PA-020: Real-World Outcomes Among Patients with Relapsed or Refractory Multiple Myeloma Initiating Teclistamab at a Large Community Oncology Center in the US

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INTRODUCTION

- Teclistamab was the first-in-class B-cell maturation antigen (BCMA) x CD3 bispecific antibody approved for the treatment of relapsed/refractory multiple myeloma (RRMM) that demonstrated an overall response rate (ORR) of 63%, after a median follow-up of 30.4 months in the MajesTEC-1 trial[1]
- Most U.S. patients with multiple myeloma (MM) are treated in community oncology clinics, where practice patterns may differ from academic centers[2]
- However, real-world data on teclistamab has been largely reported from academic centers with step-up dosing (SUD) conducted primarily in inpatient settings[3-6]

Objective

- To describe the clinical characteristics, SUD patterns, safety, and effectiveness of teclistamab in patients with RRMM treated at Texas Oncology, a large U.S. community oncology practice network

METHODS

Study design and data source

- This retrospective, observational study used patient charts and electronic medical record data for adult patients with RRMM treated with teclistamab at Texas Oncology's practices

Study population

- Adult patients with ≥1 record of MM diagnosis based on the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) code (C90.0x) and ≥1 record for teclistamab between 10/26/2022 and 12/31/2024 were included
- Patients who received teclistamab in a clinical trial were excluded
- The date of the first observed diagnosis was considered the initial MM diagnosis date, and the date of Teclistamab initiation was defined as the index date
- Eligible patients were followed from the index date to the last activity, death, or data cutoff (12/31/2024)
- Tec-1 eligible subgroup: patients eligible for teclistamab per US Prescribing Information (USPI), defined as meeting the following criteria:
  - Prior triple class exposed (TCE), including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 monoclonal antibody
  - Four prior lines of therapy prior to teclistamab initiation
  - Eastern Cooperative Oncology Group (ECOG) performance status of 0-1
  - No exposure to anti-BCMA therapy (ciltacabtagene autoleucel, idecabtagene vicleucel, elranatamab, or belantamab mafodotin) prior to teclistamab initiation

Data analysis

- All variables were summarized descriptively for all patients (the overall cohort) and for the Tec-1 eligible subgroup
- Time-to-event outcomes were estimated using the Kaplan-Meier method

RESULTS

Demographics and clinical characteristics

- A total of 50 patients met the study criteria, including 36 patients (72.0%) eligible for teclistamab per USPI. Patient characteristics are presented in **Table 1**
- At Tec initiation, 40.0% of the overall cohort and 44.4% of the Tec-1 eligible subgroup were ages ≥75 years
- Among the overall and Tec-1 eligible cohorts, 46.0% and 38.9% had high-risk cytogenetics (t(4; 14); t (14; 16); t (14; 20) del17p, or gain/amp 1q21)), respectively

SUD

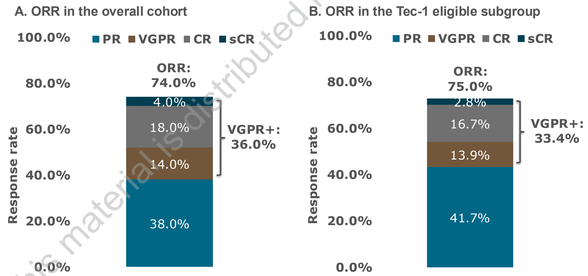
- A total of 38 patients (76.0%) in the overall cohort and 29 (80.6%) in the Tec-1 eligible subgroup were referred to another institution for inpatient SUD; the remaining patients (12 [24.0%] in the overall cohort and 7 [19.4%] in the Tec-1 eligible subgroup) completed SUD in the outpatient setting
- All patients referred to another institution for SUD returned to the community clinic within a median of 15 days after SUD completion

Table 1. Patient demographics and clinical characteristics

	Overall cohort (N = 50)	TEC-1 eligible subgroup (N = 36)
Demographics		
Age, median (IQR)	72.5 (45-88)	72.5 (45-88)
Age categories, n (%)		
<65 years	13 (26.0)	8 (22.2)
65 to <75 years	17 (34.0)	12 (33.3)
≥75 years	20 (40.0)	16 (44.4)
Sex, n (%)		
Female	24 (48.0)	18 (50.0)
Male	26 (52.0)	18 (50.0)
Race, n (%)		
White	35 (70.0)	31 (86.1)
Black or African American	9 (18.0)	4 (11.1)
Other	6 (12.0)	1 (2.8)
Primary insurance type, n (%)		
Commercial/Medicare Advantage	37 (74.0)	25 (69.4)
Medicare FFS	13 (26.0)	11 (30.6)
Clinical characteristics		
Weight, median (range), kg	76.5 (45.4-128.1)	74.1 (50.9-125.5)
ECOG score, n (%)		
0	21 (42.0)	17 (47.2)
1	23 (46.0)	19 (52.8)
2	3 (6.0)	0 (0)
Unknown	3 (6.0)	0 (0)
R-ISS stage, n (%)		
Stage I	9 (18.0)	8 (22.2)
Stage II	21 (42.0)	16 (44.4)
Stage III	18 (36.0)	12 (33.3)
Unknown or undocumented	2 (4.0)	0 (0)
Cytogenetic risk, n (%)		
Standard	27 (54.0)	22 (61.1)
High[a]	23 (46.0)	14 (38.9)
Key relevant conditions and comorbidities, n (%)		
Hypertension	30 (60.0)	22 (61.1)
Renal impairment/failure[b]	16 (32.0)	11 (30.6)
Anemia	15 (30.0)	12 (33.3)
Peripheral neuropathy	15 (30.0)	11 (30.6)
Hypogammaglobulinemia	14 (28.0)	11 (30.6)
Solid tumor	14 (28.0)	9 (25.0)
Infections[c]	12 (24.0)	6 (16.7)
QCCI score, median (range)	2 (0-9)	2 (0-9)
Treatment history		
Duration from MM diagnosis to index, median (range), years	4.8 (1.1-18.3)	5 (2.1-18.3)
Prior lines of therapy, median (range)	4 (3-8)	4 (4-7)
Radiation history, n (%)	29 (58.0)	21 (58.3)
HSCT history, n (%)	31 (62.0)	23 (63.9)
Prior BCMA exposure	3 (6.0)	0
Belantamab mafodotin	1 (2.0)	0
Ciltacabtagene autoleucel	1 (2.0)	0
Idecabtagene vicleucel	1 (2.0)	0

Abbreviations: BCMA, B-cell maturation antigen; ECOG, Eastern Cooperative Oncology Group; FFS, Fee-for-Service; QCCI, Quan-Charlson Comorbidity Index; HSCT, hematopoietic stem cell transplant; MM, multiple myeloma; R-ISS, Revised International Staging System.
[a] Defined as the presence of del17p, t(4;14), t(14;16), t(14;20), or gain/amp 1q21.
[b] Includes all stages and unspecified forms of chronic kidney disease, as well as dialysis and end-stage renal disease.
[c] Includes pneumonia, upper respiratory infections, fungal infections, hepatitis B and C, *c. difficile* infection, bacteremia, *pneumocystis jirovecii*, and tuberculosis.

Figure 1. Overall response rate



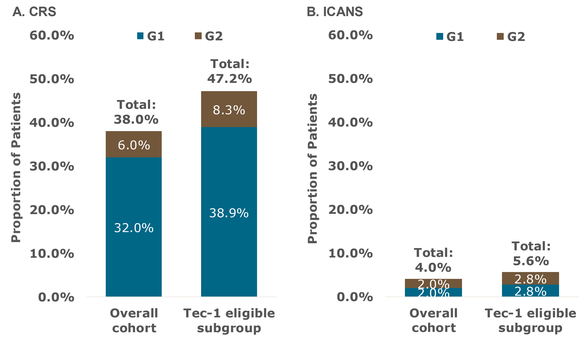
Abbreviations: ORR, overall response rate; PR, partial response; sCR, stringent complete response. VGPR, very good partial response.
Note: Patients with complete response or better require a bone marrow biopsy, and hence the rate may be underreported in the real-world setting. VGPR+ includes patients with VGPR, CR and sCR. CR, complete response.

Table 2. Safety outcomes: Treatment setting and supportive care

	Overall cohort (N = 50)	TEC-1 eligible subgroup (N = 36)
CRS during SUD		
Treatment setting for CRS events, n (%)		
Patients in hospital for IP SUD	15 (30.0)	14 (38.9)
Patient hospitalized during OP-SUD	1 (2.0)	1 (2.8)
Patient treated outpatient for CRS	2 (4.0)	2 (5.6)
Unknown	1 (2.0)	0 (0)
Supportive care, n (%)		
Acetaminophen	3 (6.0)	3 (8.3)
Dexamethasone	2 (4.0)	2 (5.6)
Diphenhydramine	1 (2.0)	0 (0)
Tocilizumab[a]	3 (6.0)	3 (8.3)
Tocilizumab + dexamethasone[a]	1 (2.0)	1 (2.8)
Antibiotics	2 (4.0)	2 (5.6)
Other steroids	1 (2.0)	1 (2.8)
Unknown	6 (12.0)	5 (13.9)
ICANS during SUD		
Treatment setting for ICANS, n (%)		
Patients in hospital for IP SUD	2 (4.0)	2 (5.6)
Supportive care, n (%)		
Dexamethasone	2 (4.0)	2 (5.6)
Infections while patients were on teclistamab		
Number of patients with infections, n (%)	34 (68.0)	25 (69.4)
Time from teclistamab initiation to infection, median (range) days	40 (6-405)	27.5 (6-405)
Primary prophylaxis for infection, n (%)[b]		
Antiviral	47 (94.0)	33 (91.7)
Antibiotics	23 (46.0)	14 (38.9)
IVIG	23 (46.0)	17 (47.2)
Antifungal	5 (10.0)	4 (11.1)
GCSF	4 (8.0)	3 (8.3)
IVIG as treatment for infection, n (%)	6 (12.0)	5 (13.9)
Treatment setting for infection, n (%)		
Patients in hospital for IP SUD	2 (4.0)	2 (5.6)
Emergency Department	1 (2.0)	1 (2.8)
Patient hospitalized during OP-SUD	2 (4.0)	2 (5.6)
Hospitalization, outpatient[c]	3 (6.0)	3 (8.3)
No treatment recommended	1 (2.0)	1 (2.8)
Patient treated OP during OP-SUD	24 (48.0)	15 (41.7)
Outpatient, already in hospital[d]	1 (2.0)	1 (2.8)

Abbreviations: CRS, cytokine release syndrome; GCSF, granulocyte colony-stimulating factor; ICANS, immune effector cell-associated neurotoxicity syndrome; IP, inpatient; IVIG, immunoglobulin; SUD, step-up dosing.
[a] Among the patients who received tocilizumab treatment for CRS (n = 4), most (3/4) received it after the first step-up dose, and 1 received it after the second step-up dose.
[b] For patients who did not have a prior infection.
[c] For patients who experienced multiple infection episodes, with the first episode occurring and being treated during hospitalization, and the subsequent episode treated in the outpatient setting.
[d] For patients who experienced multiple infection episodes, with the first episode being treated in the outpatient setting, and the subsequent episode treated while the patient was already in the hospital for other reasons.
Note: Supportive care information reported as available; data may be missing. Infection grade information was not available.

Figure 2. Rates and severity of CRS and ICANS during SUD



Abbreviations: CRS, cytokine release syndrome; G, grade; ICANS: immune effector cell-associated neurotoxicity syndrome; SUD, set-up dosing.

RESULTS (CONT.)

Effectiveness

- At a median follow-up of 14.3 months, the overall response rate (ORR) was 74.0% in the overall cohort and 75.0% in the Tec-1 eligible subgroup (**Figure 1**)
- The estimated 12-month progression-free survival rate was 65.0% in the overall cohort and 76.0% in the Tec-1 eligible subgroup
- The estimated 12-month overall survival rates were 75.0% and 78.0% in the overall cohort, and in the Tec-1 eligible subgroup, respectively
- The median PFS and OS were not reached

Safety

- Only Grade 1 or Grade 2 CRS were noted during SUD
  - CRS occurred in 19 (38.0%) of the overall patients (Grade 1: 32.0%; Grade 2: 6.0%) and in 17 (47.2%) Tec-1 eligible patients (Grade 1: 38.9%; Grade 2: 8.3%; **Figure 2**)
- Only Grade 1 or Grade 2 ICANS were noted during SUD
  - Two patients (4%) in the overall (Grade 1: 2%; Grade 2: 2%) and 2 patients (5.6%) in Tec-1 eligible cohort (Grade 1: 2.8%; Grade 2: 2.8%) experienced ICANS
- All CRS and ICANS events were resolved during SUD
- Infections occurred in 34 (68.0%) of overall patients and in 25 (69.4%) Tec-1 eligible patients
  - Among those who were not hospitalized prior to an infection event, 5 (10%) of overall patients, and 5 (13.8%) of Tec-1 eligible patients required hospitalization for treatment of infections; nearly half of the patients (Overall=48%, Tec-1 eligible= 41.7%) were treated for infections solely in the outpatient settings
- Forty-six percent of patients received at least one dose of IVIG prophylaxis in both cohorts

KEY TAKEAWAY

- **This real-world study demonstrates that teclistamab is effective and safe to administer in community settings, with robust ORRs and manageable AEs observed in both overall and Tec-1 eligible cohorts**

CONCLUSIONS

- **Real-world patients treated with teclistamab in community settings demonstrated a numerically higher ORR compared to the MajesTEC-1 trial despite being older, heavily pretreated, and having high disease burden**
- **Effectiveness outcomes were numerically similar between Tec-1 eligible subgroup patients and the overall cohort**
- **Incidence and severity of CRS and ICANS were low, with all events resolving during SUD**

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Author Disclosures

Yair Levy is a speaker/consultant for Johnson & Johnson. Laura Ensley and Siraje Mahmud report no disclosures. Monica Lisi and Lorraine Brisbin were employees of Precision Health Informatics during the conduct of this study and may own stock options and/or shares in Precision Health Informatics. Steven R. Paulson reports no disclosures. Felice Yang was a contracted employee of Johnson & Johnson during the conduct of this study and has no conflicts of interest to disclose. Arveen Kaur, Gilbert Ko, Niodita Gupta-Werner, and Jessica Fowler are employees of Johnson & Johnson and may own stock options and/or shares in Johnson & Johnson.

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