5157

Patient Characteristics, Treatment Patterns and Early Outcomes of Patients with Relapsed or Refractory Multiple Myeloma (RRMM) Initiated on Talquetamab (TAL): An Electronic Medical Record and Chart Review Study

Cesar Rodriguez[1], Hsien-yen Chang[2], Yi-hsuan Liu[2], Jinghua He[2], Hoa Le[2], Jessica Maitland[3], Alvi A. Rahman[3], Anabelle Tardif-Samson[3], Bronwyn Moore[3], Marie-Hélène Lafeuille[3], Saurabh Patel[2], Xinke Zhang[2]

[1]Mount Sinai School of Medicine, New York, New York, United States; [2]Janssen Scientific Affairs, Inc., Horsham, Pennsylvania, United States; [3]Analysis Group, Inc., Montreal, Canada

Key Takeaway

In this review of charts and electronic medical records of heavily pretreated patients with RRMM in the real world, TAL demonstrated an 81.8% overall response rate, with most patients completing SUD within one week and experiencing manageable safety events, consistent with clinical trial findings

Conclusions

- Most patients were able to complete TAL SUD within 1 week and majority of patients were on QW or Q2W schedule at the end of follow-up
- Early safety profile was consistent with the clinical trial, with most CRS events being mild, most dysgeusia events were reported to improve, and most weight loss was <10%
- Together with the observed real-world response rate to TAL of 81.8%, these early findings support the use of TAL as an effective treatment option for patients with RRMM

Scan the QR code

Poster

https://www.congresshub.com/ASH2024/Oncology/Talquetamab/Rodriguez

The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

Acknowledgments
Sponsorship: Janssen Scientific Affairs, Inc.
Medical writing/editorial support (and associated funding): Lumanity Inc.

Introduction

- TAL, a first-in-class T-cell redirecting bispecific antibody, was granted accelerated approval by the Food and Drugs Administration (FDA) in August 2023 for adults with RRMM who received ≥4 prior lines of therapy (LOT). To mitigate cytokine release syndrome (CRS), TAL is initiated with step-up dosing (SUD) including 2-3 step-up doses prior to the first full treatment dose, each 2-4 days apart
- Phase 2 MonumenTAL-1 clinical trial[1] showed high overall response rates (ORR; 67-74%, depending on dose)
  - Common adverse events (AEs) were CRS (76%), skin-related AEs (41%), nail-related AEs (50%), and dysgeusia (70%)[2]
- This study aimed to describe the real-world characteristics, SUD patterns, dosing schedule, and early data on safety and effectiveness in patients with RRMM receiving TAL

Methods

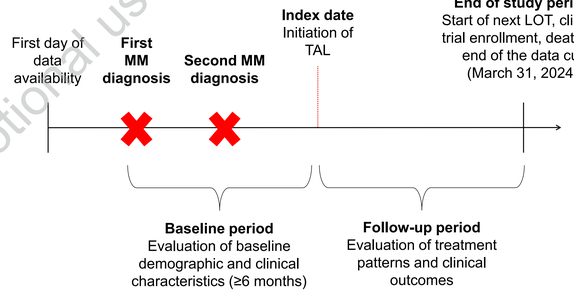
Data source

- Data was used from Loopback Analytics (formerly Acentrus), an electronic medical records database
- A chart review was conducted to supplement information from structured data, representing the safety data analysis set

Population

- A retrospective cohort study of patients who:
  - Received TAL after FDA approval
  - Had ≥2 diagnostic codes for MM, with ≥1 prior to the index date
  - Were aged ≥18 years
  - Had ≥6 months of clinical activity prior to the index date
  - Did not have clinical trial enrollment during SUD

Figure 1: Study design scheme



LOT: line of therapy; MM: multiple myeloma; TAL: talquetamab

Results

Patient characteristics

- 92 patients were included
  - Median age was 69 years, 19.6% of patients being ≥75 years
  - Prior to TAL initiation, a median of 3 prior LOTs were received – the majority of patients had received B-cell maturation antigen-targeted therapies (BCMAs; 59.8%), including bispecifics (41.3%), CAR-T therapies (28.3%), and belantamab mafodotin (12.0%) **(Table 1)**
- Of the 50 patients from the chart review **(safety data analysis set)**
  - 14 of the 43 patients (32.6%) with ECOG available had an ECOG score of ≥2
  - 24 (48.0%) patients had high-risk cytogenetic abnormalities, and 10 (20.0%) had extramedullary disease **(Table 1)**
  - Response assessments were available for 33 patients **(effectiveness analysis set)**

Table 1: Patient characteristics

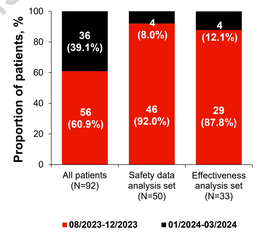
	All patients N=92	Safety data analysis set N=50	Effectiveness analysis set[1] N=33
Age (years), mean [median]	66.4 [69]	66.2 [68]	65.4 [67]
Age ≥75, n (%)	18 (19.6)	7 (14.0)	4 (12.1)
Female, n (%)	43 (46.7)	25 (50.0)	17 (51.5)
Race			
Asian	7 (7.6)	6 (12.0)	6 (18.2)
Black	8 (8.7)	4 (8.0)	3 (9.1)
White	64 (69.6)	37 (74.0)	21 (63.6)
Other	13 (14.1)	3 (6.0)	3 (9.1)
Quan-Charlson Comorbidity Index, mean [median]	2.9 [2.0]	3.3 [2.0]	3.7 [2.0]
Comorbidities, n (%)			
Hypertension	31 (33.7)	19 (38.0)	12 (36.4)
Renal impairment	21 (22.8)	12 (24.0)	9 (27.3)
Anemia	49 (53.3)	28 (56.0)	19 (57.6)
Peripheral neuropathy	35 (38.0)	17 (34.0)	13 (39.4)
Hypogammaglobulinemia	29 (31.5)	15 (30.0)	10 (30.3)
Pneumonia	11 (12.0)	8 (16.0)	6 (18.2)
Fracture	20 (21.7)	11 (22.0)	8 (24.2)
Prior BCMA exposure	55 (59.8)	28 (56.0)	19 (57.6)
CAR-T	26 (28.3)	14 (28.0)	10 (30.3)
Bispecifics (teclistamab, elranatamab)	38 (41.3)	19 (38.0)	13 (39.4)
Belantamab mafodotin	11 (12.0)	6 (12.0)	5 (15.2)
ECOG score ≥2[2]	-	14 (32.6)	12 (36.4)
High-risk cytogenetic abnormalities[3]	-	24 (48.0)	15 (45.5)
Extramedullary disease[3]	-	10 (20.0)	8 (24.2)

BCMA: B-cell maturation antigen; CAR-T: chimeric antigen receptor T-cell; ECOG: Eastern Cooperative Oncology Group
1. Consists of 33 patients from the safety analysis data set (i.e., with chart review data) with evaluable response.
2. ECOG is reported out of those with ECOG data (n=43); 7 patients had unknown/missing ECOG data. Based on ECOG score, 38/43 (88.4%) of patients would have met eligibility criteria for the MonumenTAL-1 trial
3. Includes patients with del17p, t[14;16], t[14;20], and t[4;14] abnormalities
4. All patients without reported extramedullary disease were reported as missing/unknown

Treatment patterns

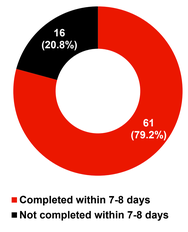
- The majority (60.9%) of patients initiated TAL between August 2023 and December 2023, with similar trends in the safety data (92.0%) and effectiveness analyses sets (87.8%; **Figure 2**)
- Over a median duration of follow-up of 3.4 months, 83.7% of patients had complete SUD data **(Figure 3)**, of which 79.2% completed the SUD phase in 7-8 days, and the most common TAL SUD phase was bi-weekly (67.5%)
- In the TAL treatment phase, 57.1% of patients received ≥3 doses
  - 14 (31.8%) and 28 (63.6%) patients were initially on weekly (QW) and biweekly (Q2W) schedules, respectively **(Table 2)**
  - Most patients were on QW (11.9%) or Q2W (64.3%) schedule at the end of follow-up **(Table 2)**

Figure 2: TAL initiation date



SUD: step-up dosing; TAL: talquetamab

Figure 3: TAL SUD phase



SUD: step-up dosing; TAL: talquetamab

Table 2: Dosing frequency at the end of follow-up, by initial dosing schedule[1]

Initial dosing schedule	QW (6-11 days)	Q2W (12-17 days)	Q3W (18-24 days)	Q4W (25-31 days)
QW (6-11 days; n=14)	4	7	2	1
Q2W (12-17 days; n=28)	1	20	1	6

QW: weekly; Q2W: every 2 weeks; Q3W: every 3 weeks; Q4W: every 4 weeks; SUD: step-up dosing
1. Among patients with ≥3 treatment doses after SUD who received QW and Q2W doses (n=42). There were two patients who received each of Q3W and Q4W doses.

Adverse events of interest

- For the 50 patients with abstracted chart review data, 23 (46.0%) had reported CRS; 10 (20.0%) had grade 1 CRS, 10 (20.0%) had grade 2 CRS, 1 (2.0%) had grade 3 CRS, and 2 (4.0%) had CRS of unknown grade **(Table 3)**
  - CRS was managed using tocilizumab in 14 (28.0%) patients and dexamethasone in 9 (18.0%) patients
- Dysgeusia was reported in 34 (68.0%) patients, of which 21 (61.8%) had an improvement in dysgeusia within a median of 77.5 days **(Table 3)**
- Weight loss was reported in 24 (48.0%) patients, with a median loss of 6.5% of body weight from TAL initiation; most (87.5%) reported <10% weight loss **(Table 3)**

Table 3: Adverse events of interest

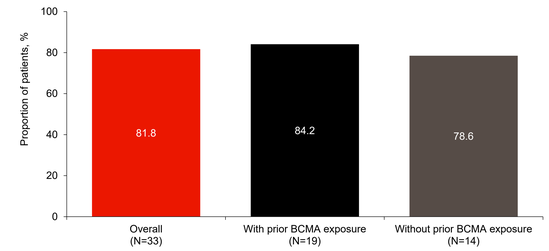
Safety data analysis set	N=50
CRS[1], n (%)	23 (46.0)
Grade 1 (Mild)	10 (20.0)
Grade 2 (Moderate)	10 (20.0)
Grade 3 (Severe)	1 (2.0)
Grade 4 (Life threatening)	0 (0.0)
Grade 5 (Death)	0 (0.0)
Missing/unknown	2 (4.0)
Use of tocilizumab	14 (28.0)
Therapeutic	13 (92.9)
Prophylactic	1 (7.1)
Use of dexamethasone[2]	9 (18.0)
Dysgeusia, n (%)	34 (68.0)
Improvement	
Yes	21 (61.8)
Days to improvement, mean [median]	79.0 [77.5]
No	6 (17.6)
Missing/unknown	7 (20.6)
Decrease in weight, n (%)	24 (48.0)
Median relative change (first to last TAL administration, kg),(%)	-6.5%
<5	9 (37.5)
5 - <10	12 (50.0)
10 - <20	3 (12.5)
≥20	0 (0.0)

CRS: Cytokine release syndrome; kg: kilograms; TAL: talquetamab
1. Of patients without reported CRS, 5 had no CRS reported and 22 were reported as missing/unknown. CRS grading is reported as highest grade (i.e., mutually exclusive).
2. All dexamethasone use was therapeutic.

Physician-reported response

- Over a median duration of follow-up of 5.3 months, the ORR was 81.8% for overall patients with evaluable response; 84.2% and 78.6% for patients with and without prior BCMA exposure, respectively **(Figure 4)**

Figure 4: Overall response rate by prior BCMA exposure



BCMA: B-cell maturation antigen-targeted therapy

References
1. 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.
2. Talvey (U.S. Food and Drug Administration) (2023). https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761342s000lbl.pdf

Multiple Myeloma

Presented by C Rodriguez at American Society of Hematology 2024; December 9, 2024; San Diego, CA, US