

Real-world characteristics and effectiveness and safety of talquetamab among patients with relapsed or refractory multiple myeloma: an electronic medical record and chart review study

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Key Takeaway



Overall, these findings support the use of TAL as an effective and safe treatment for pts with RRMM.

Conclusions



In this rw study of pts initiating TAL, over 60% were using TAL as per USPI criteria, and some pts were using TAL as BT and/or as a combination regimen.



Effectiveness was consistent with findings from the pivotal trial.



The majority of CRS events were mild and the majority of pts with dysgeusia had improvement reported, with common management strategies including biotene or dexamethasone mouthwash.



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Poster

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Acknowledgments

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Disclosures

CR has served on an advisory board for Janssen Pharmaceuticals. HC, YL, EC, JH, SP and XZ are employees of Janssen Scientific Affairs, LLC. Johnson & Johnson Innovative Medicine and stockholders of Johnson & Johnson. JM, AR, ATS, AP and PTL are employees of Analysis Group ULC, a consulting company that has provided paid consulting services to Johnson & Johnson Innovative Medicine, which funded the development and conduction of this study.

Introduction

- Talquetamab (TAL) is a first-in-class GPRC5D-targeted bispecific antibody that was granted accelerated US approval in August 2023 for adult patients (pts) with triple-class exposed (TCE) relapsed or refractory multiple myeloma (RRMM) who received ≥4 prior lines of therapy (LOTs).¹
- Overall response rates (ORR) in phase 2 MonumentAL-1 clinical trial were 74% among pts receiving 0.4 mg/kg once a week and 69% among pts receiving 0.8 mg/kg every 2 weeks.²
- Common adverse events (AEs) included cytokine release syndrome (CRS; 76%), dysgeusia (70%) and weight loss (34-39%).^{1,3}
- This study sought to describe pt characteristics, effectiveness, and safety of pts initiating TAL in a real-world (rw) setting, as well as rw dysgeusia management strategies.

Methods

- Electronic medical records from the Loopback Analytics database (1/2019–11/2024) were used, supplemented by abstraction of unstructured data available in pt charts (5/2006–10/2024).

Results

Pt characteristics and treatment patterns

- A total of 125 pts were included with a median follow-up of 8.4 mos (Table 1).
 - TAL was used as BT for CAR-T in 29 pts (23%)
 - Among 23 pts (18%) who had received CAR-T at the time of data collection, median time to CAR-T infusion was 61 days
 - BCMA-exposed: n=78 (62%); BCMA-naïve: n=47 (38%); USPI-indicated without TAL as BT: n=76 (61%)
- Fifteen pts (12%) received TAL as a combination regimen, such as TAL+pomalidomide (7%) and TAL-daratumumab (2%).

Table 1: Pt characteristics

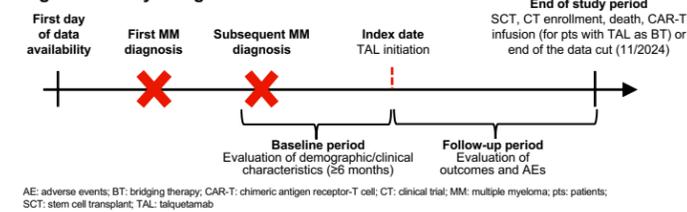
	N=125
Age (years), mean [median]	65.8 [66]
≥75 years, n (%)	18 (14.4)
Female, n (%)	61 (48.8)
Race, n (%)	
Asian	9 (7.2)
Black	9 (7.2)
White	84 (67.2)
Other	23 (18.4)
Payer type, n (%)	
Medicare	65 (52.0)
Commercial	31 (24.8)
Medicaid	7 (5.6)
Other	21 (16.8)
Quan-CCI, mean [median]	2.6 [2]
Comorbidities, n (%)	
Anemia	64 (51.2)
Hypertension	45 (36.0)
Hypogammaglobulinemia	37 (29.6)
Peripheral neuropathy	36 (28.8)
Fracture	28 (22.4)
Renal impairment	25 (20.0)
Prior SCT, n (%)	93 (74.4)
ECOG score ≥2¹, n (%)	30 (30.3)
High-risk cytogenetic abnormalities², n (%)	42 (33.6)
Extramedullary disease³, n (%)	23 (18.4)
≥4 prior LOT, n (%)	119 (95.2)
Prior TCE, n (%)	122 (97.6)
Prior BCMA exposure, n (%)	78 (62.4)
CAR-T cell therapy	38 (30.4)
Bispecifics (teclistamab, elranatamab)	48 (38.4)
Belantamab mafodotin	13 (10.4)

BCMA: B-cell maturation antigen; CAR: chimeric antigen receptor; CCI: Charlson Comorbidity Index; ECOG: Eastern Cooperative Oncology Group; LOT: line of therapy; pt: patient; SCT: stem cell transplant; TCE: triple-class exposed
 1. Reported among those with ECOG data (n=99)
 2. Included pts with evidence of del(17p) in sorted plasma cells ≥20%, TP53 mutation, biallelic del(1p32) or any two of the following abnormalities together: t(4;14) or t(4;16) or t(14;20), t(1q gain or amplification), monosallelic del(1p32)
 3. A total of 100 pts (80%) had unknown extramedullary disease status

References

- Talvey (U.S. Food and Drug Administration) (2023). https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761342s0001bl.pdf.
- Chari et al. Safety and activity of talquetamab in patients with relapsed or refractory multiple myeloma (MonumentAL-1): a multicentre, open-label, phase 1–2 study. *The Lancet*. April 2025.
- Rasche et al. Long-term efficacy and safety results from the phase 1/2 monumental-1 study of talquetamab, a GPRC5D x CD3 bispecific antibody, in patients with relapsed/refractory multiple myeloma. 2024 European Hematology Association Hybrid Congress. June 2024.

Figure 1: Study design



AE: adverse events; BT: bridging therapy; CAR-T: chimeric antigen receptor-T cell; CT: clinical trial; MM: multiple myeloma; pts: patients; SCT: stem cell transplant; TAL: talquetamab

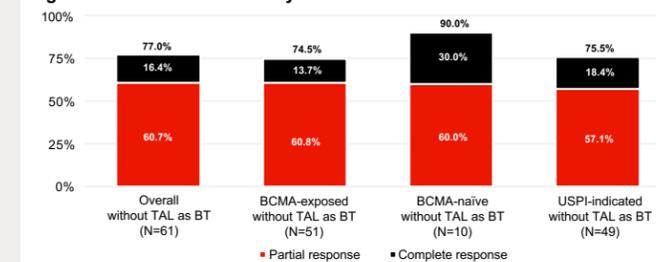
Population

- Received TAL after Food and Drug Administration (FDA) approval (8/2023)
- ≥2 diagnostic codes for MM, including ≥1 prior to TAL initiation (i.e., index date)
- ≥6 months (mos) of clinical activity prior to index date
- ≥18 years of age at index date
- Did not participate in a clinical trial during the LOT in which TAL was received

Effectiveness

- Among the 29 pts with TAL as BT, rwORR was 78% in 23 pts with evaluable response.
- Among the 96 pts without TAL as BT, rwORR was 77% in 61 pts with evaluable response (Figure 2).
 - BCMA-exposed: 75%; BCMA-naïve: 90%; USPI-indicated without TAL as BT: 76%

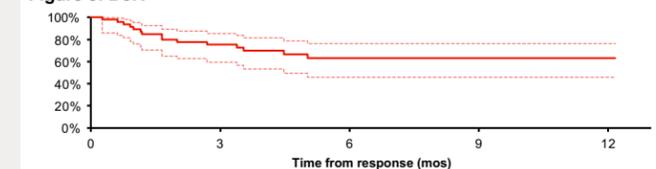
Figure 2: rwORR overall and by sub-cohort¹



BCMA: B-cell maturation antigen; BT: bridging therapy; pts: patients; rwORR: real-world overall response rate; TAL: talquetamab; USPI: US Prescribing Information
 1. rwORR was calculated as the proportion of pts with a best response reported as partial response or complete response over the number of pts with evaluable response (i.e., ≥1 instance of response or disease progression status available in the data)

- Among pts without TAL as BT (n=46), median DoR was not reached (NR; Figure 3), with a 12-mo rate of 63%.
 - Median DoR for BCMA-exposed, BCMA-naïve and USPI-indicated without TAL as BT sub-cohorts were NR with 12-mo rates of 57%, 88% and 55%, respectively.

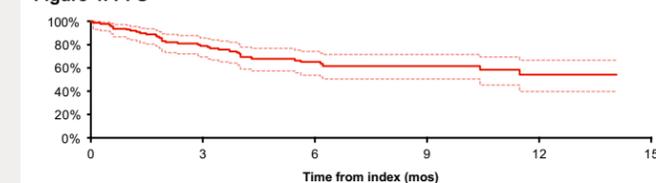
Figure 3: DoR¹



DoR: duration of response; mos: months
 1. Time between the first record of partial response or complete response, and the date of disease progression, death, or end of data availability

- Median PFS for pts without TAL as BT was NR (Figure 4), with a 12-mo rate of 54%.
 - Median PFS for BCMA-exposed sub-cohort was 11.5 mos with 12-mo rate of 47%; median PFS for BCMA-naïve sub-cohort was NR with a 12-mo rate of 74%; median PFS for the USPI-indicated without TAL as BT sub-cohort was 11.5 mos with 12-mo rate of 48%

Figure 4: PFS¹



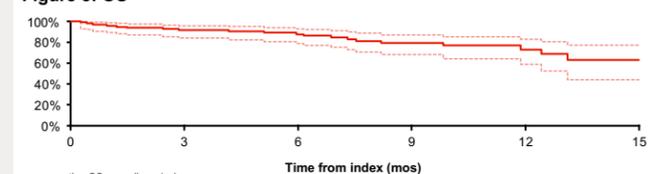
mos: months; PFS: progression-free survival
 1. Time between TAL initiation and the date of progression, death, or end of data availability

Analyses and sub-cohorts

- Pt characteristics, treatment patterns and safety were reported for all pts.
- Effectiveness was analyzed separately for pts who used TAL as a bridging therapy (BT) for chimeric antigen receptor (CAR)-T cell therapy and non-BT users. For BT users, ORR was reported; for non-BT users, ORR, duration of response (DoR), progression-free survival (PFS) and overall survival (OS) were reported.
- Among non-BT pts, three sub-cohorts were analyzed:
 - B-cell maturation antigen (BCMA)-exposed prior to index;
 - BCMA-naïve prior to index;
 - Met US Prescribing Information (USPI) criteria for TAL (i.e., TCE, received TAL as monotherapy, had ≥4 prior LOTs) and did not use TAL as BT for CAR-T cell therapy

- Median OS among pts without TAL as BT was NR (Figure 5), with a 12-mo OS rate of 73%.
 - Median OS for BCMA-exposed, BCMA-naïve and USPI-indicated without TAL as BT sub-cohorts were NR, with 12-mo OS rates of 68%, 90% and 71%, respectively.

Figure 5: OS¹



mos: months; OS: overall survival
 1. Time between TAL initiation and death or end of data availability

Safety

- CRS was reported in 71 pts (57%; Table 2).
- Ninety-four pts (75%) reported skin-related events, and 61 (49%) reported a decrease in weight with a median weight loss of 4.7 kilograms (kg) or 8% mean decrease.
- Dysgeusia occurred in 101 pts (81%) with improvement reported for 65% of these and median time to improvement of 78 days; common management strategies in Table 2.
- Among pts with improvement in dysgeusia, 71% of pts improvement occurred after switching to once every 3 weeks (Q3W; confirmed by 3 consecutive Q3W doses) dosing or less frequent.

Table 2: AEs of interest

	N=125
CRS¹, n (%)	71 (56.8)
Grade 1	41 (32.8)
Grade 2	23 (18.4)
Grade 3	2 (1.6)
Missing/unknown	5 (4.0)
Dysgeusia, n (%)	101 (80.8)
Improvement reported	66 (65.3)
Days to improvement, mean [median]	98.5 [78]
Management strategies, n (%)	42 (41.6)
Biotene mouthwash/spray	23 (22.8)
Dexamethasone mouthwash	13 (12.9)
Saline mouthwash	7 (6.9)
Nystatin mouthwash	5 (5.0)
Skin-related event, n (%)	94 (75.2)
Nail-related event, n (%)	47 (37.6)
Decrease in weight², n (%)	61 (48.8)
Median absolute change (first to last TAL administration), kg	-4.7
Mean relative change (first to last TAL administration), %	-7.6
<5	17 (13.6)
5 - <10	15 (12.0)
10 - <20	10 (8.0)
≥20	2 (1.6)

AE: adverse event; CRS: cytokine release syndrome; kg: kilograms; TAL: talquetamab
 1. Reported as highest grade per pt
 2. For 17 pts with missing weight information, weight change could not be calculated

