ELSEVIER

Blood 142 (2023) 1028–1032

The 65th ASH Annual Meeting Abstracts

ORAL ABSTRACTS

705.CELLULAR IMMUNOTHERAPIES: LATE PHASE AND COMMERCIALLY AVAILABLE THERAPIES

Idecabtagene Vicleucel (ide-cel) Versus Standard (std) Regimens in Patients (pts) with Triple-Class-Exposed (TCE) Relapsed and Refractory Multiple Myeloma (RRMM): Updated Analysis from KarMMa-3

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Introduction

A single ide-cel infusion showed significantly longer median progression-free survival (PFS) vs std regimens (13.3 vs 4.4 months [mo], HR 0.49, 95% CI 0.38-0.65, $P < 0.001$) with deep, durable responses in heavily pretreated TCE RRMM at an interim analysis

(IA) of KarMMa-3 (NCT03651128); safety data were consistent with prior studies (Rodríguez-Otero et al. *NEJM* 2023). Ide-cel benefits were consistent across pts in high-risk subgroups and across 2-4 prior lines of therapy (Tx). Results of the preplanned final PFS analysis of KarMMa-3 with 12.3 mo additional follow-up are reported.

Methods

In the phase 3 KarMMa-3 trial, pts with RRMM who received 2-4 prior regimens, including an immunomodulatory agent, proteasome inhibitor, and daratumumab, and were refractory to last regimen were randomized 2:1 to ide-cel or a std regimen (DPd, DVd, IRd, Kd, or EPd). In the ide-cel arm, pts could receive ≤ 1 cycle of optional bridging Tx for disease control. Pts in the std regimens arm could receive ide-cel after confirmed disease progression (PD). The primary endpoint was IRC-assessed PFS in the ITT population; final PFS was planned to be analyzed with ~289 events. Key secondary endpoints were IRC-assessed overall response rate (ORR) and overall survival (OS); other secondary endpoints included complete response rate (CRR), duration of response (DOR), minimal residual disease (MRD) status, time to next anti-myeloma Tx (TTNT; time from randomization to next anti-myeloma Tx [MTx]), event-free survival (EFS; time from randomization to first PD, next MTx or any-cause death, whichever is first), PFS2 (time from randomization to second objective PD or any-cause death, whichever is first), safety, and health-related quality of life (QOL).

Results

Of 386 randomized pts (ide-cel, n = 254; std regimens, n = 132), 225 received ide-cel and 126 received a std regimen. Baseline characteristics were generally balanced. Median follow-up from randomization to data cutoff (April 28, 2023) was 30.9 mo (range 12.7-47.8). Ide-cel significantly improved median PFS (95% CI) vs std regimens (13.8 [11.8-16.1] vs 4.4 [3.4-5.8] mo), representing a 51% reduced risk of PD or death (HR 0.49, 95% CI 0.38-0.63; **Figure**); 18 mo PFS rates were 41% vs 19%, respectively. Ide-cel significantly improved ORR vs std regimens (71% vs 42%) with deeper (CRR 44% vs 5%; ≥CR and MRD negative status [sensitivity level 10^{-5}], 22% vs 1%), more durable responses (median DOR 16.6 vs 9.7 mo; **Table**). PFS and ORR benefits of ide-cel vs std regimens were consistent with the IA. Interim OS will be included in the presentation. In pts who received ide-cel (n = 225) or a std regimen (n = 126), median PFS (95% CI) was 15.7 (12.5-18.9) vs 4.4 (3.4-5.8) mo, respectively. In the ITT population, median TTNT, EFS, and PFS2 were numerically longer with ide-cel vs std regimens. Median (range) TTNT was 20.9 (16.6-24.2) vs 7.0 (5.3-8.5) mo. Median (95% CI) EFS was 13.3 (11.3-15.7) vs 3.9 (3.0-5.3) mo. Median PFS2 (95% CI) was 23.5 (18.4-27.9) vs 16.7 (12.2-20.3) mo; ide-cel was next MTx in 70 (53%) pts in the std regimens arm. In the treated population, grade (gr) 3/4 infections occurred in 66/249 (27%) pts in the ide-cel arm vs 25/126 (20%) in the std regimens arm. In the ide-cel safety population, any gr cytokine release syndrome occurred in 197/225 (88%) pts, gr ≥ 3 in 11 (5%); median time to first onset was 1 d (1-14), median duration was 4 d (1-51). Any gr investigator-identified neurotoxicity occurred in 34/225 (15%) pts, gr ≥ 3 in 7 (3%); median time to onset was 3 d (range 1-317); median duration was 2.5 d (range 1-252). Ide-cel continued to demonstrate durable, clinically meaningful improvements in pt-reported outcomes, including symptoms, functioning, and QOL vs std regimens.

Conclusions

In this final PFS analysis of KarMMa-3, significantly longer PFS was maintained with ide-cel; PD or death risk reduced by 51%; responses were deeper and more durable vs std regimens. CRR with ide-cel increased since the IA, indicating a deepening response, but were unchanged with std regimens. A single ide-cel infusion vs continuous treatment with std regimens resulted in longer median TTNT and PFS2, indicating improved long-term disease control. The ide-cel safety profile was consistent with previous reports, with no parkinsonism or Guillain-Barré syndrome reported. These data continue to support use of ide-cel in pts with TCE RRMM.

Study support

2seventy bio and Celgene, a Bristol-Myers Squibb Company.

Disclosures Rodríguez Otero: *Oncopeptides:* Membership on an entity's Board of Directors or advisory committees; *AbbVie:* Consultancy, Membership on an entity's Board of Directors or advisory committees; *Regeneron:* Other: Honoraria for lectures; *Amgen:* Other: Honoraria for lectures; *Roche:* Consultancy; *Pfizer:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Travel grants; *GlaxoSmithKline:* Membership on an entity's Board of Directors or advisory committees, Other: Honoraria for lectures; *Sanofi:* Membership on an entity's Board of Directors or advisory committees, Other: Honoraria for lectures; *Janssen:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Honoraria for lectures; *Bristol Myers Squibb:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Honoraria for lectures. **Ailawadhi:** *AbbVie, Amgen, Ascentage, BMS, Cellectar, GSK, Janssen, Pharmacyclics, Sanofi:* Research Funding; *Beigene, BMS, Cellectar, GSK, Janssen, Pfizer, Regeneron, Sanofi, Takeda:* Consultancy. **Arnulf:** *Bristol Myers Squibb:* Consultancy, Honoraria, Other: Meeting travel payments; *Sanofi:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Meeting travel payments; *Amgen:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Meeting travel payments; *Takeda:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Meeting travel payments; *Janssen:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Meeting travel payments, Research Funding. **Patel:** *Takeda:* Consultancy; *AbbVie; Allogene Therapeutics, Inc.; Arcellx; Bristol Myers Squibb/Celgene Corporation; Cellectis; Janssen Pharmaceuticals, Inc.; Nektar Therapeutic; Poseida Therapeutics; Precision BioSciences, Inc.; and Takeda Pharmaceuticals U.S.A., Inc.:* Research Funding; *AbbVie; Arcellx, AstraZeneca; Bristol Myers Squibb/Celgene Corporation; Caribou Science; Cellectis; Curio Bioscience; Genentech; Janssen Pharmaceuticals, Inc.; Karyopharm; Legend Biotech; Merck & Co., Inc.; Oncopeptides; Pfizer; Precision BioSciences:* Consultancy. **Cavo:** *Adaptive:* Honoraria; *Celgene/Bristol Myers Squibb:* Consultancy, Hono-

raria, Speakers Bureau; *Sanofi:* Consultancy, Honoraria; *Janssen:* Consultancy, Honoraria, Speakers Bureau; *Takeda:* Honoraria; *GlaxoSmithKline:* Honoraria; *AbbVie:* Consultancy, Honoraria; *Amgen:* Honoraria; *Roche:* Honoraria. **Nooka:** *Aduro Biotech, Amgen, Arch Oncology, Bristol Myers Squibb, Cellectis, Genentech, GlaxoSmithKline, Janssen, Karyopharm, Kite Pharma, Merck, Pfizer, Takeda:* Honoraria, Research Funding; *Adaptive Biotechnologies, Amgen, BeyondSpring, Bristol Myers Squibb, Cellectar Biosciences, GlaxoSmithKline, Janssen, Karyopharm, Oncopeptides, ONK therapeutics, Pfizer, Sanofi, Secura Bio, Takeda:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees. **Manier:** *Amgen:* Honoraria; *BMS:* Honoraria; *Abbvie, Amgen, Celgene/BMS, GlaxoSmithKline, Janssen, Novartis, Pfizer, Regeneron, Roche, Sanofi, Takeda:* Membership on an entity's Board of Directors or advisory committees; *Janssen:* Honoraria. **Costa:** *Adaptive biotechnologies:* Consultancy, Honoraria; 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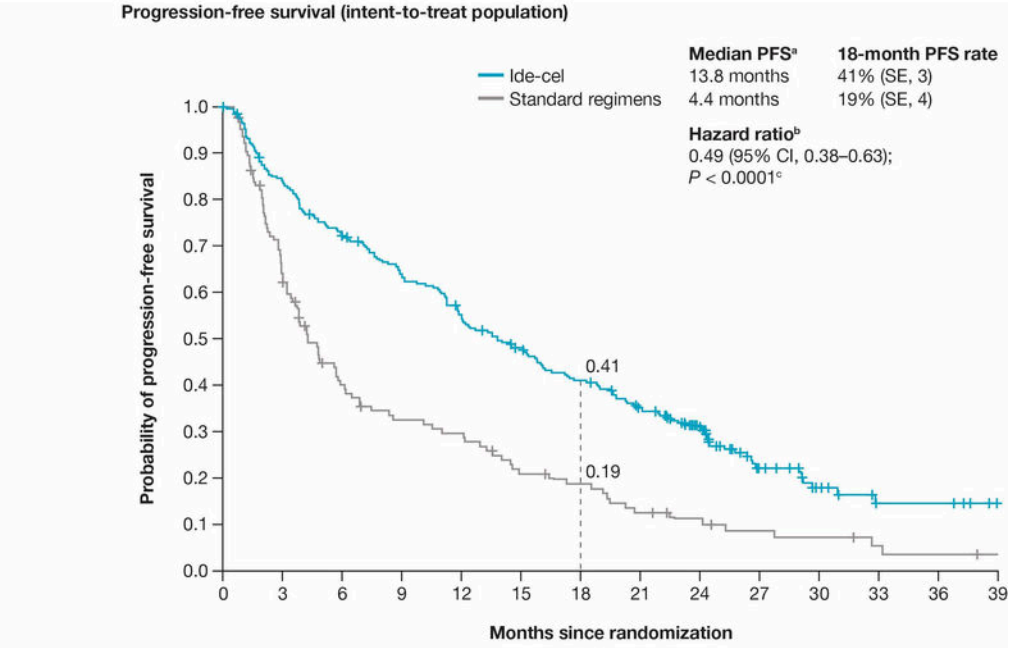
search Funding; *GSK:* Research Funding; *Genentech:* Research Funding; *Fate Therapeutics:* Research Funding; *EMD Serono:* Research Funding; *CRISPR Therapeutics:* Consultancy, Research Funding; *Celularity:* Research Funding; *Cartesian:* Research Funding; *CARsgen:* Research Funding; *C4 Therapeutics:* Research Funding; *Celgene:* Consultancy, Research Funding; *Amgen:* Research Funding; *AbbVie:* Research Funding; *Bristol Myers Squibb:* Consultancy, Research Funding; *Acetylon:* Research Funding; *2seventy bio:* Consultancy, Research Funding; *Legend Biotech:* Consultancy; *Lilly:* Research Funding; *Novartis:* Research Funding; *Poseida:* Research Funding; *Sanofi:* Research Funding; *Takeda:* Consultancy, Research Funding; *Roche:* Consultancy; *Teva:* Research Funding. **Truppel-Hartmann:** *2seventy bio:* Current Employment. **Bhatnagar:** *Bristol Myers Squibb:* Consultancy; *Syneos Health:* Current Employment. **Wu:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company. **Piasecki:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company, Divested equity in a private or publicly-traded company in the past 24 months, Other: Current holder of stock options in publicly-traded company. **Eliason:** *GlaxoSmith-Kline:* Ended employment in the past 24 months; *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company. **Dhanda:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company. **Felten:** *Bristol Myers Squibb:* Current Employment. **Caia:** *Bristol Myers Squibb:* Current Employment. **Cook:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company. **Popa-McKiver:** *Bristol Myers Squibb:* Current Employment, Current equity holder in publicly-traded company. **Giralt:** *Amgen, Actinuum, Celgene/BMS, Kite Pharma, Janssen, Jazz Pharmaceuticals, Johnson & Johnson, Novartis, Spectrum Pharma, Takeda:* Membership on an entity's Board of Directors or advisory committees; *Amgen, Actinuum, Celgene/BMS, Omeros, Johnson & Johnson, Miltenyi, Takeda:* Research Funding.

OffLabel Disclosure: In the US, ide-cel is indicated for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. The current abstract presents data from the phase 3 KarMMa-3 trial of ide-cel vs standard regimens in patients with RRMM who had received two to four prior regimens and were refractory to the last regimen.

Figure: Kaplan–Meier curve of progression-free survival (intent-to-treat population)



No. at risk														
Ide-cel	254	206	177	153	131	111	94	77	54	25	14	7	7	2
Standard regimens	132	76	43	34	31	21	18	12	9	6	5	3	2	1

Per IRC based on IMWG criteria.
[a]Based on Kaplan-Meier approach; [b]Statified HR based on univariate Cox proportional hazard model. CI is two-sided;
[c]Based on stratified log-rank test.
CI, confidence interval; ide-cel, idacabtagene vicleuel; IMWG, International Myeloma Working Group;
IRC, Independent Response Committee; PFS, progression-free survival; SE, standard error

Table. Efficacy outcomes

	Ide-cel (n = 254)	Standard regimens (n = 132)
ORR,[a] % (95% CI)	71.3 (65.7–76.8)	42.4 (34.0–50.9)
OR (95% CI)[b]	3.4 (2.2–5.2)	
CR rate,[c] % (95% CI)	43.7 (37.6–49.8)	5.3 (1.5–9.1)
Median DOR, months (95% CI)[d,e]	16.6 (12.1–19.6)	9.7 (5.5–16.1)
DOR rate at 18 months, % (SE)[f]	46.1 (3.8)	27.6 (6.4)
MRD negativity in patients with ≥ CR, n/N (%)[g]	57/254 (22.4)	1/132 (0.8)
95% CI	(17.3–27.6)	(0.0–2.2)
Median TTNT, months (range)[d,h]	20.9 (16.6-24.2)	7.0 (5.3-8.5)
Median EFS, months (95% CI)[d]	13.3 (11.3–15.7)	3.9 (3.0–5.3)
Median PFS2, months (95% CI)[d]	23.5 (18.4–27.9)	16.7 (12.2–20.3)[i]

[a]Patients with PR or better; [b]Unstratified OR. Calculated based on the observed response rate with 2-sided Wald CI;
[c]Patients with CR or sCR; [d]Based on Kaplan–Meier estimation per IRC based on IMWG criteria; [e]In patients with a response; [f]Based on Greenwood formula; [g]Defined as ≥ 1 negative MRD value within 3 months prior to achieving ≥ CR until PD or death. MRD was assessed by next-generation sequencing at a sensitivity of 10^{-5} per IMWG Uniform Response Criteria and as specified by the protocol. 95% CI was calculated using 2-sided Wald interval; [h]Time from randomization to first subsequent anti-myeloma therapy; [i]Includes 70 (53%) patients from the standard regimens arm who received ide-cel as subsequent therapy after experiencing confirmed disease progression.
CR, complete response; DOR, duration of response; EFS, event-free survival; IMWG, International Myeloma Working Group; IRC, Independent Response Committee; ITT, intent-to-treat; MRD, minimal residual disease; OR, odds ratio; ORR, overall response rate; PD, progressive disease; PFS2, progression-free survival 2; PR, partial response; sCR, stringent complete response; SE, standard error; TTNT, time to next anti-myeloma therapy.

Figure 1

https://doi.org/10.1182/blood-2023-178933