PA-371

Prophylactic Tocilizumab to Mitigate Cytokine Release Syndrome and Facilitate Dosing of Talquetamab in All Practice Settings in Relapsed/Refractory Multiple Myeloma: Results From MonumenTAL-1

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Key Takeaway

Incidence and severity of CRS was reduced with the addition of prophylactic tocilizumab with or without a modified talquetamab SUD schedule, and efficacy remained consistent compared with the MonumenTAL-1 study population

Conclusions

No increase in neutropenia or infections were observed with prophylactic tocilizumab vs the MonumenTAL-1 population

No increase in ICANS was observed with modified step-up dosing

ORR was high across cohorts and similar to the overall MonumenTAL-1 population

These results support broader use of talquetamab with tocilizumab prophylaxis and postdose dexamethasone in both inpatient and outpatient settings for patients with RRMM; regimens with 1 or 2 SUDs may warrant further evaluation

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Disclosures

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Introduction

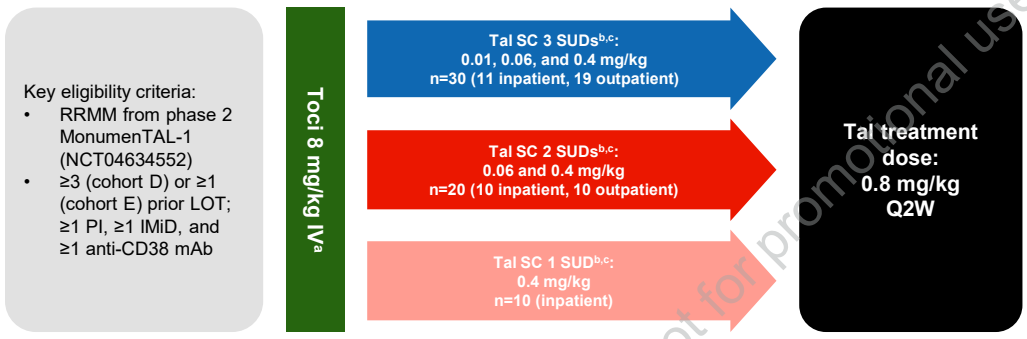
- In the phase 1/2 MonumenTAL-1 study, cytokine release syndrome (CRS) occurred in 75.3% (grade 3: 0.6%) of patients receiving talquetamab 0.8 mg/kg (preceded by 3 step-up doses [SUDs]) every other week (Q2W) without prophylactic tocilizumab,[1] and 37% of patients received tocilizumab treatment for a CRS event[2]
- Real-world experience with prophylactic tocilizumab in patients with relapsed/refractory multiple myeloma (RRMM) receiving bispecific antibodies demonstrated low CRS (10.1%, all grade 1/2), with no grade 3 events or need for further treatment with tocilizumab or corticosteroids[3]

To enable safe and effective outpatient dosing of talquetamab, we report the impact of prophylactic tocilizumab with or without alternative step-up dosing in patients from MonumenTAL-1

Methods

- The first 11 patients from cohort D and the first 10 patients from cohort E for each SUD regimen received the SUDs and first full treatment dose in a hospital, and subsequent patients were outpatients
  - Patients and caregivers in the outpatient setting were made aware of the signs/symptoms of CRS, immune effector cell–associated neurotoxicity syndrome (ICANS), infections, among other adverse events (AEs). They were instructed to measure body temperature 2 times daily (≥8 hours apart) for 48 hours after all SUDs and the first full treatment dose

Figure 1: Study design in patients receiving talquetamab and prophylactic tocilizumab



[a]Given approximately 3 hours prior to Tal with required pretreatments (glucocorticoid, antihistamine, and antipyretic). [b]8 mg PO/IV was given daily for 2 days after each SUD and first full treatment dose. [c]2–4 days elapsed between each SUD; 2–9 days elapsed between the last SUD and the first Tal treatment dose. IMiD, immunomodulatory drug; IV, intravenous; LOT, line of therapy; mAb, monoclonal antibody; PI, proteasome inhibitor; PO, oral; Q2W, every other week; SC, subcutaneous; Tal, talquetamab; toci, tocilizumab.

Results

Table 1: In total, 60 patients received treatment; baseline characteristics were representative of the MonumenTAL-1 population[2]

Parameter	Prophylactic tocilizumab	
	Cohort D (3 SUDs; N=30)	Cohort E (1 or 2 SUDs; N=30)
Follow-up, months, median (range)	17.3 (0.6–32.7)	6.2 (1.6–11.3)
Age, years, median (range)	68.5 (45–87)	65.5 (49–81)
White, n (%)	24 (80.0)	29 (96.7)
Male, n (%)	19 (63.3)	22 (73.3)
ECOG PS, n (%)		
0–1	29 (96.7)	29 (96.7)
2	1 (3.3)	1 (3.3)
Extramedullary plasmacytomas, n (%)		
0	24 (80.0)	26 (86.7)
≥1	6 (20.0)	4 (13.3)
ISS stage,[a] n (%)		
I/II	25 (86.2)	27 (90.0)
III	4 (13.8)	3 (10.0)
Prior LOT, median (range)	4 (3–10)	4 (2–10)
Refractory status, n (%)		
Triple-class[b]	21 (70.0)	20 (66.7)
Penta-drug[c]	7 (23.3)	4 (13.3)
To last LOT	27 (90.0)	24 (80.0)

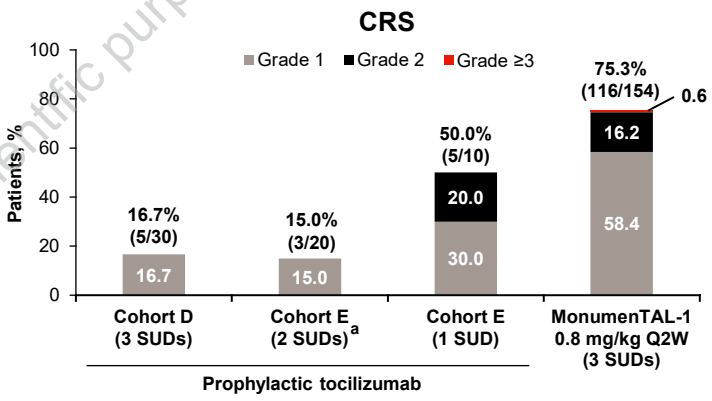
[a]ISS staging is derived based on serum β_2-microglobulin and albumin; calculated from n=29 in Cohort D. [b]≥1 PI, ≥1 IMiD, and ≥1 anti-CD38 mAb. [c]≥2 PIs, ≥2 IMiDs, and ≥1 anti-CD38 mAb. ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System.

Table 3: TEAEs were consistent with the safety profile in MonumenTAL-1, with no increase in neutropenia, infections, ICANS, or other AEs

AE, n (%)	Prophylactic tocilizumab (N=60)	
	Any Grade	Grade 3/4
Any TEAE	60 (100)	37 (61.7)
Hematologic AEs		
Neutropenia	15 (25.0)	10 (16.7)
Anemia	13 (21.7)	4 (6.7)
Thrombocytopenia	10 (16.7)	3 (5.0)
Lymphopenia	9 (15.0)	8 (13.3)
Leukopenia	5 (8.3)	4 (6.7)
Nonhematologic AEs of interest		
Taste changes[a]	53 (88.3)	NA
Skin AEs[b]	38 (63.3)	0
Infections[c]	32 (53.3)	7 (11.7)
Nail AEs[d]	27 (45.0)	0
Dry mouth	23 (38.3)	0
Weight decrease	17 (28.3)	2 (3.3)
Rash AE[e]	17 (28.3)	2 (3.3)
Neurotoxicity[f]	21 (35.0)	0
ICANS	3 (5.0)	0

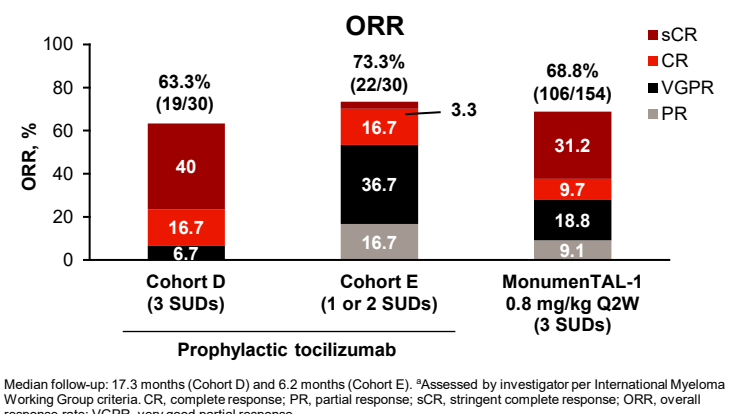
1 patient discontinued treatment due to an AE. Deaths occurred in 6 patients in cohort D (2 due to AEs [pneumonia and chronic obstructive pulmonary disease exacerbation] and 4 due to disease progression). [a]Dysgeusia, ageusia, hypogeusia, and taste disorder; maximum grade for taste changes is 2 per CTCAE. [b]Skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome. [c]Infections described on a System Organ Class basis, and thus not grouped with Preferred Term data in terms of incidence. [d]Nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, nail dystrophy, nail toxicity, and nail ridging. [e]Rash, maculopapular rash, erythematous rash, and erythema. [f]Excluding ICANS. CTCAE, Common Terminology Criteria for Adverse Events; NA, not applicable. TEAEs, treatment-emergent AEs.

Figure 2: Reduced incidence of CRS with prophylactic tocilizumab compared with patients who received 0.8 mg/kg Q2W in MonumenTAL-1



[a]1 patient with grade 1 CRS did not receive prophylactic tocilizumab due to a pump issue.

Figure 3: ORR in prophylactic tocilizumab cohorts D and E were high, consistent with patients who received 0.8 mg/kg Q2W in MonumenTAL-1[a]



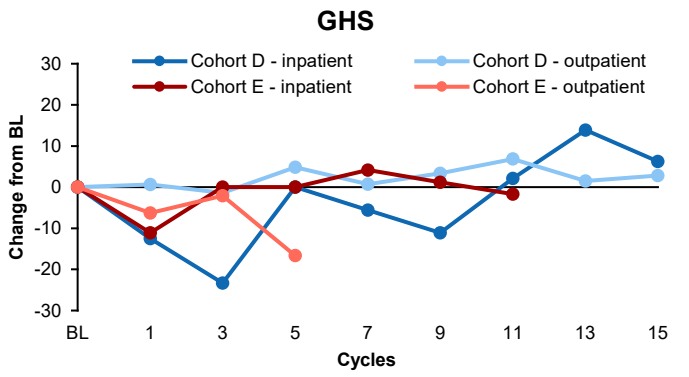
Median follow-up: 17.3 months (Cohort D) and 6.2 months (Cohort E). [a]Assessed by investigator per International Myeloma Working Group criteria. CR, complete response; PR, partial response; sCR, stringent complete response; ORR, overall response rate; VGPR, very good partial response.

Table 2: Reduced incidence of CRS with prophylactic tocilizumab in the outpatient setting; there was 1 report of CRS across 29 patients (3.4%) who received tocilizumab in the outpatient setting

CRS Inpatient vs outpatient	Cohort D Prophylactic toci		Cohort E Prophylactic toci		MonumenTAL-1 0.8 mg/kg Q2W
	Inpatient	Outpatient	Inpatient	Outpatient	Inpatient
	3 SUDs (n=11)[a]	3 SUDs (n=19)[a]	1 or 2 SUDs (n=20)	2 SUDs (n=10)	3 SUDs (N=154)
Incidence, n (%)	4 (36.4)[a]	1 (5.3)[a]	8 (40.0)[b]	0	116 (75.3)
Grade 1	4 (36.4)	1 (5.3)	6 (30.0)	0	90 (58.4)
Grade 2	0	0	2 (10.0)	0	25 (16.2)
Grade 3	0	0	0	0	1 (0.6)
Onset,[c] days, median (range)	2 (2–12)	8 (8–8)	2 (1–5)	–	2 (1–15)
Duration, days, median (range)	1 (1–6)	1 (1–1)	1 (1–38)	–	2 (1–29)
During SUD 1, n (%)	0	0	8 (40.0)	0	42 (27.3)
During SUD 2, n (%)	2 (18.2)	0	1 (10.0)[d]	0	63 (40.9)
During SUD 3, n (%)	1 (9.1)	0	–	–	56 (36.4)
During C1D1, n (%)	1 (9.1)	0	0	0	22 (14.3)
Recovered or resolved, number of events (%)	5/5 (100.0)	1/1 (100.0)	10/10 (100.0)	–	213/213 (100)

[a]1 patient treated on an outpatient basis had CRS while hospitalized for bone pain. [b]1 patient with grade 1 CRS did not receive prophylactic toci due to a pump issue. [c]Relative to the most recent dose. [d]Denominator includes only the 10 patients with 2 SUDs. C, cycle; D, day.

Figure 4: Patient-reported Global Health Status (GHS) was consistent with the overall MonumenTAL-1 population and did not appear to differ between inpatient and outpatient settings



GHS and physical and emotional functioning are measured with European Organisation for Research and Treatment of Cancer quality of life questionnaire core 30 scales, which range from 0–100, with higher values indicating improvements. BL, baseline; D-in, cohort D inpatient; D-out, cohort D outpatient; E2-in, cohort E, 2 SUD, inpatient; E2-out, cohort E, 2 SUD, outpatient.

References

1. Rasche L, et al. *Blood.* Online ahead of print. 2. Chari A, et al. *Lancet Haematol* 2025;12:e269-81. 3. Kowalski A, et al. *Blood Adv* 2025;9:4979-86.

Multiple Myeloma

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