MM-1078

OPTec/OPTal: A phase 2 study to evaluate outpatient (OP), step-up administration of teclistamab (Tec) or talquetamab (Tal) with prophylactic tocilizumab (prophyToci) in patients with relapsed/refractory multiple myeloma (RRMM)

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Key Takeaways

- ProphyToci before outpatient SUD1 of Tec or Tal reduced CRS incidence by approximately 5-fold
- The addition of prophyToci had no negative impact on safety and efficacy
- Data support administration of bispecific antibodies (bsAbs) in the community-based outpatient setting

Conclusions

- ProphyToci before Tec or Tal SUD1 reduced the CRS rate to approximately 12.2%; no grade ≥3 CRS or ICANS events were observed
- Outpatient SUD of Tec or Tal with prophyToci in the community setting did not negatively impact safety or efficacy, with ORRs of 68.9% and 71.4% and grade ≥3 infection rates of 17.8% and 28.6%, respectively
- Arm C has been opened to assess whether prophylactic oral dexamethasone enables safe community-based outpatient administration of Tec

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Disclosures

Thomas S. Lin is a current employee of Johnson & Johnson and may hold stock in Johnson & Johnson.

Introduction

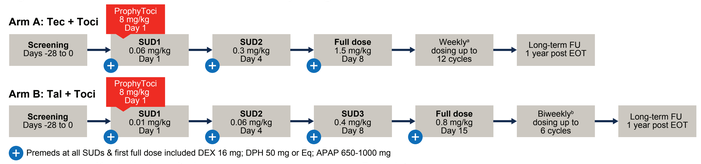
- Cytokine release syndrome (CRS) is a common adverse event (AE) with bispecific T-cell engagers for multiple myeloma (MM), which is why inpatient hospitalization for the step-up dosing (SUD) schedule is recommended
- Cohorts in the MajesTEC-1 and MonumenTAL-1 studies received a single intravenous (IV) dose of prophylactic tocilizumab (prophyToci), resulting in a lower rate of CRS at 26% and 18%, respectively[1,2]
- OPTec/OPTal is a two-arm, community practice-based trial evaluating outpatient administration and SUD monitoring for teclistamab (Tec) and talquetamab (Tal) with prophyToci across 15 sites in the United States (**Figure 1**)

Figure 1. OPTec/OPTal study sites in the United States

Methods

- The study design for the phase 2 OPTec/OPTal outpatient study is shown in **Figure 2**
- Safety monitoring for outpatient administration included:
  - Requirement to be within 60 minutes of the clinic and in the company of a competent adult for 48 hours following each treatment in the SUD schedule
  - 60-minute post-administration observation following all doses for the first 2 cycles
  - Daily investigator assessments for 2 days following each treatment in the SUD schedule
  - Home monitoring of temperature and oxygen saturation twice daily for the first 2 cycles
  - Neurological exams for the first 2 cycles

Figure 2. Phase 2 OPTec/OPTal outpatient study design



Premeds at all SUDs & first full dose included DEX 16 mg; DPH 50 mg or Eq: APAP 650-1000 mg

Key inclusion criteria

- ≥18 years
- ECOG: 0-1
- 2 or more prior MM therapies
  - PI, IMiD, and/or CD38 antibody
- Measurable disease at screening
- Body weight >35 kg
- Stable clinical labs
- Within 60 minutes of site during SUDs & first full dose

Endpoints

Primary Endpoint:
- Incidence of CRS from SUD1 to the end of C2

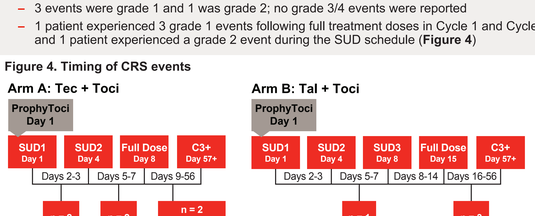
Secondary Endpoints:
- Recurrent CRS or CRS during 12 months Tec or 6 months Tal
- ORR per IMWG
- TTR, TTBR, and DOR from first SUD1 to first efficacy eval
- PFS[c] & OS
- Grade ≥3 and any grade infections

APAP, acetaminophen; C, cycle; CRS, cytokine release syndrome; DEX, dexamethasone; DOR, duration of response; DPH, diphenhydramine; ECOG, Eastern Cooperative Oncology Group; EOT, end of treatment; Eq, equivalent; FU, follow up; IMiD, immunomodulatory drug; IMWG, International Myeloma Working Group; MM, multiple myeloma; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; PR, partial response; prophyToci, prophylactic tocilizumab; SUD, step-up dosing; Tal, talquetamab; Tec, teclistamab; Toci, tocilizumab; TTBR, time to best response; TTR, time to response; VGPR, very good partial response.
[a]Dosing can be adjusted to biweekly based on response (≥PR) post C6.
[b]Dosing can be adjusted to monthly based on response (≥VGPR) post C4.
[c]PFS is the time from the date of the first SUD of TecTal to the date of first documented disease progression, as defined in the IMWG response criteria, or death due to any cause, whichever occurs first.

Results

- As of 6 March 2026, 45 patients enrolled in the Tec + Toci group and 7 in the Tal + Toci group (**Figure 3**)

Figure 3. Overall patient disposition



AE, adverse event; IMWG, International Myeloma Working Group; PD, progressive disease; Tal, talquetamab; Tec, teclistamab; Toci, tocilizumab.
[a]Arm A closure: March 31, 2026; Arm B closure, November 5, 2025.
[b]Includes physician decision.
[c]Includes clinical PD in the absence of IMWG PD.

- Baseline characteristics are shown in **Table 1**

Table 1. Baseline characteristics

	Arm A: Tec + Toci (n = 45)	Arm B: Tal + Toci (n = 7)
Baseline characteristics, n (%)		
Median age (range), years	74.0 (53-87)	66.0 (58-83)
Male	25 (55.6)	4 (57.1)
White	32 (71.1)	5 (71.4)
ECOG score 1	35 (77.8)	5 (71.4)
Number of prior lines		
Median prior lines (n, range)	5.0 (1-11)	6.0 (2-9)
Prior exposure, n (%)		
IMiD (lenalidomide/pomalidomide)	42 (93.3)	7 (100)
PI	44 (97.8)	7 (100)
CD38 monoclonal antibody	42 (93.3)	7 (100)
Triple-class exposure[a]	40 (88.9)	7 (100)
Penta-class exposure[b]	18 (40.0)	5 (71.4)

ECOG, Eastern Cooperative Oncology Group; IMiD, immunomodulatory drug; PI, proteasome inhibitor; Tal, talquetamab; Tec, teclistamab; Toci, tocilizumab.
[a]1 IMiD, 1 PI, an anti-CD38.
[b]2 IMiD, 2 PI, an anti-CD38.

- In the Tec + Toci group, 6 CRS events were reported in 4 of 45 patients (8.9%)
  - All events were grade 1; no grade 3/4 events were reported
  - 4 events occurred during the SUD schedule and 2 events occurred following full treatment doses in Cycle 1 and Cycle 2 (**Figure 4**)
- In the Tal + Toci group, 4 CRS events were reported in 2 of 7 patients (28.5%)
  - 3 events were grade 1 and 1 was grade 2; no grade 3/4 events were reported
  - 1 patient experienced 3 grade 1 events following full treatment doses in Cycle 1 and Cycle 2 and 1 patient experienced a grade 2 event during the SUD schedule (**Figure 4**)

Figure 4. Timing of CRS events

C, cycle; prophyToci, prophylactic tocilizumab; SUD, step-up dose; Tal, talquetamab; Tec, teclistamab; Toci, tocilizumab.

- Management of the CRS events is described in **Table 2**
- No immune effector cell-associated neurotoxicity syndrome (ICANS) events were reported in either group

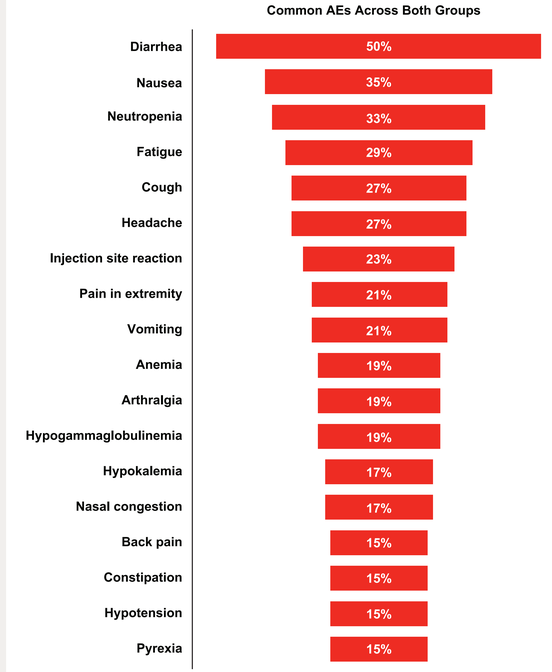
Table 2. Management of CRS events during treatment

Arm A: Tec + Toci (n = 45) 4 of 45 patients had CRS, all grade 1	
Grade 1	• No patients were admitted • All patients were managed with dexamethasone • Dexamethasone dose range: 8-20 mg
Arm B: Tal + Toci (n = 7) 2 of 7 patients had CRS, 1 grade 1 and 1 grade 2	
Grade 1	• One patient experienced 3 grade 1 CRS events (D34, D41, D53) • Patient was admitted for all 3 events (SAEs) • Patient was given dexamethasone (8 mg) and/or antibiotics
Grade 2	• One patient hospitalized (SAE) • Patient given dexamethasone (10 mg), fluid hydration, & tocilizumab • Resolved within 3 days • Tal held for 1 week post resolution of CRS • Repeated SUD2 (7 days after resolution of CRS) • No further CRS reported during time on treatment

CRS, cytokine release syndrome; D, day; SAE, serious adverse event; SUD, step-up dose; Tal, talquetamab; Tec, teclistamab; Toci, tocilizumab.

- The most common AEs across both groups are shown in **Figure 5**

Figure 5. Common AEs across both groups



AE, adverse event.

- The most common grade ≥3 events across both groups included neutropenia (n = 13), sepsis (n = 4; defined by positive blood culture results), and anemia (n = 4)
- 1 fatal AE occurred in treated patients (sepsis, Tec + Toci group)
  - No hypogammaglobulinemia or IVIg replacement was reported
- Infections were common in both study groups (**Table 3**)

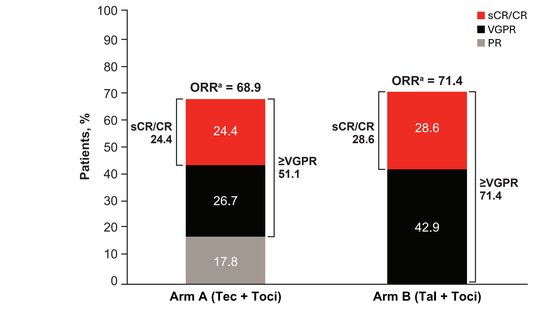
Table 3. Infections

	Arm A: Tec + Toci	Arm B: Tal + Toci
Total infections, any grade		
Total events	n = 23	n = 5
Total incidence	23/45 (51.1%)	5/7 (71.4%)
Total infections, grade ≥3		
Total events	n = 8	n = 2
Total incidence	8/45 (17.8%)	2/7 (28.6%)

Tal, talquetamab; Tec, teclistamab; Toci, tocilizumab.

- Overall response rate (ORR) was 68.9% in the Tec + Toci group and 71.4% in the Tal + Toci group (**Figure 6**)

Figure 6. Response rates



Best overall response, n (%)	Arm A: Tec + Toci (n = 45)	Arm B: Tal + Toci (n = 7)
sCR	3 (6.7)	1 (14.3)
CR	8 (17.8)	1 (14.3)
VGPR	12 (26.7)	3 (42.9)
PR	8 (17.8)	0
Not evaluable	6 (13.3)	2 (28.6)

CR, complete response; IMWG, International Myeloma Working Group; ORR, overall response rate; PR, partial response; sCR, stringent complete response; Tal, talquetamab; Tec, teclistamab; Toci, tocilizumab; VGPR, very good partial response.
[a]ORR is defined as the proportion of patients who achieve ≥PR according to IMWG.

- With median 11.8 months follow-up, 75.6% of patients in the Tec + Toci group did not experience progression
  - 24.4% have experienced either clinical or objective progression as end of treatment reason (n = 11)
  - 6 patients were discontinued from the study for the following reasons before eventually dying due to progressive disease
    - 2 due to an AE
    - 3 due to physician decision (subsequent therapy and death)
    - 1 withdrew consent (subsequent death during follow up)
- In the Tal + Toci group, no progression events have been reported to-date
- Data continues to mature as 10+ patients remain active

References

1. Martin TG, Mateos MV, Nooka A, et al. *Cancer.* 2023;129(13):2035–2046. 2. Chari A, Touzeau C, Schinke C, et al. *Lancet Hematol.* 2025;12(4):e269–e281.

Multiple Myeloma

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