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Real-world Treatment Patterns, Efficacy, and Safety of Daratumumab-based Regimens in Chinese Patients with Multiple Myeloma: Final Analysis of the MMY4032 Study

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Key Takeaway

This RW study represents one of the largest and first of its kind studies designed to explore patient characteristics, treatment patterns, and clinical outcomes in Chinese MM patients who received DARA-based therapy in clinical practice. Favorable clinical outcomes were observed, with greater benefits seen in earlier DARA treatment.

Conclusions

The final analysis of MMY4032 study provided valuable insight into the treatment patterns and clinical outcomes for Chinese patients with MM in routine clinical practice.

The rate of ≥VGPR were higher when DARA was initiated in earlier lines of therapy. Similarly, more favorable survival outcomes (i.e., PFS and OS) were observed with earlier DARA treatment, consistent with the results of TTNT.

With additional follow-up, DARA-based regimens demonstrated robust effectiveness and manageable safety profiles, which further supports the clinical utility of DARA and highlights its role in improving long-term outcomes in MM.

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Disclosures

N/A

Introduction

- Daratumumab (DARA) is a human IgGκ monoclonal antibody targeting CD38 with a direct on-tumor[1-4] and immunomodulatory mechanism of action[5-7]. In multiple clinical controlled trials (RCT), DARA demonstrated significant efficacy and safety in patients with multiple myeloma (MM), enabling it as the standard of care recommended by clinical guidelines in many countries[8-12].
- Real-world (RW) studies provide important complementary data to RCT and additional insight into routine clinical practice. Thus, a non-interventional observational phase 4 study (MMY4032, ChiCTR2200055491) was designed to investigate the treatment patterns and clinical outcomes of MM patients receiving DARA in China in routine clinical practice.
- The first interim and updated analysis of the MMY4032 study described patient characteristics, RW treatment patterns, preliminary effectiveness and safety for DARA in Chinese patients with MM who received DARA-based regimens[13-14].
  - Here, we presented the final analysis of this study including treatment patterns, treatment response, survival outcomes, and safety in Chinese patients with MM who were treated with DARA-based regimens in routine clinical practice.

Methods

Study design and patients

- This was a multicenter, non-interventional, observational study enrolled Chinese MM patients across 13 sites.
- All patients were aged ≥18 years, had symptomatic newly diagnosed or relapsed/refractory MM, and had either started DARA after August 1, 2019, and were to continue DARA at the time of study initiation (November 3, 2021), or started DARA after study initiation.
- Patients who had received ≥4 prior lines of MM therapy before starting DARA-based treatment, who had a diagnosis of other cancers (prior to MM diagnosis), or who were currently participating in another investigational study were excluded.
- The decision to treat with DARA must have been made prior to and independently of the patient's inclusion in the study, and treatment was administered in accordance with local clinical practice.

Study endpoints

- The primary objectives of this study were to describe treatment patterns and clinical outcomes in routine clinical practice among Chinese patients with MM who were treated with DARA. The secondary objective of this study was to assess the safety and tolerability of DARA in Chinese patients with MM.
- Continuous and categorical variables were summarized using descriptive statistics, and time-to-event variables were estimated using the Kaplan–Meier method.
- The safety set (SAF) was defined as all enrolled patients who received at least one dose of daratumumab.
- The response-evaluable set (RES) was all treated patients with MM who initiated daratumumab treatment and have at least one tumor measurement, disease progression, or death.

Results

Patients and study disposition

- As of the cutoff date (December 30, 2024), a total of 212 patients with MM who had received ≥1 DARA treatment, were included in this study.
- A summary of patient demographic and disease characteristics overall and by DARA-based regimen was presented in **Table 1**.
  - For the overall population, the median (range) age at baseline was 61 (29-89) years and the median time since MM diagnosis to DARA initiation was 1 (0-12) year.
- At the date cutoff, 24 patients were ongoing in this study and 137 patients had discontinued due to withdrawal (n=62), death (n=43), and lost to follow-up (n=15).

Table 1: Patient demographic and baseline disease characteristics[a]

Characteristic	Overall N=212	Dara Mono N=23	Dara+Dexa N=21	Dara+Pls (+Dexa) N=58	Dara+IMiDs (+Dexa) N=72	Dara+Pls+ IMiDs(+Dexa) N=32	Dara+Others N=6
Age, median (range), y	61 (29-89)	61 (47-81)	61 (42-83)	61.5 (37-89)	61 (29-81)	59 (41-74)	59.5 (43-66)
Time from diagnosis to DARA initiation							
n	211	23	21	58	71	32	6
Median (range), y	1 (0-12)	2 (0-8)	1 (0-9)	0 (0-6)	1 (0-12)	0 (0-12)	3 (0-7)
Sex, n (%)							
Male	122 (57.5)	14 (60.9)	10 (47.6)	39 (67.2)	38 (52.8)	18 (56.3)	3 (50.0)
Female	90 (42.5)	9 (39.1)	11 (52.4)	19 (32.8)	54 (47.2)	14 (43.8)	3 (50.0)
ISS disease stage, n (%)							
n	141	14	13	34	54	23	3
I	30 (21.3)	3 (21.4)	2 (15.4)	3 (8.8)	16 (29.6)	6 (26.1)	0
II	53 (37.6)	6 (42.9)	7 (53.8)	11 (29.4)	19 (35.2)	10 (43.5)	1 (33.3)
III	58 (41.1)	5 (35.7)	4 (30.8)	21 (61.8)	19 (35.2)	7 (30.4)	2 (66.7)
ECOG PS, n (%)							
n	131	16	12	33	44	22	4
0	30 (22.9)	3 (18.8)	2 (16.7)	9 (27.3)	13 (29.5)	2 (9.1)	1 (25.0)
1	76 (58.0)	9 (56.3)	6 (50.0)	18 (54.5)	23 (52.3)	14 (77.3)	3 (75.0)
2	16 (12.2)	3 (18.8)	3 (25.0)	3 (9.1)	4 (9.1)	2 (13.6)	0
≥3	9 (6.9)	1 (6.3)	1 (8.3)	3 (9.1)	4 (9.1)	0	0

DARA, daratumumab; Mono, monotherapy, Dexa, dexamethasone; PI, proteasome inhibitor; IMiD, immunomodulatory drug; y, year; ISS, International Staging System; ECOG PS, Eastern Cooperative Oncology Group performance status.
[a]Data from safety set, defined as all enrolled patients who received at least one dose of daratumumab.

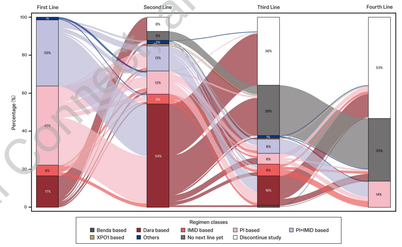
Treatment patterns

- In the SAF, most patients (n = 177 [83.5%]) had received ≥1 line of therapy before initiating DARA.
- More than half of patients (n = 115 [54.2%]) initiated DARA as 2nd-line therapy; DARA + IMiD ± Dexa (n = 72) and DARA + PI ± Dexa (n = 58) were the most frequently reported DARA-based regimens. **(Figure 1)**
- The median (range) duration of DARA exposure was 8.4 (0-63.2) months overall and was longest when DARA was initiated in earlier lines of therapy: 9.8 (0.3-46.9) months in the 1st line, 8.2 (0-63.2) months in the 2nd line, 8.6 (0.1-35.4) months in the 3rd line, and 4.7 (0.5-31.2) months in the >3rd line.

Clinical outcomes

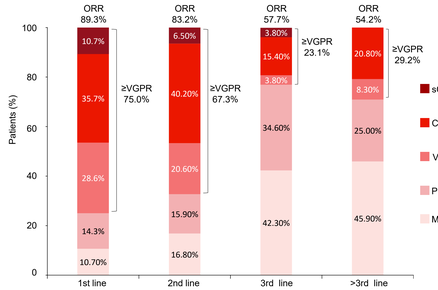
- In the RES, at a median follow-up time of 23.7 months, the overall response rate (ORR) was 76.8%, with 57.2% achieving very good partial response or better (≥VGPR).
  - The higher response rates were observed when DARA was initiated in earlier lines of therapy with ORR of 89.3% and ≥VGPR of 75.0% in 1st line therapy. **(Figure 2)**
- The median PFS and OS was 34.1 (95% confidence interval [CI], 29.5-not estimate) months and not reached, respectively, and estimated 36-month rates were 49.0% and 76.5%. **(Table 2)**
  - PFS and OS rates at 36 months were higher when DARA was initiated in earlier lines of therapy with 60.4% and 84.3% observed in 1st line therapy. **(Table 2 and Figure 3)**
- The median TTNT was not reached with the 24-month TTNT rate of 75.6%. **(Table 3)**
  - TTNT rates at 24months were higher when DARA was initiated in earlier lines of therapy with 79.5% observed in 1st line therapy. **(Table 3 and Figure 4)**

Figure 1: Sankey diagram to regimen used by therapy lines[a]



Benda, bendamustine; DARA, daratumumab; IMiD, immunomodulatory drug; PI, proteasome inhibitor; XPO1, exportin 1.
[a]Data from safety set, defined as all enrolled patients who received at least one dose of daratumumab.

Figure 2: Response by line of therapy in which DARA was initiated[a]



DARA, daratumumab; ORR, overall response rate; sCR, stringent complete response; CR, complete response; VGPR, very good partial response; PR, partial response; MR, minimal response; SD, stable disease; PD, progressive disease; NE, not evaluable.
[a]Data from response-evaluable set, defined as all treated patients with MM who initiated daratumumab treatment and have at least one tumor measurement, disease progression, or death.

Table 2: Survival outcomes by line of therapy in which DARA was initiated[a]

Survival outcome	1st line	2nd line	3rd line	>3rd line
PFS				
Median (95% CI), mo	NE (32.5-NE)	NE (34.1-NE)	25.3 (7.5-NE)	23.85 (8.9-29.5)
12-mo PFS, %	84.1 (63.1-93.7)	86.6 (78.0-92.0)	65.3 (42.5-80.9)	67.0 (42.7-82.8)
36-mo PFS, %	60.4 (34.0-79.0)	58.3 (40.3-72.6)	28.8 (6.8-56.1)	20.1 (5.1-42.2)
OS				
Median (95% CI), mo	NE (NE-NE)	NE (NE-NE)	37.3 (25.3-NE)	NE (29.5-NE)
12-mo PFS, %	100.0 (100.0-100.0)	91.7 (84.0-95.8)	82.9 (60.7-93.2)	86.7 (64.0-95.5)
36-mo PFS, %	84.3 (58.2-94.8)	82.4 (72.2-89.1)	62.5 (34.9-81.0)	50.7 (15.4-78.1)

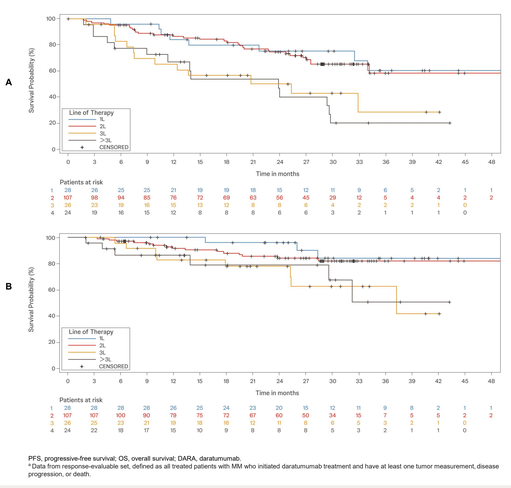
DARA, daratumumab; PFS, progressive-free survival; CI, confidence interval; mo, month; NE, not estimable; OS, overall survival.
[a]Data from response-evaluable set, defined as all treated patients with MM who initiated daratumumab treatment and have at least one tumor measurement, disease progression, or death.

Table 3: TTNT by line of therapy in which DARA was initiated[a]

	1st line	2nd line	3rd line	>3rd line
TTNT				
Median (95% CI), mo	NE (34.0-NE)	NE (NE-NE)	32.8 (10.1-NE)	29.5 (11.3-NE)
12-mo TTNT, %	96.4 (77.2-99.5)	88.0 (79.8-93.0)	70.2 (47.4-84.6)	71.4 (46.6-86.2)
24-mo TTNT, %	79.5 (57.3-91.0)	79.5 (69.6-86.5)	65.5 (42.6-81.1)	64.3 (38.1-81.7)

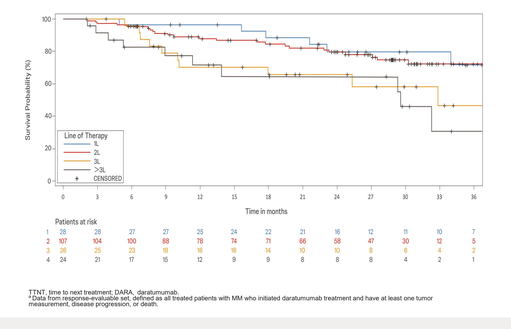
TTNT, time to next treatment; DARA, daratumumab; CI, confidence interval; mo, month; NE, not estimable.
[a]Data from response-evaluable set, defined as all treated patients with MM who initiated daratumumab treatment and have at least one tumor measurement, disease progression, or death.

Figure 3: PFS A) and OS B) by line of therapy in which DARA was initiated[a]



PFS, progressive-free survival; OS, overall survival; DARA, daratumumab.
[a]Data from response-evaluable set, defined as all treated patients with MM who initiated daratumumab treatment and have at least one tumor measurement, disease progression, or death.

Figure 4: TTNT by line of therapy in which DARA was initiated[a]



TTNT, time to next treatment; DARA, daratumumab.
[a]Data from response-evaluable set, defined as all treated patients with MM who initiated daratumumab treatment and have at least one tumor measurement, disease progression, or death.

Safety

- No new safety concerns were observed with additional follow-up.
- ADRs and serious TEAEs were reported in 47 (22.2%) and 35 (16.5%) patients, respectively.
- Among the 43 reported deaths, progressive disease (n = 21) and other/unknown (n = 14) were the most common primary causes.

References

1. de Weers M, et al. J Immunol. 2011;186(3):1840-1848. 2. Lammerts van Bueren J, et al. Blood. 2014;124(21):3474. 3. Overdijk MB, et al. MAbs. 2015;7(2):311-321. 4. Overdijk MB, et al. J Immunol. 2016;197(3):807-813. 5. Krejcik J, et al. Blood 2016;128(3):384-394. 6. Adams HC III, et al. Cytometry A. 2019;95(3):279-289. 7. Casneuf T, et al. Leukemia. 2021;35(2):573-584. 8. Dimopoulos MA, et al. Ann Oncol. 2021;32(3):309-322. 9. NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma (Version 2.2026).2025;26. 10. Usmani SZ, et al. Blood Adv. 2023;7(14):3739-3748. 11. Mateos MV, et al. Lancet Oncol. 2025;26(5):596-608. 12. Moreau P, et al. Lancet Oncol. 2024;25(8):1003-1014. 13. Wang L, et al. BMC Cancer. 2025;25(1):836. 14. Wang L, et al. EHA 2024. Poster 1981.

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