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Analysis of Patients With Prior BCMA-Targeted Therapy and Those Achieving CR in REALiTAL: A Multi-Country Observational Study of Talquetamab in RRMM Outside of Clinical Trials

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Key Takeaway

These findings highlight talquetamab's potential as an effective real-world treatment for RRMM both before and after BCMA-targeting therapies

Conclusions

- Talquetamab was effective for patients with prior anti-BCMA therapy, including anti-BCMA TCRT. For TCRT-exposed patients, ORR and DOR were best for patients with prior CAR-T
- AEs were clinically manageable, with no new safety signals, and the safety profile of talquetamab was consistent with that observed in MonumenTAL-1; safety in the prior anti-BCMA cohort was similar to the overall cohort
- Overall, talquetamab continues to demonstrate durable responses, especially in patients achieving ≥CR and ≥VGPR, including those who had prior anti-BCMA TCRT

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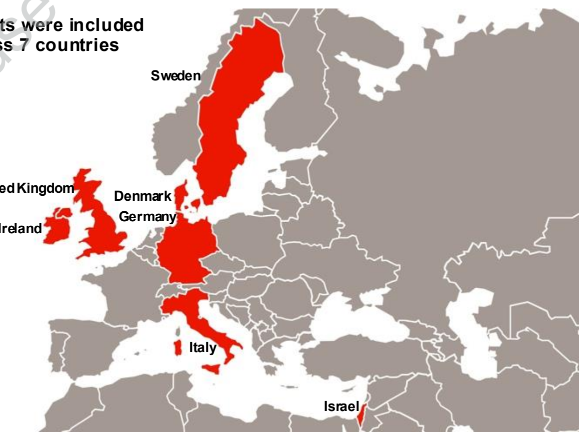
Introduction

- Talquetamab is the first and only approved bispecific antibody targeting G protein–coupled receptor class C group 5 member D and CD3 for the treatment of triple-class-exposed relapsed/refractory multiple myeloma (RRMM)[1–3]
- In previous results from the phase 1/2 MonumenTAL-1 study (clinical cut-off: Jan 2024; median follow-up, 21–30 months), talquetamab elicited deep, durable responses with low discontinuation rates[1]
- Previously presented REALiTAL results showed:
  - Overall response rates (ORRs) of 66.7% (95% CI, 56.1–76.1), with 57% of patients achieving a very good partial response (VGPR) or better
  - With a median follow-up of 15 months (range, 0.4–25.3), median duration of response (DOR), progression-free survival (PFS), and overall survival (OS) were 12.3 months (95% CI, 7.9–not estimable [NE]), 8.2 months (95% CI, 6.1–10.7), and 25.3 months (95% CI, 17.3–NE), respectively
- Here, we report outcomes in patient subgroups based on prior therapy and depth of response

Methods

- REALiTAL is a retrospective, international, noninterventional study that aims to describe the management and outcomes of patients treated with talquetamab outside of clinical trials
- REALiTAL included 26 sites across 7 countries (**Figure 1**)
- Data were collected from patient medical records, including demographics, disease characteristics, prior therapies, effectiveness, and safety
  - Treatment outcomes were assessed based on response rates, time to first and best response, DOR, PFS, and OS
  - Responses were evaluated according to International Myeloma Working Group criteria
- Informed consent was obtained for all patients

Figure 1: 93 patients were included from 26 sites across 7 countries



Results

Patients

- REALiTAL included 93 eligible patients receiving talquetamab on or before December 31, 2023; most patients received talquetamab via preapproval access programs
- Patient baseline characteristics are shown in **Table 1**

Table 1: Baseline characteristics

Characteristic	Overall (N=93)[a]	Prior CAR-T[b] subgroup (n=12)	Prior BsAb[b] subgroup (n=23)
Age, years, median (range)	65 (24–86)	56.5 (50–70)	66.1 (46–85)
<65 years, n (%)	42 (45.2)	8 (66.7)	10 (43.5)
≥65 to <75 years, n (%)	37 (39.8)	4 (33.3)	7 (30.4%)
≥75 years, n (%)	14 (15.1)	0	6 (26.1%)
Male, n (%)	55 (59.1)	8 (66.7)	13 (56.5%)
ECOG PS ≥1, n (%)	21/35 (60.0)	3/6 (50.0)	5/9 (55.6)
ISS stage II or III,[c] n (%)	42/69 (60.9)	3/8 (37.5)	12/20 (60.0)
High-risk cytogenetics,[d] n (%)	35/48 (72.9)	3/5 (60.0)	12/17 (70.6)
Extramedullary plasmacytoma, n (%)	8/51 (15.7)	0/5 (0)	2/14 (14.3)
LDH >245 U/L, n (%)	43/80 (53.8)	4/11 (36.4)	11/18 (61.1)
Years since diagnosis, median (range)	6.0 (1.5–23.1)	6.4 (2.4–14.5)	6.6 (1.5–18.8)

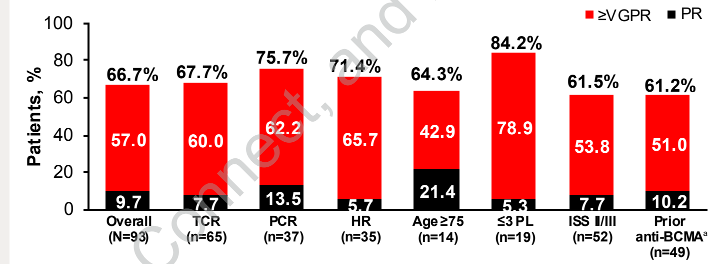
[a]Data available added as denominators if some were missing and not available in the clinical chart for the whole cohort. [b]11 of 12 patients with prior CAR-T had anti-BCMA CAR-T and 22 of 23 with prior BsAb had anti-BCMA BsAb. Patients may have received >1 CAR-T or BsAb treatment. [c]At baseline or at diagnosis, if missing. [d]High risk defined as having presence of t(4;14), t(14;16), del17p13, and amp1q21. BCMA, B-cell maturation antigen; BsAb, bispecific antibody; CAR, chimeric antigen receptor, ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; LDH, lactate dehydrogenase.

- Median duration of follow-up was 14.95 months (range, 0.36–25.26)
- Patients were heavily pretreated with a median 5 (range, 2–16) prior lines of therapy
- Most patients (n=80; 86.0%) were penta-class exposed and almost all (n=91; 97.8%) were triple-class exposed
- 65 (69.9%) patients were triple-refractory and 37 (39.8%) were penta-refractory
- 49 (52.7%) patients had previously received anti-BCMA treatments
  - Of these, 33 (35.5%) patients received prior anti-BCMA T-cell redirection therapy (TCRT); 12 received prior CAR-T and 23 received prior BsAb therapy
  - 24 (25.8%) patients received antibody-drug conjugate (ADC) therapy
- 82 (88.2%) patients started talquetamab every-other-week (Q2W) administration; 11 (11.8%) started weekly dosing; and 18 (22.0%) switched from Q2W to monthly dosing after a median 6 months

Efficacy

- Overall response rate was 66.7%; 36 (36.4%) patients achieved VGPR, 17 (17.2%) ≥CR, 37 (37.4%) near ≥CR, and 9 (9.1%) achieved PR
- Response rates across key subgroups were consistent with the overall patient population, with ORRs ranging from 61.5% to 84.2% and ≥VGPR rates from 51.4% to 65.7% (**Figure 2**)

Figure 2: Response rates by subgroups



[a]Prior anti-BCMA therapy cohort includes prior ADC, CAR-T and BsAbs. HR, high risk; PCR, penta-class refractory; PL; prior lines of therapy; PR, partial response; TCR, triple-class refractory.

Safety

- Safety data for the overall population have been reported previously[4]
- For those with prior BCMA, cytokine release syndrome (CRS) occurred in 63.3% (1 grade 3) of patients, and immune effector cell–associated neurotoxicity syndrome (ICANS) occurred in 2.0% (0 grade ≥3; **Table 2**)
- Skin- and nail-related adverse events (AEs) occurred in 32 (65.3%) patients; all were grade 1/2
- Oral toxicity occurred in 36 (73.5%) patients, mostly grade 1/2. Dysgeusia occurred in 63.3% of patients, majority grade 1

Table 2: TEAEs of clinical interest

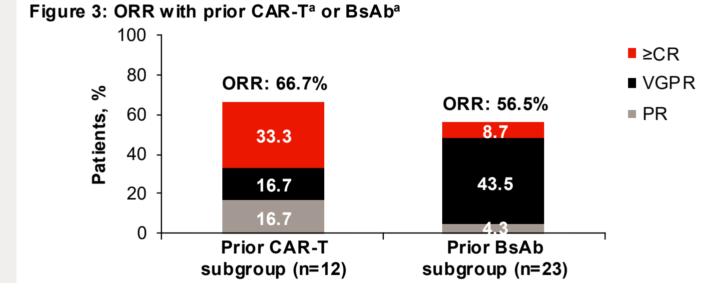
TEAE, n (%)	Total (N=93)		Prior anti-BCMA[a] (n=49)	
	Any Grade	Grade 3/4	Any Grade	Grade 3/4
Any TEAE	92 (98.9)	35 (37.6)	49 (100.0)	23 (46.9)
Infections	44 (47.3)	9 (9.7)	26 (53.1)	4 (8.2)
Hematological TEAEs				
Anemia	13 (14.0)	8 (8.6)	8 (16.3)	4 (8.2)
Neutropenia	9 (9.7)	6 (6.5)	9 (18.4)	6 (12.2)
Thrombocytopenia	7 (7.5)	6 (6.5)	5 (10.2)	5 (10.2)
Nonhematological TEAEs				
Skin/nail toxicity	63 (67.7)	1 (1.1)	32 (65.3)	0
Oral toxicity	62 (66.7)	1 (1.1)	36 (73.5)	0
Dysgeusia[b]	53 (57.0)	NA	31 (63.3)	NA
CRS	52 (55.9)	1 (1.1)	31 (63.3)	1 (2.0)
Neurological TEAEs of interest				
ICANS	2 (2.2)	0	1 (2.0)	0

[a]Prior anti-BCMA therapy cohort includes prior ADC, CAR-T and BsAbs. [b]Includes dysgeusia, ageusia, and taste disturbance. Maximum grade is 2. NA, not applicable; TEAE, treatment-emergent adverse event.

Prior CAR-T and BsAb subgroups

- ORR was 66.7% (95% CI, 34.9–90.1) for patients with prior CAR-T and 56.5% (95% CI, 34.5–76.8) with prior BsAb (**Figure 3**)
- Median time to first response was 1.6 months for those with prior CAR-T and 1 month with prior BsAb, after a median duration of talquetamab treatment of 11.7 months and 6.3 months, respectively
- For the prior CAR-T group, median DOR was NE (95% CI, 1.45–NE), PFS was 10.7 months (95% CI, 2.23–NE), and OS was NE (95% CI, 4.47–NE; **Table 3**)

Figure 3: ORR with prior CAR-T[a] or BsAb[a]



[a]11 of 12 patients with prior CAR-T had anti-BCMA CAR-T and 22 of 23 with prior BsAb had anti-BCMA BsAb. Patients may have received >1 CAR-T or BsAb treatment.

- In the prior BsAb group, median DOR, PFS, and OS were 16.1 months (95% CI, 5.95–NE), 7.4 months (95% CI, 3.88–18.20), and NE (95% CI, 9.20–NE), respectively

Table 3: mDOR, mPFS, and mOS rates

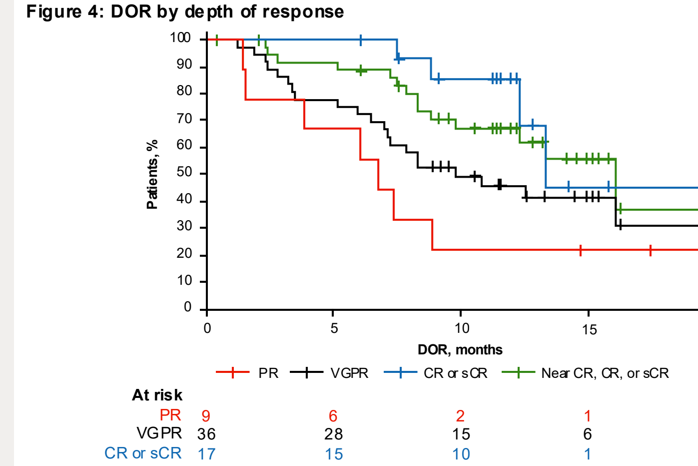
Response (95% CI)	Overall population (N=93)	Prior CAR-T subgroup[a] (n=12)	Prior BsAb subgroup[a] (n=23)
mDOR, months	12.32 (7.85–NE)	NE (1.45–NE)	16.1 (5.95–NE)
mPFS, months	8.18 (6.05–10.71)	10.71 (2.23–NE)	7.36 (3.88–18.20)
12-month PFS rate	38.3% (28.3–48.2%)	48.6% (19.2–73.0%)	32.8% (14.8–52.1%)
mOS, months	25.26 (17.31–NE)	NE (4.47–NE)	NE (9.2–NE)
12-month OS rate	68.3% (57.6–76.8%)	75% (40.8–91.2%)	55.3% (32.7–73.0%)

[a]11 of 12 patients with prior CAR-T had anti-BCMA CAR-T and 22 of 23 with prior BsAb had anti-BCMA BsAb. Patients may have received >1 CAR-T or BsAb treatment. mDOR, median duration of response; mOS, median OS; mPFS, median progression-free survival.

DOR by depth of response

- Median DOR was 16.1 (95% CI, 9.82–NE) in patients achieving near ≥CR, 13.37 (95% CI, 12.32–NE) in those achieving ≥CR, 9.82 (95% CI, 7.00–NE) in those achieving VGPR, and 6.77 (95% CI, 1.45–NE) in those achieving PR (**Figure 4**)

Figure 4: DOR by depth of response



sCR, stringent complete response.

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Multiple Myeloma

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