly improved post-ASCT outcomes in patients with NDMM who received VTd induction/consolidation**
- **Longer follow-up is needed to assess potential PFS2 or OS benefit in patients who received D-VTd induction/consolidation**
- **Updated results from Part 1 support the early use of DARA-containing regimens as induction/consolidation**
  - These findings are further supported by higher rates of dropout in the VTd group compared with the D-VTd group
- **Ongoing studies such as GRIFFIN, PERSEUS, and AURIGA will shed light on optimal maintenance strategies using DARA plus lenalidomide**

ASCT, autologous stem cell transplant; D-VTd, daratumumab, bortezomib, thalidomide, and dexamethasone; DARA, daratumumab; NDMM, newly diagnosed multiple myeloma; OS, overall survival; PFS2, progression-free survival after next line of therapy; VTd, bortezomib, thalidomide, and dexamethasone.

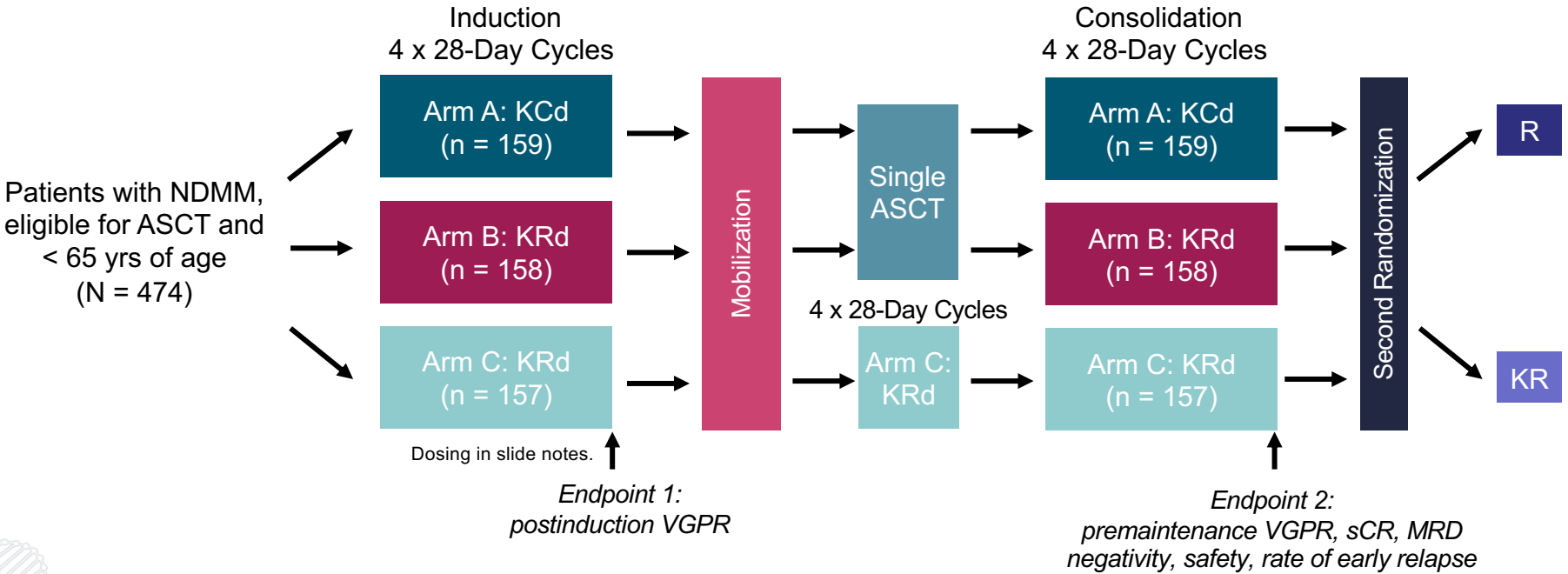
Carfilzomib-based induction/consolidation +/- ASCT followed by R or KR maintenance: Efficacy in high-risk patients

Agha M, et al. ASCO (abstr 8013)



FORTE: Study Design

- Multicenter, randomized, open-label phase II study



Gay F, et al. ASCO (abstr 8002)

Authors' Conclusions

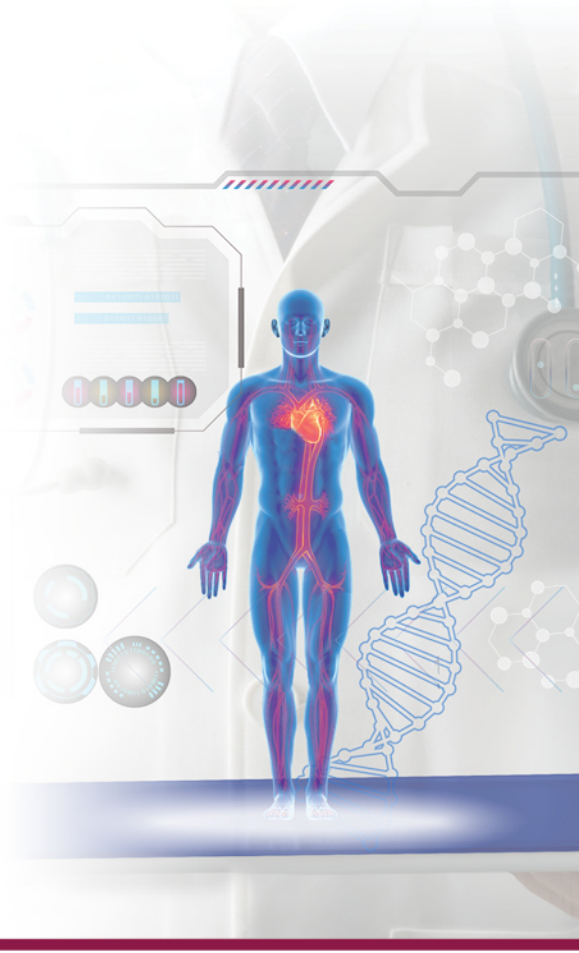
- KRd_ASCT and KR maintenance are highly effective in standard-risk and also in high-risk and double hit patients
- Impressive 4-year PFS from diagnosis (KRd_ASCT: HiR 62%, DH 55%) and 3-year PFS from maintenance (KR: HiR 69%, DH 67%), thus supporting their use in HiR pts, who represent an unmet medical need

Updates from ASCO

RRMM

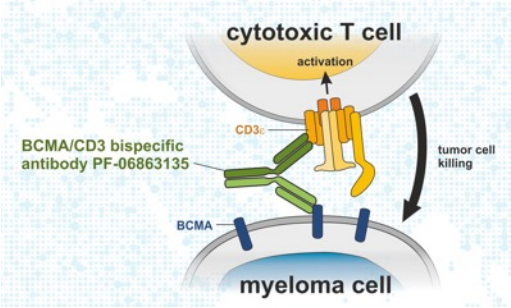
Efficacy and safety of elranatamab, a BCMA-CD3 bispecific antibody, in patients with RRMM

Bahlis NJ, et al. ASCO (abstr 8006)



Introduction

- BCMA is a member of the TNF receptor superfamily universally expressed in MM[1]
- Elranatamab (PF-06863135) is a humanized heterodimeric bispecific antibody (IgG2a) that targets BCMA on MM cells and CD3 on T cells[2]
- MagnetisMM-1 (NCT03269136) is a phase 1 study designed to evaluate the safety, pharmacokinetics, pharmacodynamics, and efficacy of elranatamab for patients with RRMM
- IV dosing of elranatamab demonstrated evidence of anti-myeloma activity in RRMM[3]
- We now extend these findings and report results for **SC dosing** of elranatamab
  - Primary objectives: assess safety/tolerability of elranatamab SC and determine the RP2D
  - Secondary objectives: evaluation of anti-myeloma activity, including duration of responses

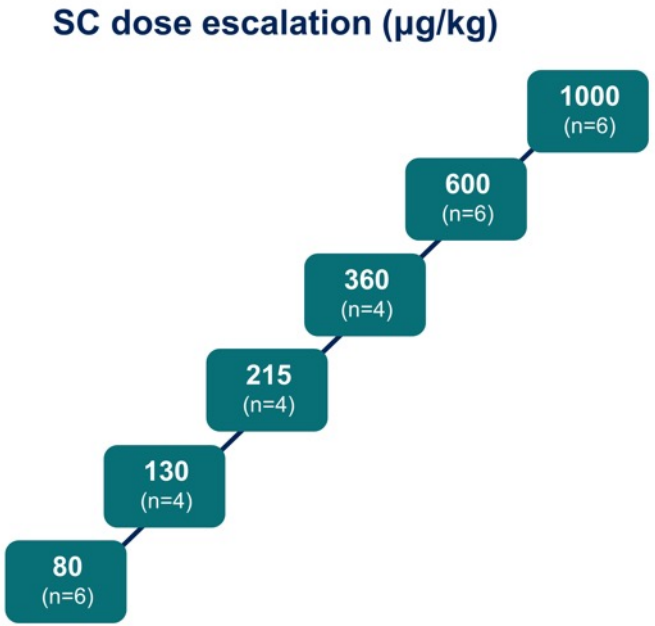


1. Shah N, et al. Leukemia 2020;34:985. 2. Panowski SH, et al. Blood 2016;128:383. 3. Raje NS, et al. Blood 2019;134(suppl.1):1869.

BCMA=B-cell maturation antigen; IgG2a=immunoglobulin G2a; IV=intravenous; MM=multiple myeloma; RP2D=recommended phase 2 dose; RRMM=relapsed/refractory multiple myeloma; SC=subcutaneous; TNF=tumor necrosis factor

Methods

- Key eligibility criteria
  - RRMM
  - Prior treatment with IMiD, PI, and anti-CD38 mAb
  - Measurable disease by IMWG criteria
  - ANC: ≥1.0 × 10^9/L; platelets: ≥25 × 10^9/L; Hb: ≥8 g/dL
  - Prior BCMA-directed therapy allowed
- Elranatamab was administered SC every week
- Safety assessments
  - AEs were graded by CTCAE version 4.03
  - CRS was graded by ASTCT criteria[1]
  - DLT was monitored to the end of the first 3-week cycle
- PK, pharmacodynamics, and immunogenicity were evaluated
- Response was assessed by IMWG criteria
- Data cutoff was February 4, 2021



1. Lee DW, et al. Biol Blood Marrow Transplant 2019;25:625.

AE=adverse event; ANC=absolute neutrophil count; ASTCT=American Society for Transplantation and Cellular Therapy; BCMA=B-cell maturation antigen; CRS=cytokine release syndrome; CTCAE=Common Terminology Criteria for Adverse Events; DLT=dose-limiting toxicity; Hb=hemoglobin; IMiD=immunomodulatory imide drug; IMWG=International Myeloma Working Group; mAb=monoclonal antibody; PI=proteasome inhibitor; PK=pharmacokinetics; RRMM=relapsed/refractory multiple myeloma; SC=subcutaneous

Patient and Disease Characteristics

- 30 patients had received elranatamab SC by the data cutoff
  - 80 (n=6), 130 (n=4), 215 (n=4), 360 (n=4), 600 (n=6), and 1000 (n=6) µg/kg weekly

Characteristics	SC dosing total (N=30)
Gender, n (%)	
Female	17 (56.7)
Median age, y (range)	63.0 (46–80)
≥65 y, n (%)	12 (40.0)
R-ISS stage at initial diagnosis, n (%)	
Stage I	6 (20.0)
Stage II	12 (40.0)
Stage III	7 (23.3)
Not reported	5 (16.7)
Cytogenetic risk	
High	7 (23.3)
Standard	19 (63.3)
Unknown	4 (13.3)

Data cutoff was February 4, 2021.
R-ISS=Revised International Staging System; SC=subcutaneous
Definition of high cytogenetic risk includes t(4;14), t(14;16), del(17p), and del(13q).

Prior Treatments

Prior treatments	SC dosing total (N=30)
Prior anti-myeloma therapies, median (range)	8.0 (3–15)
Triple-class refractory disease, n (%)[a]	26 (86.7)
Prior PIs, n (%)	30 (100.0)
Prior IMiDs, n (%) Lenalidomide Pomalidomide Thalidomide	30 (100.0) 29 (96.7) 27 (90.0) 8 (26.7)
Prior anti-CD38 therapy, n (%) Daratumumab Isatuximab Other	29 (96.7) 28 (93.3) 4 (13.3) 2 (6.7)
Prior BCMA-targeted therapy, n (%) Anti-BCMA ADC CAR-T	7 (23.3) 6 (20.0) 3 (10.0)

Data cutoff was February 4, 2021. Patients may have received more than 1 treatment within a given therapy class.

[a] Triple-class refractory disease is refractory to at least 1 PI, 1 IMiD, and 1 anti-CD38 therapy.

ADC=antibody drug conjugate; BCMA=B-cell maturation antigen; CAR-T=chimeric antigen receptor T-cell therapy; IMiD=immunomodulatory imide drug; PI=proteasome inhibitor; SC=subcutaneous

Treatment-Emergent Adverse Events Occurring in ≥20% of Patients

Adverse event, n (%)	Grade 1	Grade 2	Grade 3	Grade 4	Total (N=30)
Hematological					
Lymphopenia	0	0	6 (20.0)	19 (63.3)	25 (83.3)
Anemia	0	3 (10.0)	15 (50.0)	0	18 (60.0)
Neutropenia	0	0	7 (23.3)	9 (30.0)	16 (53.3)
Thrombocytopenia	3 (10.0)	2 (6.7)	5 (16.7)	6 (20.0)	16 (53.3)
Leukopenia	1 (3.3)	3 (10.0)	7 (23.3)	1 (3.3)	12 (40.0)
Non-hematological					
CRS	17 (56.7)	5 (16.7)	0	0	22 (73.3)
Injection site reaction	13 (43.3)	2 (6.7)	0	0	15 (50.0)
Nausea	5 (16.7)	5 (16.7)	1 (3.3)	0	11 (36.7)
Increased AST	5 (16.7)	2 (6.7)	3 (10.0)	0	10 (33.3)
Increased ALT	5 (16.7)	1 (3.3)	3 (10.0)	0	9 (30.0)
Diarrhea	6 (20.0)	2 (6.7)	1 (3.3)	0	9 (30.0)
Vomiting	7 (23.3)	1 (3.3)	0	0	8 (26.7)
Decreased appetite	5 (16.7)	2 (6.7)	0	0	7 (23.3)
Dry skin	5 (16.7)	2 (6.7)	0	0	7 (23.3)
Hypokalemia	1 (3.3)	5 (16.7)	1 (3.3)	0	7 (23.3)
Arthralgia	3 (10.0)	2 (6.7)	1 (3.3)	0	6 (20.0)
ICANS	3 (10.0)	3 (10.0)	0	0	6 (20.0)
Pyrexia	5 (16.7)	1 (3.3)	0	0	6 (20.0)

- No DLT was observed

Data cutoff was February 4, 2021. Reporting of TEAEs based on CTCAE version 4.03, except for CRS (Lee DW, et al. Biol Blood Marrow Transplant 2019;25:625).

ALT=alanine aminotransferase; AST=aspartate aminotransferase; CRS=cytokine release syndrome; CTCAE=Common Terminology Criteria for Adverse Events; DLT=dose-limiting toxicity; ICANS=immune effector cell-associated neurotoxicity syndrome; TEAE=treatment-emergent adverse event

Cytokine Release Syndrome

- Patients did not receive premedication or priming/step-up dosing to mitigate CRS
  - Overall incidence of CRS was 73.3%
- CRS was limited to Grade 1 or 2, with no events >Grade 2
  - Median (range) time to onset was 1 (1–3) day
  - Median (range) duration was 3 (1–10) days
  - Nine (30%) patients received tocilizumab and 3 (10%) received steroid treatment for CRS
  - No permanent treatment discontinuations, dosing interruptions, or dose reductions occurred due to CRS

Patients with CRS, n (%)	80 µg/kg (n=6)	130 µg/kg (n=4)	215 µg/kg (n=4)	360 µg/kg (n=4)	600 µg/kg (n=6)	1000 µg/kg (n=6)	Total (N=30)
Overall	2 (33.3)	2 (50.0)	3 (75.0)	3 (75.0)	6 (100.0)	6 (100.0)	22 (73.3)
Grade 1	1 (16.7)	2 (50.0)	3 (75.0)	2 (50.0)	4 (66.7)	5 (83.3)	17 (56.7)
Grade 2	1 (16.7)	0	0	1 (25.0)	2 (33.3)	1 (16.7)	5 (16.7)

Data cutoff was February 4, 2021. Reporting of CRS based on Lee DW, et al. Biol Blood Marrow Transplant 2019;25:625.
CRS=cytokine release syndrome

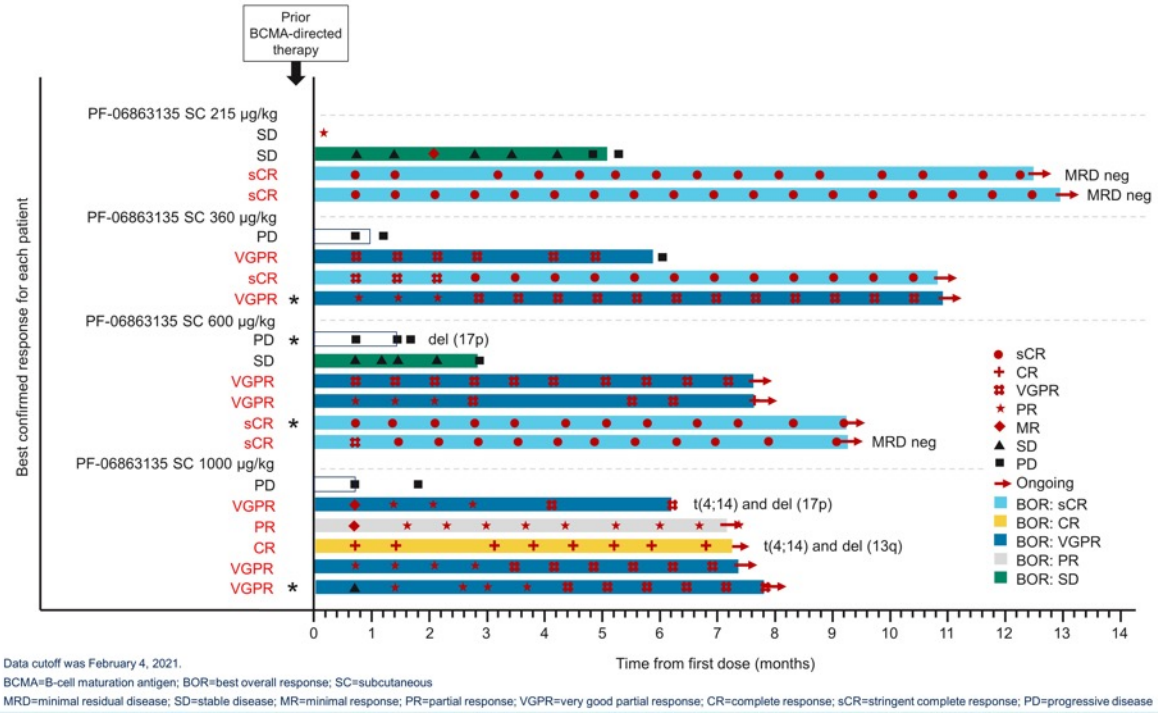
Investigator IMWG Response

- Responses were observed beginning at 215 µg/kg
- At doses ≥215 µg/kg (n=20), confirmed ORR was 70% and CR/sCR rate was 30%
- At the RP2D of 1000 µg/kg (n=6), confirmed ORR was 83.3%
- Median (range) time to response in these 14 responders was 22 (21–50) days
- Probability of responders being event free at 6 months was 92.3% (56.7–98.9)

IMWG response, n (%)	215 µg/kg (n=4)	360 µg/kg (n=4)	600 µg/kg (n=6)	1000 µg/kg (n=6)	Total ≥215 µg/kg (n=20)
sCR	2 (50.0)	1 (25.0)	2 (33.3)	0	5 (**25.0**)
CR	0	0	0	1 (16.7)	1 (**5.0**)
VGPR	0	2 (50.0)	2 (33.3)	3 (50.0)	7 (35.0)
PR	0	0	0	1 (16.7)	1 (5.0)
MR	0	0	0	0	0
SD	2 (50.0)	0	1 (16.7)	0	3 (15.0)
PD	0	1 (25.0)	1 (16.7)	1 (16.7)	3 (15.0)
Confirmed ORR	2 (50.0)	3 (75.0)	4 (66.7)	5 (**83.3**)	14 (**70.0**)

CR=complete response; IMWG=International Myeloma Working Group; MR=minimal response; ORR=objective response rate; PD=progressive disease; PR=partial response; RP2D= recommended phase 2 dose; sCR=stringent complete response; SD=stable disease; VGPR=very good partial response

Duration of Response



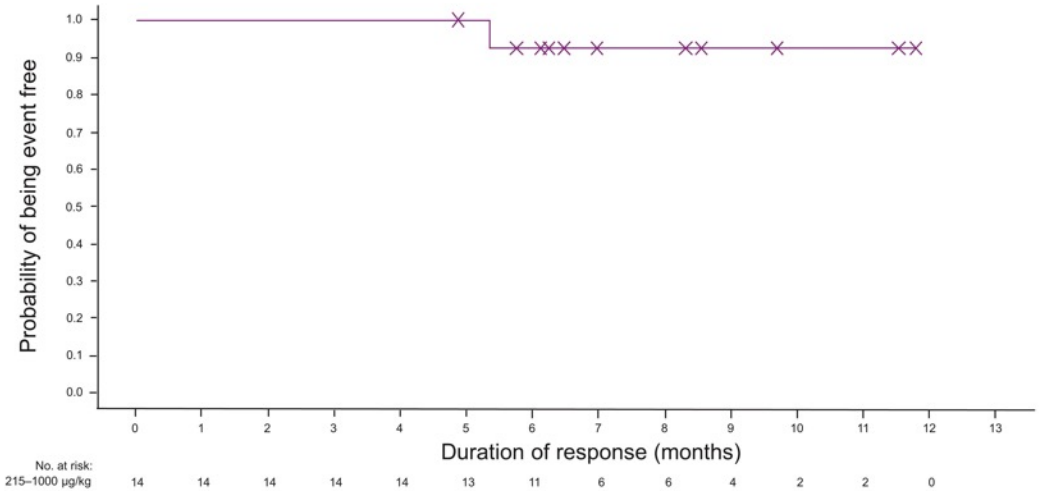
Data cutoff was February 4, 2021.

BCMA=B-cell maturation antigen; BOR=best overall response; SC=subcutaneous

MRD=minimal residual disease; SD=stable disease; MR=minimal response; PR=partial response; VGPR=very good partial response; CR=complete response; sCR=stringent complete response; PD=progressive disease

- 3 of 4 patients with prior BCMA-directed therapy achieved response: 2 VGPR and 1 sCR
- 3 patients assessed were MRD negative

Duration of Response



- For the 14 patients with IMWG-confirmed response, median duration of response has not yet been reached
- Probability (95% CI) of responders being event free at 6 months was 92.3% (56.7–98.9)

Data cutoff was February 4, 2021.
IMWG=International Myeloma Working Group

Authors' Conclusions

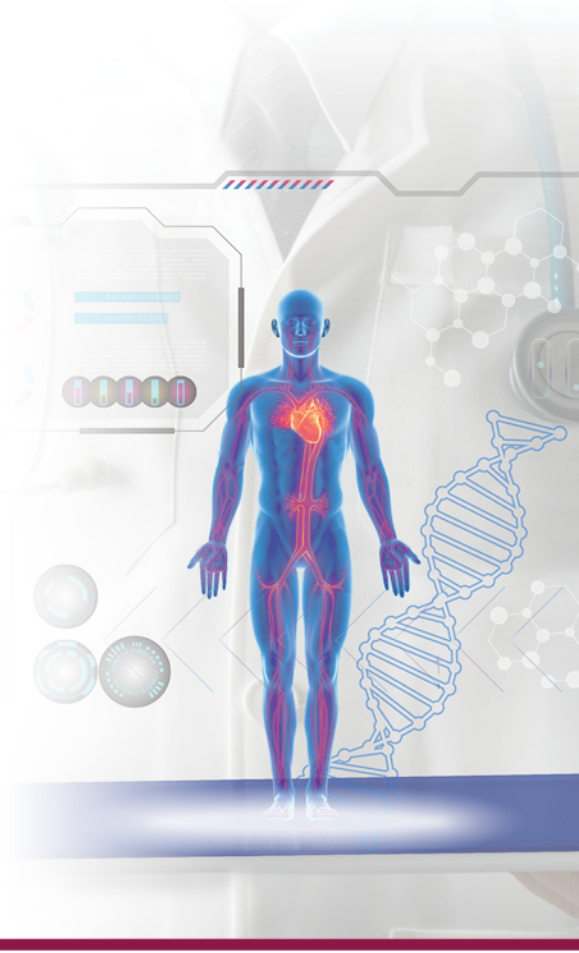
- Elranatamab at doses up to 1000 µg/kg SC weekly had a manageable safety profile for patients with RRMM
  - No DLT was observed
  - CRS was reported in 22 (73.3%) patients, but all events were limited to Grade 1 or 2
  - Premedication and priming/step-up dosing will be explored to mitigate CRS
- Safety, PK, pharmacodynamics, and efficacy support a weekly SC dosing regimen
- At doses ≥215 µg/kg, elranatamab demonstrated confirmed ORR of 70% and CR/sCR rate of 30%
  - Probability (95% CI) of responders being event free at 6 months was 92.3% (56.7–98.9)
  - 3 of 4 patients with prior BCMA-directed therapy achieved response (2 VGPR and 1 sCR)
- At RP2D of 1000 µg/kg, confirmed ORR was 83%
- These results support further development of elranatamab both as monotherapy and in combination with other agents

Data cutoff was February 4, 2021.

BCMA=B-cell maturation antigen; CR=complete response; CRS=cytokine release syndrome; DLT=dose-limiting toxicity; ORR=objective response rate; PK=pharmacokinetics; RP2D=recommended phase 2 dose; RRMM=relapsed/refractory multiple myeloma; SC=subcutaneous; sCR=stringent complete response; VGPR=very good partial response

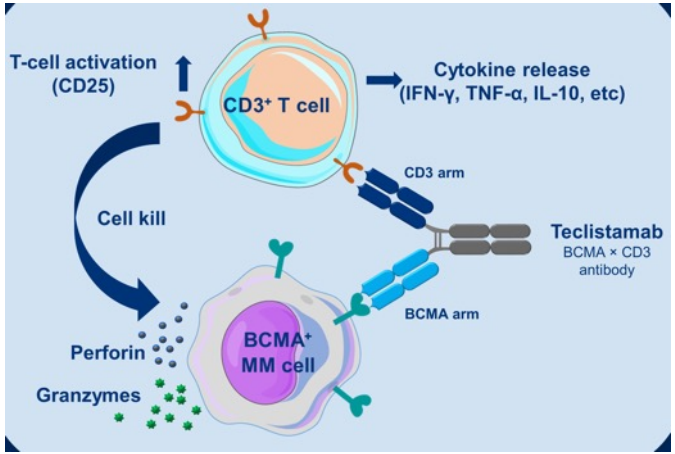
Updated phase I results of teclistamab, a BCMA x CD3 bispecific antibody, in RRMM

Krishnan A, et al. ASCO (abstr 8007)

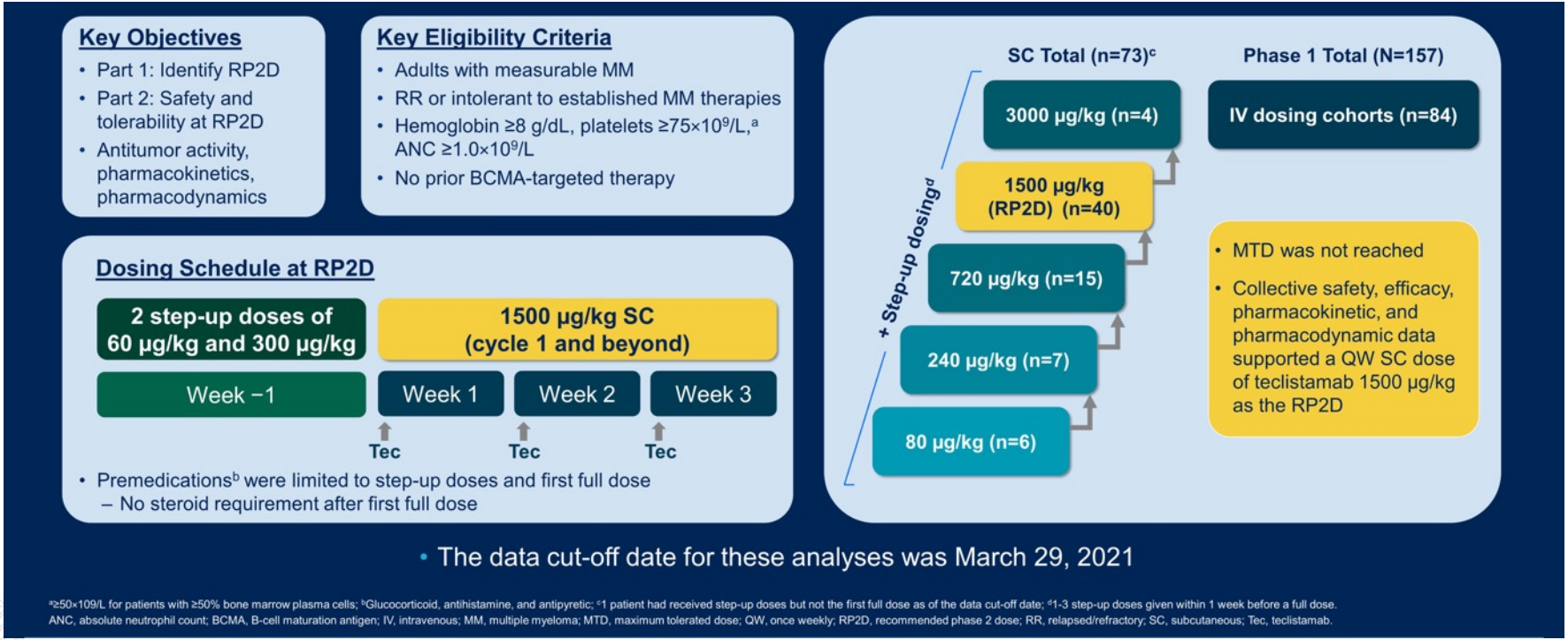


Teclistamab: A BCMA x CD3 Bispecific Antibody

- Teclistamab is an off-the-shelf, BCMA x CD3, T-cell redirecting, bispecific antibody
- In the phase 1, first-in-human study in patients with RRMM (NCT03145181), teclistamab was administered IV or SC in different dosing cohorts (Garfall AL, et al. ASH [abstr 180])
  - The RP2D was identified as QW SC dose of teclistamab 1500 μg/kg with step-up doses of 60 μg/kg and 300 μg/kg
  - This presentation includes updated RP2D results with additional patients and longer follow-up



MajesTEC-1 Study Design



[a]≥50×109/L for patients with ≥50% bone marrow plasma cells; [b]Glucocorticoid, antihistamine, and antipyretic; [c]1 patient had received step-up doses but not the first full dose as of the data cut-off date; [d]1-3 step-up doses given within 1 week before a full dose.
ANC, absolute neutrophil count; BCMA, B-cell maturation antigen; IV, intravenous; MM, multiple myeloma; MTD, maximum tolerated dose; QW, once weekly; RP2D, recommended phase 2 dose; RR, relapsed/refractory; SC, subcutaneous; Tec, teclistamab.

Patient Demographics and Disease Characteristics

Characteristic	SC Total n=73	RP2D (1500 µg/kg SC QW)[a] n=40
Age, years, median (range)	64.0 (39–84)	62.5 (39–84)
Aged ≥70 years, n (%)	18 (25)	9 (23)
Sex, n (%)		
Male	43 (59)	26 (65)
Female	30 (41)	14 (35)
Time since diagnosis, years, median (range)	5.9 (0.8–23.5)	5.7 (0.8–17.4)
Extramedullary soft tissue plasmacytomas ≥1, n (%)[b]	11 (15)	8 (20)
Bone marrow plasma cells ≥60%, n (%)[c]	12 (18)	3 (8)
High-risk cytogenetics, n (%)[d]	16 (30)	10 (37)
ISS stage, n (%)[e]		
I	36 (50)	24 (62)
II	25 (35)	11 (28)
III	11 (15)	4 (10)

Characteristic	SC Total n=73	RP2D (1500 µg/kg SC QW)[a] n=40
Prior number of lines of therapy, median (range)	5.0 (2–14)	5.0 (2–11)
Prior transplantation, n (%)	63 (86)	34 (85)
Exposure status, n (%)		
Triple-class[f]	71 (97)	40 (100)
Penta-drug[g]	50 (68)	26 (65)
Refractory status, n (%)		
PI[h]	65 (89)	35 (88)
Carfilzomib	49 (67)	27 (68)
IMiD[i]	70 (96)	38 (95)
Pomalidomide	55 (75)	28 (70)
Anti-CD38 mAb[j]	68 (93)	39 (98)
Triple-class[f]	58 (79)	33 (83)
Penta-drug[g]	28 (38)	15 (38)
Refractory to last line of therapy	64 (88)	33 (83)

Krishnan A, et al. ASCO (abstr 8007)

Safety Profile

- First onset of grade 3/4 cytopenias generally confined to step-up dosing and cycles 1 and 2
- Infections reported in 51% of SC-treated patients (grade 3/4: 21%); 45% at RP2D (grade 3/4: 23%)
- Neurotoxicity occurred in 1 (1%) SC-treated patient
  - Patient treated at RP2D and remains on therapy
  - Event was grade 1 and resolved without intervention
- Injection-site reactions reported in 42% of SC-treated patients (50% at RP2D)
  - Events were mild (all grade 1/2) and manageable
- 2 deaths due to AEs across SC cohorts (none at RP2D) were unrelatable to teclistamab
  - General health deterioration (n=1)
  - Sepsis(n=1)

AE (≥20% of total SC), n (%)	SC Total n=73		RP2D (1500 µg/kg SC QW)[a] n=40	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Hematologic				
Neutropenia	46 (63)	32 (44)	26 (65)	16 (40)
Anemia	37 (51)	19 (26)	20 (50)	11 (28)
Thrombocytopenia	30 (41)	15 (21)	18 (45)	8 (20)
Leukopenia	19 (26)	9 (12)	13 (33)	7 (18)
Nonhematologic				
CRS	44 (60)	0	28 (70)	0
Nausea	23 (32)	0	13 (33)	0
Fatigue	21 (29)	1 (1)	15 (38)	1 (3)
Injection site erythema	20 (27)	0	13 (33)	0
Headache	18 (25)	0	8 (20)	0
Diarrhea	17 (23)	2 (3)	9 (23)	2 (5)
Cough	15 (21)	1 (1)	4 (10)	0
Pyrexia	15 (21)	0	5 (13)	0

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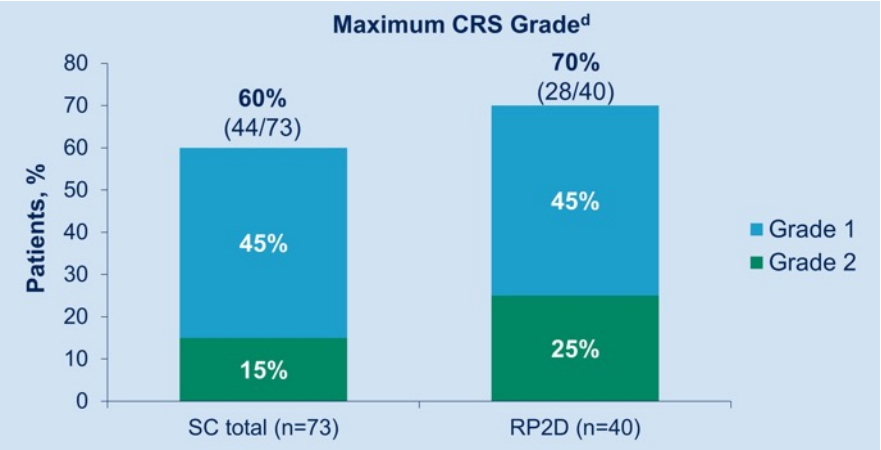
Cytokine Release Syndrome

Parameter	SC Total n=73	RP2D (1500 µg/kg SC QW)[a] n=40
Patients with CRS, n (%)	44 (60)	28 (70)
Median time to onset (range), days[b]	2.0 (1–6)	2.0 (1–6)
Median duration (range), days	2.0 (1–8)	2.0 (1–8)
Supportive measures, n (%)[c]	44 (60)	28 (70)
Tocilizumab	16 (22)	14 (35)
Steroids	7 (10)	5 (13)
Low-flow oxygen by nasal cannula	4 (5)	3 (8)



- No grade 3 or greater CRS events and no treatment discontinuations due to CRS
- CRS generally confined to step-up and first full doses
- CRS resolved in all patients

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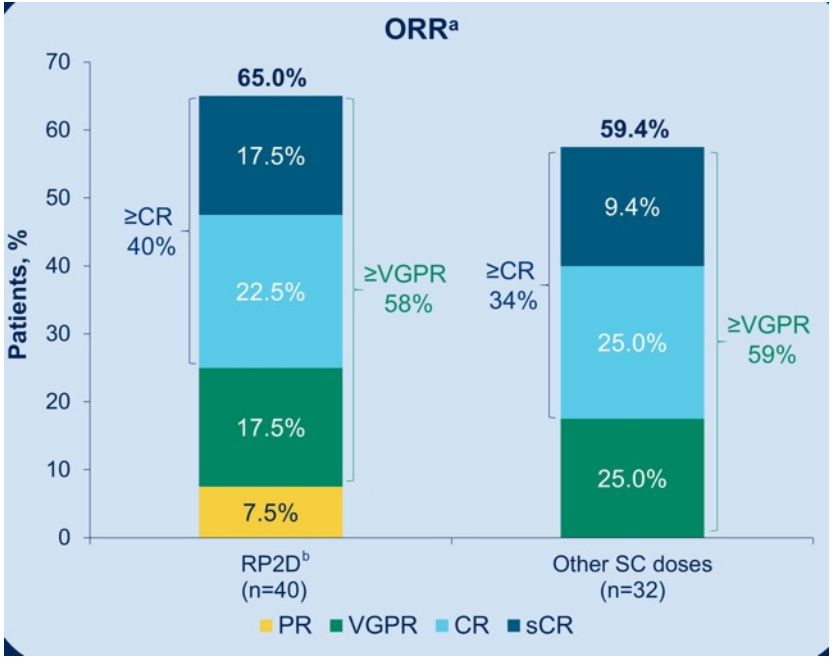
Overall Response Rate

- The RP2D of 1500 μg/kg SC QW has been administered to 40 patients with a median duration of follow-up of 6.1 months
  - ORR was 65%, with 58% of patients achieving a VGPR or better and 40% achieving CR or better
  - Median time to first confirmed response was 1.0 month
  - ORR in 33 triple-class refractory patients was 61%
- Of 6 evaluable patients in RP2D cohorts at the data cut-off date, all achieved MRD-negative CR/sCR at 10^{-6} (n=5) or 10^{-5} (n=1)
  - Across IV and SC cohorts, 18/26 evaluable patients (69%) had MRD-negative CR/sCR at 10^{-6} (n=16) or 10^{-5} (n=2)
  - 2 evaluable patients with CR >12 months had sustained MRD negativity



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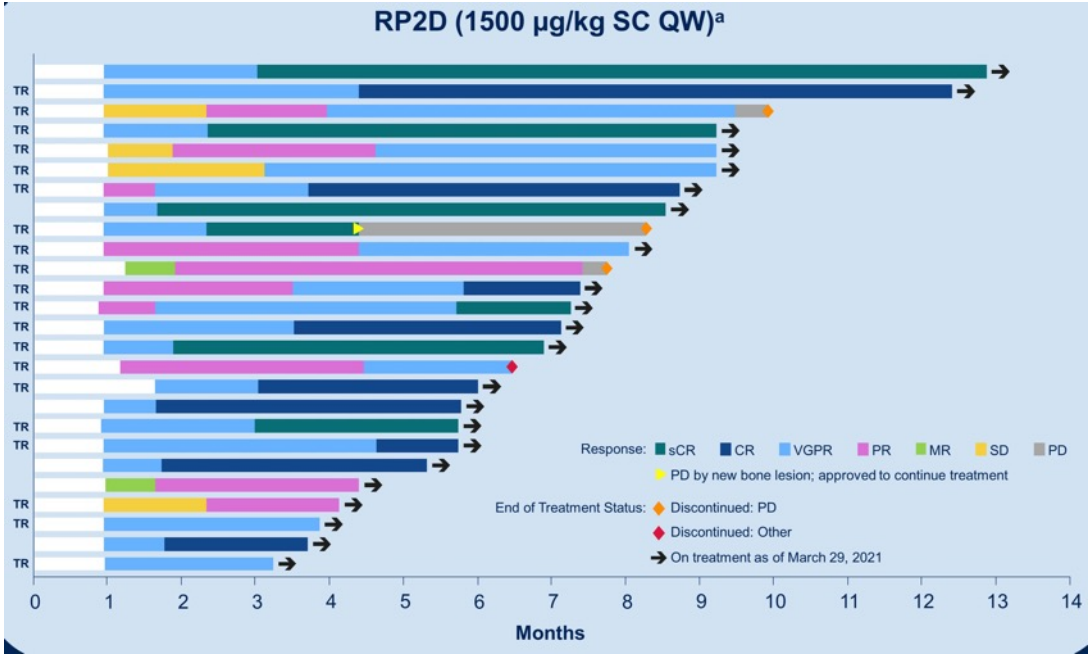
Duration of Response at RP2D

- At the RP2D of 1500 μg/kg SC QW
  - Responses were durable and deepened over time
  - Median duration of response was not reached
  - 22/26 responders (85%), after median follow-up of 7.1 months, were alive and continuing on treatment
- Across SC cohorts 36/45 responders (80%), after median follow-up of 9.3 months, were alive and continuing on treatment
- Across IV cohorts 19/32 responders (59%), after median follow-up of 15.6 months, were alive and continuing on treatment
  - 6 (19%) had 18 months or greater of follow-up



Krishnan A, et al. ASCO (abstr 8007)

Authors' Conclusions

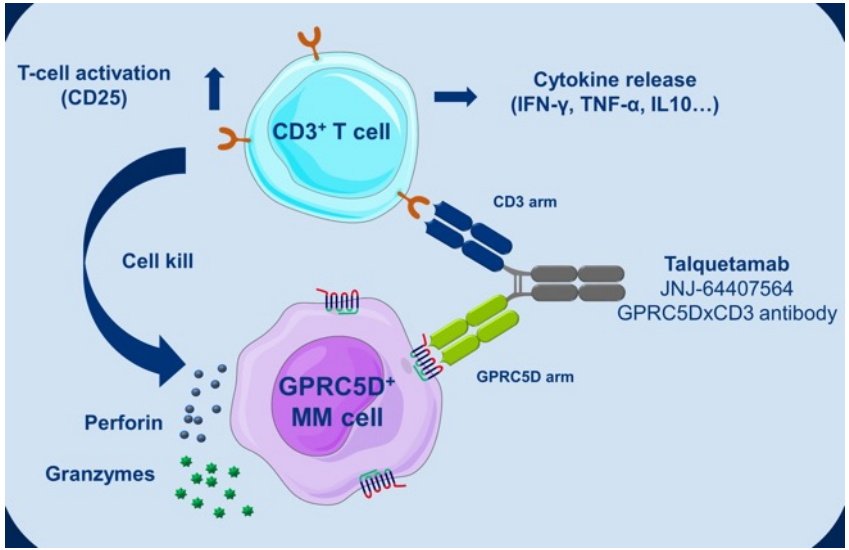
- Teclistamab is a novel, steroid-sparing treatment approach for RRMM
- Additional patients and longer follow-up continue to support the RP2D
  - Teclistamab was well tolerated, with no new safety signals; CRS was low grade and manageable
  - A high response rate was observed; responses were durable and deepened over time
  - Teclistamab administration resulted in consistent T-cell activation
- Teclistamab showed encouraging efficacy and safety relative to other approved agents for triple-class exposed RRMM
  - Teclistamab has the advantage of ready availability compared with CAR T-cell therapies
- Findings from this phase 1 study (N=157) support further clinical development of teclistamab
  - An international, open-label, phase 2 expansion study of teclistamab at the RP2D in patients with RRMM is underway (NCT04557098)
  - Future studies will evaluate teclistamab in earlier line MM and in combination with other agents

Updated results of a phase 1, first-in-human study of talquetamab, a G protein-coupled receptor family C Group 5 Member D x CD3 bispecific antibody, in RRMM

Berdeja JG, et al. ASCO (abstr 8008)

Talquetamab: GPRC5D x CD3 Bispecific Antibody

- GPRC5D is a highly expressed receptor in MM, with limited expression in healthy human tissue
- Talquetamab is a first-in-class antibody that binds to CD3 and GPRC5D to redirect T cells to kill MM cells
- In the ongoing, phase 1, first-in-human study of talquetamab in patients with RRMM, the RP2D was identified as a QW SC dose of 400 μg/kg (NCT03399799)
- The results presented here are updated safety and efficacy of talquetamab at the RP2D, with additional patients and longer follow-up



Berdeja JG, et al. ASCO (abstr 8008)

MonumenTAL-1 Study Design

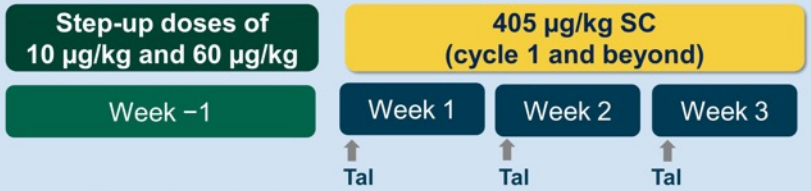
Key Objectives

- Part 1: Identify RP2D
- Part 2: Safety and tolerability at RP2D
- Antitumor activity, pharmacokinetics, pharmacodynamics

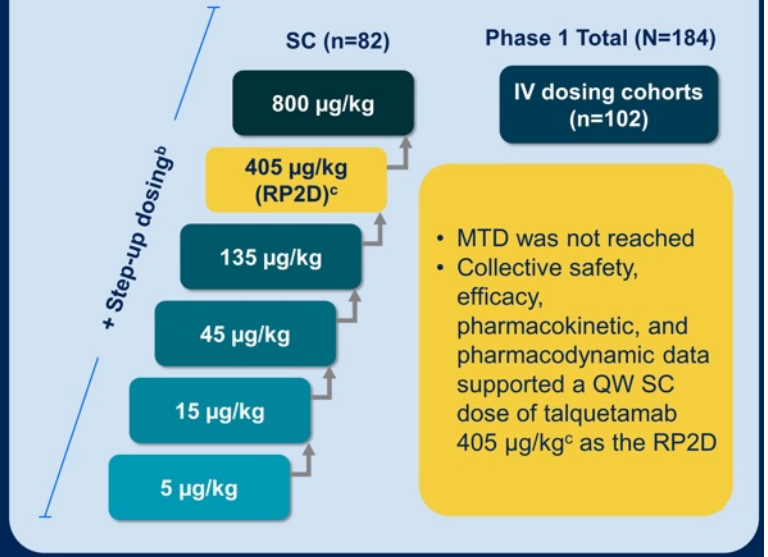
Key Eligibility Criteria

- Adults with measurable MM
- RR or intolerant to established MM therapies
- Hemoglobin ≥8 g/dL, platelets ≥50×10^9/L, ANC ≥1.0×10^9/L
- Prior BCMA-targeted therapy allowed

Dosing Schedule at RP2D



- Premedications[a] were limited to step-up doses and first full dose
  - No steroid requirement after first full dose



- The data cut-off date for these analyses was April 18, 2021

Patient Demographics and Disease Characteristics

Characteristic	SC Total n=82	RP2D (405 µg/kg SC QW)[a] n=30
Age, years, median (range)	63.0 (42–80)	61.5 (46–80)
Age ≥70 years, n (%)	22 (27)	7 (23)
Sex, n (%)		
Male	47 (57)	19 (63)
Female	35 (43)	11 (37)
Years since diagnosis, median (range)	5.9 (1–20)	5.6 (2–20)
Extramedullary plasmacytomas ≥1, n (%)[b]	27 (33)	10 (33)
Bone marrow plasma cells ≥60%, n (%)[c]	13 (17)	6 (21)
ISS stage, n (%)[d]		
I	26 (32)	12 (40)
II	36 (44)	13 (43)
III	13 (16)	3 (10)
Prior transplantation, n (%)	71 (87)	27 (90)

Characteristic	SC Total n=82	RP2D (405 µg/kg SC QW)[a] n=30
Prior lines of therapy, n, median (range)	6.0 (2–17)	6.0 (2–14)
Exposure status, n (%)		
Prior BCMA therapy[e]	20 (24)	8 (27)
Triple-class[f]	81 (99)	30 (100)
Penta-drug[g]	64 (78)	24 (80)
Refractory status, n (%)		
Pi[h]	69 (84)	25 (83)
Carfilzomib	54 (66)	19 (63)
IMiD[i]	76 (93)	28 (93)
Pomalidomide	67 (82)	26 (87)
Anti-CD38 mAb[j]	77 (94)	30 (100)
BCMA[e]	14 (17)	5 (16)
Triple-class[f]	62 (76)	23 (77)
Penta-drug[g]	23 (28)	6 (20)
To last line of therapy	69 (84)	26 (87)

Safety Profile

- Talquetamab has a tolerable safety profile at the RP2D of 405 μg/kg
  - No DLTs at the RP2D
  - Cytopenias mostly confined to step-up doses and cycles 1/2
  - Neutropenias generally resolved within a week and were limited to cycles 1/2
- Infections in 37% of SC and RP2D patients (grade 3/4: 9% for SC total; 3% for RP2D)
- Neurotoxicities (all grade 1/2) in 4 patients with SC dosing; 2 patients (7%) at RP2D
- Injection-site reactions in 17% of SC patients were all grade 1/2
- Skin-related AEs in 67% of SC patients; 77% at RP2D
  - Nail disorders in 21% of patients; 27% at RP2D

AE (≥20% of total SC), n (%)	SC Total n=82		RP2D (405 μg/kg SC QW)[a] n=30	
	Any grade	Grade 3/4	Any Grade	Grade 3/4
Hematologic				
Neutropenia	47 (57)	40 (49)	20 (67)	18 (60)
Anemia	37 (45)	23 (28)	17 (57)	8 (27)
Thrombocytopenia	23 (28)	15 (18)	10 (33)	6 (20)
Leukopenia	21 (26)	16 (20)	11 (37)	8 (27)
Lymphopenia	19 (23)	19 (23)	9 (30)	9 (30)
Nonhematologic				
CRS	55 (67)	1 (1)	22 (73)	1 (2)
Dysgeusia	38 (46)	NA	18 (60)	NA
Fatigue	26 (32)	0	9 (30)	0
Pyrexia	23 (28)	1 (1)	7 (23)	1 (2)
Dry mouth	22 (27)	0	8 (27)	0
Dysphagia	21 (26)	0	11 (37)	0
Headache	19 (23)	1 (1)	7 (23)	0
Diarrhea	18 (22)	0	7 (23)	0
Nausea	18 (22)	0	7 (23)	0

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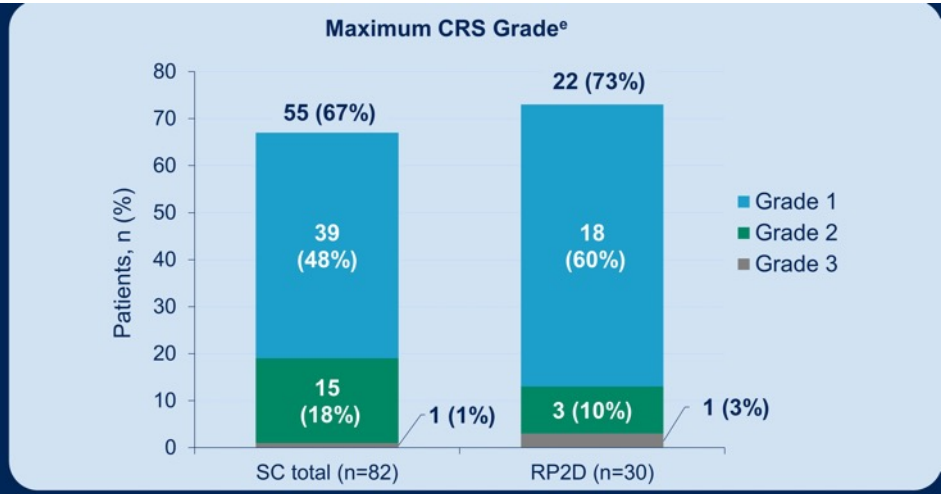
Cytokine Release Syndrome

Parameter	SC Total n=82	RP2D (405 µg/kg SC QW)[a] n=30
Patients with CRS, n (%)	55 (67)	22 (73)
Time to onset, days,[b] median (range)	2 (1–22)	2 (1–22)
Duration, days, median (range)	2 (1–7)	2 (1–3)
Supportive measures, n (%)[c]	55 (67)	22 (73)
Tocilizumab[d]	43 (52)	18 (60)
Steroids	5 (6)	1 (3)
Low-flow oxygen by nasal cannula	6 (7)	1 (3)
Vasopressor	2 (2)	1 (3)

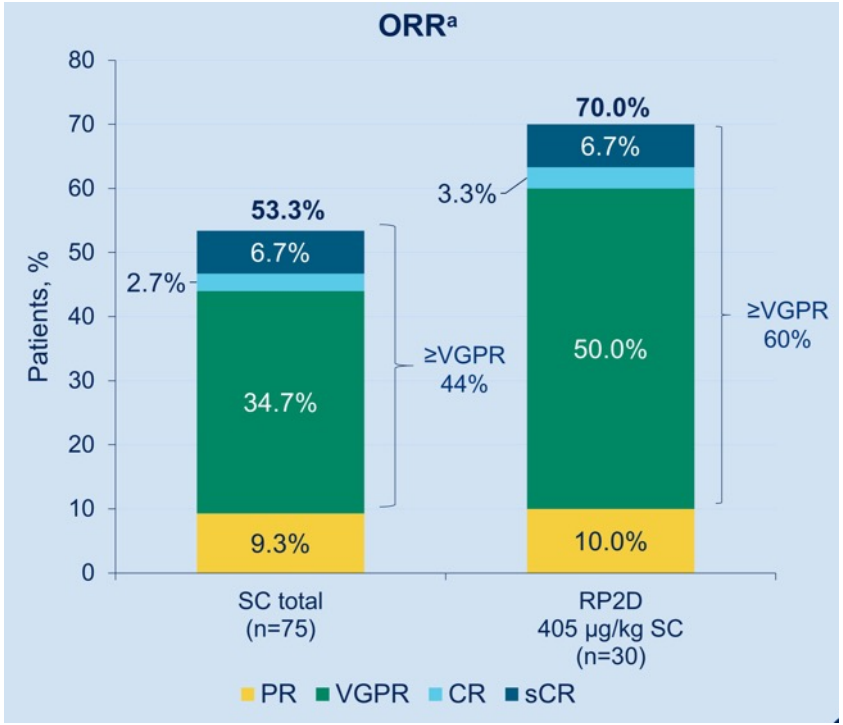


- CRS was generally confined to step-up and first full doses
- Across all SC cohorts, CRS was limited to grade 1/2 in all patients, with the exception of 1 patient with grade 3 CRS
  - Majority of patients only had 1 dose of tocilizumab as a supportive measure for CRS

Berdeja JG, et al. ASCO (abstr 8008)

Overall Response Rate

- The RP2D of 405 μg/kg SC QW has been administered to 30 patients with a median follow-up of 6.3 mo in responders
- At the RP2D
  - 70% ORR
  - Median time to first confirmed response was 1 mo
  - 65.2% (15/23) of triple-refractory patients responded
  - 83.3% (5/6) of penta-refractory patients responded
- Of 6 evaluable patients across IV and SC cohorts, 4 had MRD negative CR/sCR at 10^{-6}, including 1 patients in RP2D cohort
  - MRD negativity was sustained 7 months post CR in 1 evaluable patient



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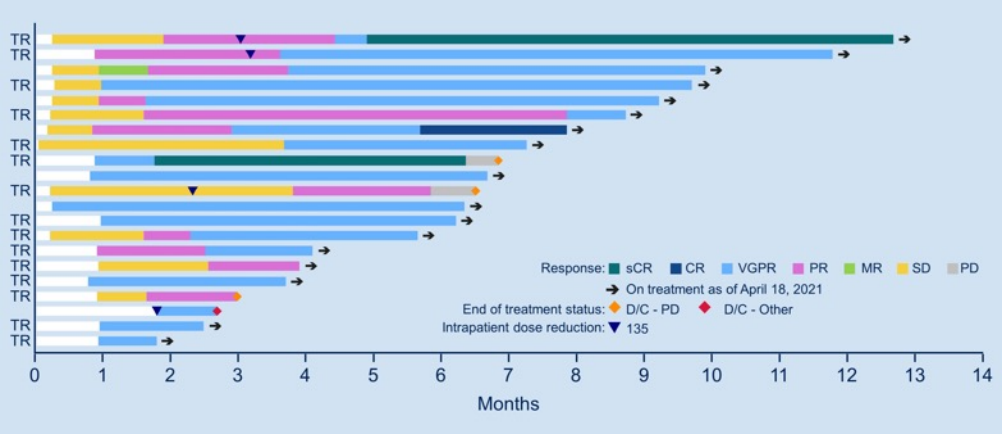
Duration of Response

- Response were durable and deepened over time
- At the RP2D of 405 μg/kg SC QW:
  - Median duration of response was not reached
  - 17/21 responders (81%) were continuing on treatment, after median follow-up of 6.3 months
- Data from IV cohorts (not shown) were more mature
  - Even at subtherapeutic doses, responses are ongoing at 22+ months in patients with longer follow-up



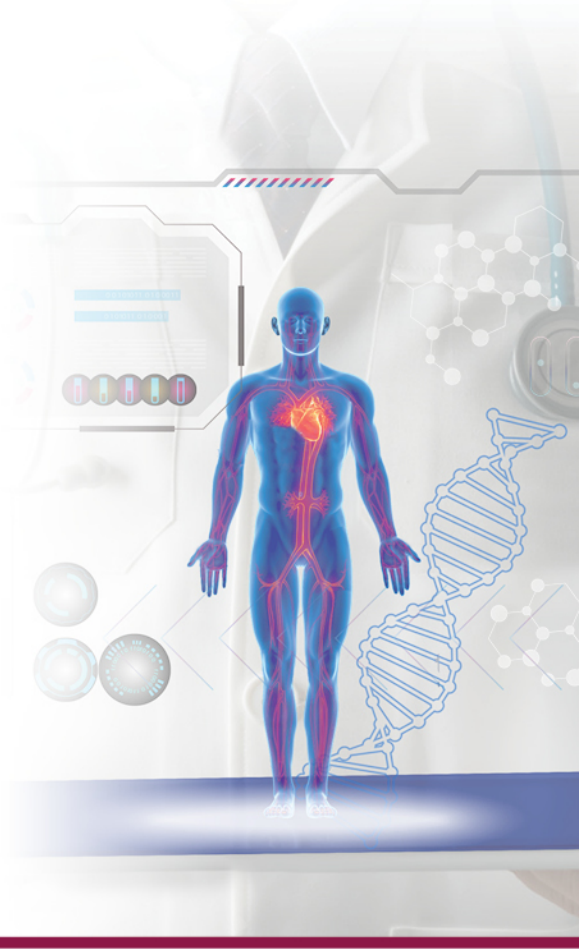
Berdeja JG, et al. ASCO (abstr 8008)

Authors' Conclusions

- Talquetamab is an off-the-shelf T-cell redirecting, GPRC5D targeting agent that requires limited steroid use and has a manageable safety profile at a dose of 405 μγ/kg SC QW
- Additional patients and longer follow-up support the RP2D
  - A high response rate was observed
  - High response rate was maintained in triple-refractory and penta-refractory patients
  - Responses were durable and continued to deepen over time
  - PK and PD data continue to support the RP2D
- Talquetamab showed encouraging efficacy in heavily pretreated patients with RRMM
  - A phase 2 expansion study of talquetamab at the RP2D is in progress (NCT04634552)

CARTITUDE-2: Efficacy and safety of ciltacabtagene autoleucel, a BCMA-directed CAR T-cell therapy in patients with progressive MM after 1-3 prior lines of therapy

Agha M, et al. ASCO (abstr 8013)

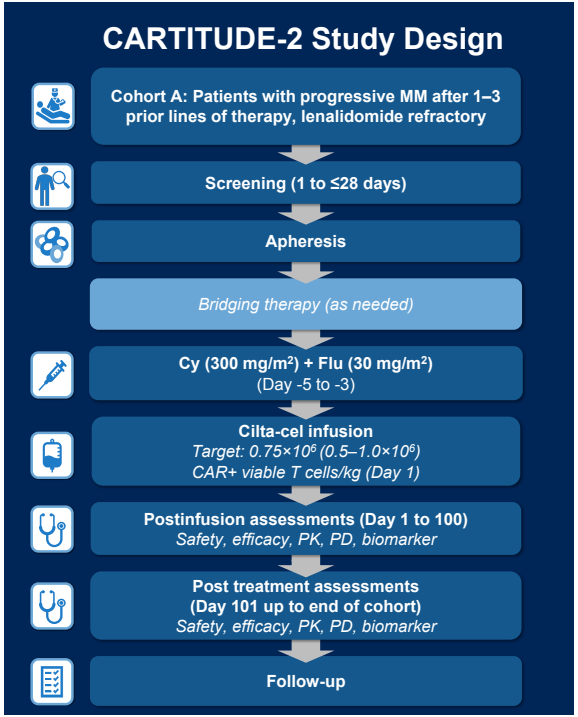


Introduction

- Patients who have progressive multiple myeloma (MM) after 1–3 lines of treatment and are refractory to lenalidomide and/or protease inhibitors, including bortezomib and carfilzomib, have limited treatment options
- Ciltacabtagene autoleucel (cilta-cel) is a chimeric antigen receptor T-cell therapy expressing 2 B-cell maturation antigen–targeting, single-domain antibodies designed to confer avidity
- In CARTITUDE-2, a multicohort phase 2 study, cilta-cel is being evaluated in patients with MM in earlier line settings than in CARTITUDE-1
  - Suitability of outpatient administration for cilta-cel is also being explored
- These results are from patients in Cohort A of CARTITUDE-2 who had progressive MM after 1–3 prior lines of therapy, and were refractory to lenalidomide

Methods

- The primary objective was minimal residual disease (MRD) 10^{-5} negativity
- The secondary outcomes were overall response rate (ORR), duration of response, time and duration of MRD negativity, and incidence and severity of adverse events (AEs)
  - ORR was assessed per International Myeloma Working Group response criteria
  - AEs were assessed according to the Common Terminology Criteria for AEs version 5.0
  - Cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity (ICANS) were graded according to the American Society for Transplantation and Cellular Therapy criteria



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Study Population and Baseline Characteristics

- As of Jan 2021 data cut-off, patients from Cohort A had a median follow-up of 5.8 months (range, 2.5–9.8)
- The 20 patients receiving cilta-cel had a median age of 60 years (range, 38–75) and 65% were male (
- 1 patient was treated in an outpatient setting
- Patients received a median of 2 (range, 1–3) prior lines of therapy; 12 patients received <3 prior lines and 8 patients received 3 prior lines of therapy
- All patients were exposed to PI, IMiD, and dexamethasone, 95% to alkylating agents, and 65% to daratumumab

Characteristics	N=20
Male, n (%)	13 (65.0)
Years since diagnosis, median (range)	3.5 (0.7–8.0)
Extramedullary plasmacytomas ≥1, n (%)	3 (15)
Bone marrow plasma cells[a] ≥60%, n (%)	3 (15)
High-risk cytogenetic profile, n (%)	7 (35)[b]
del17p	3 (15)
t(14;16)	5 (25)
t(4;14)	0
Prior lines of therapy, median (range)	2 (1–3)
Previous stem cell transplantation, n (%)	
Autologous	17 (85)
Allogeneic	0
Triple-class exposed,[c] n (%)	13 (65)
Triple-class refractory,[c] n (%)	8 (40)
Penta-drug exposed,[d] n (%)	4 (20)
Penta-drug refractory,[d] n (%)	1 (5)
Refractory status, n (%)	
Bortezomib	8 (40)
Carfilzomib	2 (10)
Pomalidomide	7 (35)
Daratumumab	12 (60)
Refractory to last line of therapy, n (%)	19 (95)

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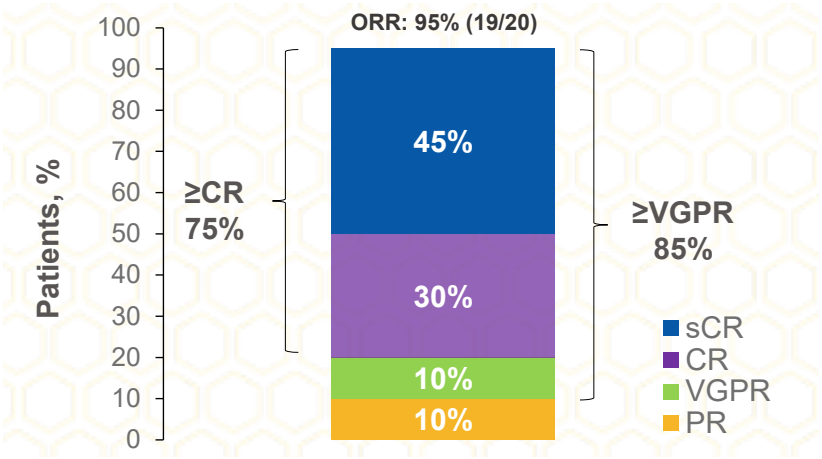
Efficacy

- ORR was 95%, with 75% of patients achieving CR/sCR
  - 85% of patients achieved ≥VGPR
- The median time to first response was 1.0 month and the median time to best response was 1.9 months
- Median duration of response was not reached
- All patients (n=4) with MRD-evaluable samples at the 10^{-5} threshold were MRD negative at data cut-off
  - Additional samples are being evaluated and will be updated at a later follow-up



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Safety

- Incidence of prolonged Grade 3/4 cytopenias beyond Day 60 was 25% for neutropenia, 0% for thrombocytopenia, and 45% for lymphopenia
- CRS occurred in 17 patients (85%); 2 patients (10%) had Grade 3/4 events
  - CRS resolved or recovered in 94% of patients at the time of data cut-off
- 3 patients had ICANS (1 Grade 1; 2 Grade 2); median time to onset was 8 days, and median duration was 2 days
- There were no cases of movement and neurocognitive AEs in patients of Cohort A in CARTITUDE-2

	N=20	
AEs ≥20%, n (%)	**Any grade**	**Grade 3/4**
Hematologic		
Neutropenia	19 (95)	18 (90)
Thrombocytopenia	16 (80)	7 (35)
Anemia	13 (65)	8 (40)
Lymphopenia	12 (60)	11 (55)
Leukopenia	11 (55)	11 (55)
CAR-T–related AEs		
CRS	17 (85)	2 (10)
Neurotoxicity	4 (20)	0 (0)

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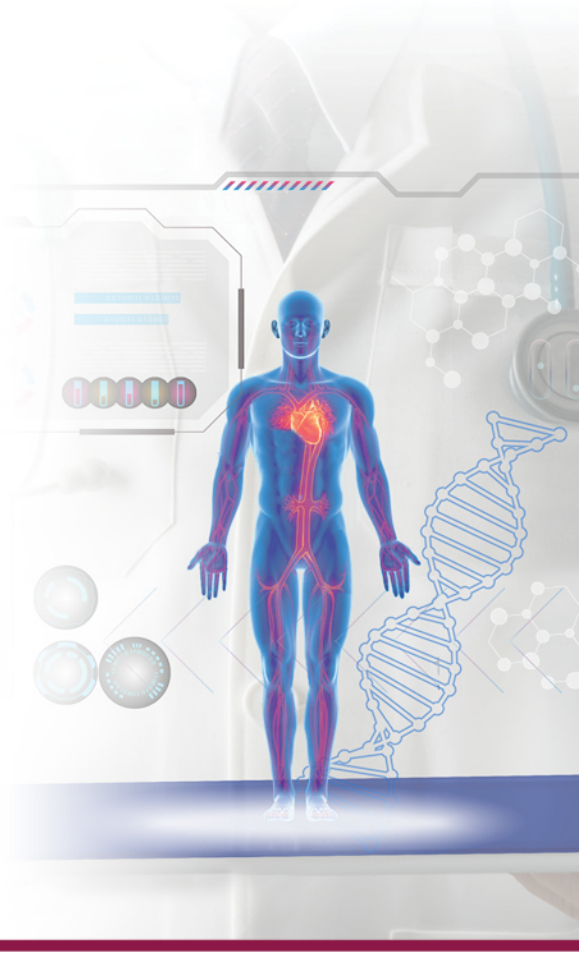
Authors' Conclusions

- A single infusion of cilta-cel led to early and deep responses in patients with MM who received 1–3 prior lines of therapy, and were lenalidomide refractory
  - Cilta-cel–treated patients who had received a median of 2 prior lines of treatment and were refractory to lenalidomide had an ORR of 95%, with 75% achieving CR or better, and 85% achieving VGPR or better
  - The safety profile was manageable, including in the patient treated in an outpatient setting
- Cilta-cel is being evaluated in other cohorts of CARTITUDE-2 in earlier line settings and in the phase 3 CARTITUDE-4 study in patients with 1–3 prior lines of therapy

Updates from EHA

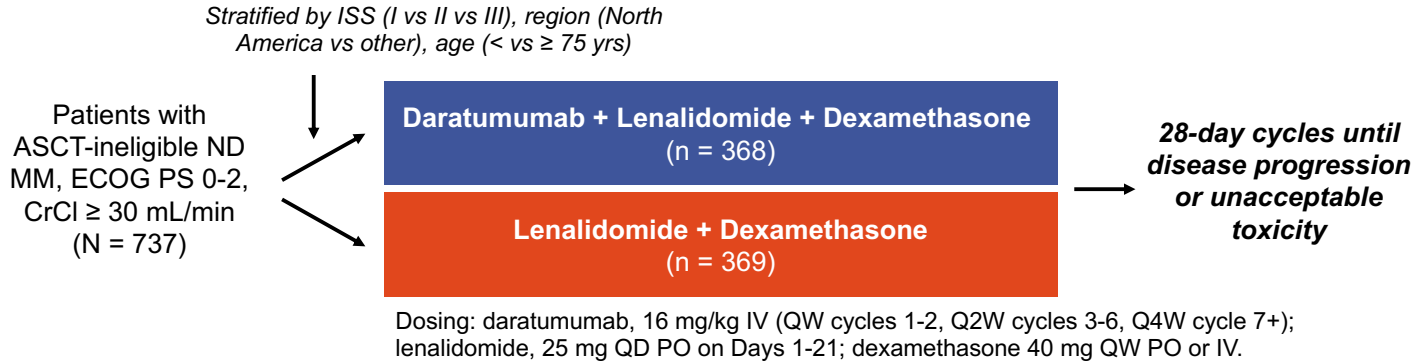
Overall Survival Results With Daratumumab, Lenalidomide, And Dexamethasone Versus Lenalidomide And Dexamethasone In Transplant-ineligible Newly Diagnosed Multiple Myeloma: Phase 3 MAIA Study

Facon T, et al. EHA (abstr LB1901)



MAIA: Study Design

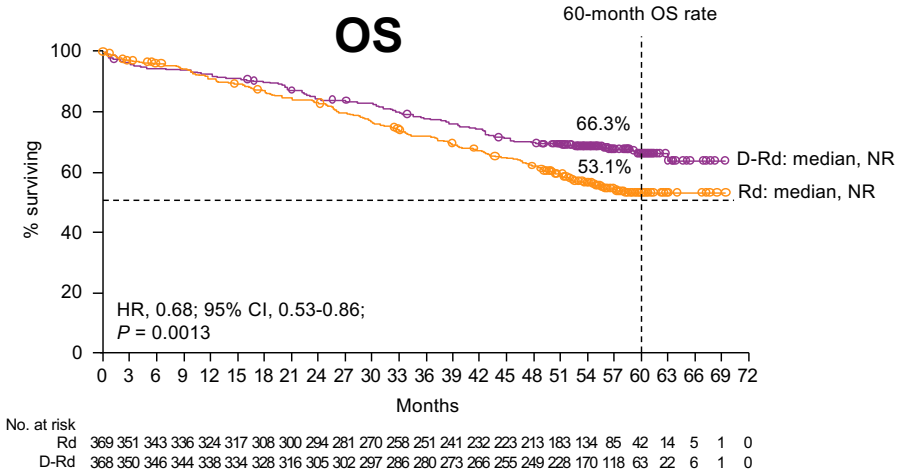
- Multicenter, open-label, randomized phase III trial

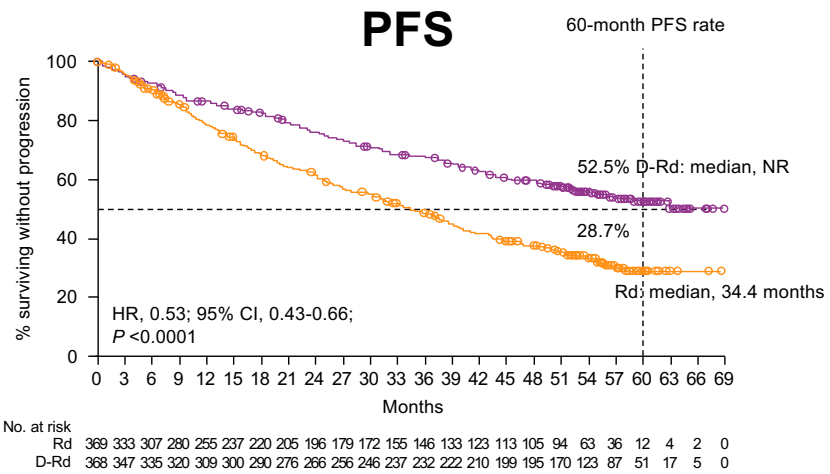


Dosing: daratumumab, 16 mg/kg IV (QW cycles 1-2, Q2W cycles 3-6, Q4W cycle 7+); lenalidomide, 25 mg QD PO on Days 1-21; dexamethasone 40 mg QW PO or IV.

- Primary endpoint: PFS
- Secondary endpoints: TTP, CR/sCR, MRD by NGS (10^{-5}), PFS2, OS, ORR, safety

MAIA: OS and PFS with D-Rd and Rd





D-Rd, daratumumab plus lenalidomide and Dexamethasone; Rd, lenalidomide and Dexamethasone; HR, hazard ration; CI, confidence interval; NR, not reached.

Authors' Conclusions

- After almost 5 years of follow-up, a significant and clinically meaningful OS improvement was demonstrated with the use of D-Rd versus Rd in patients with NDMM who are transplant ineligible, representing a 32% reduction in the risk of death
- The significant PFS benefit of D-Rd versus Rd from the primary analysis (median follow-up, 28 months) was maintained, with a 47% reduction in risk of disease progression or death and a median PFS for D-Rd NR
- The favorable benefit-risk profile observed supports the use of D-Rd in transplant-ineligible patients with NDMM
- These results, together with the OS benefit observed in ALCYONE, support the use of frontline DARA-based combination regimens to maximize PFS for optimal long-term outcomes

Overall Conclusions

- In transplant candidates, the role of daratumumab maintenance remains to be determined
- The addition to carfilzomib to lenalidomide in the maintenance setting after autotransplant is associated with improved outcomes in standard and high risk patients.
- Bispecific antibodies against multiple targets will soon become part of the standard care of patients with myeloma
- In the newly diagnosed, non transplant patient, the combination of dara/len/dex is associated with an overall survival advantage to len/dex alone

Thank You!

Next presentation: Wednesday, August 18
Agents Targeting BCMA
Presented by Noopur Raje, MD