Talquetamab, a GPRC5D×CD3 bispecific antibody, in Chinese patients with relapsed/refractory multiple myeloma: efficacy and safety from the phase 1/2 MonumenTAL-1 study

Disease burden of multiple myeloma (MM), a common malignant disease, tends to be higher in developed countries (e.g., USA) than in developing ones (e.g., China); however, similar to developed countries, in China the incidence of MM has doubled over the past three decades (partly due to the growing total and aging population in China), highlighting the need for effective treatment strategies.[1] Innovative treatment approaches in the relapsed/refractory MM setting include T-cell redirecting B-cell maturation antigen (BCMA)-targeted therapies such as chimeric antigen receptor T-cell therapies[2,3] and bispecific antibodies.[4,5] Despite these advances, patients with relapsed/refractory MM experience cycles of remission and relapse, with a worsening prognosis with each successive relapse.[6,7] Talquetamab, a first-in-class, off-the-shelf, T-cell redirecting bispecific antibody targeting GPRC5D and CD3, was recently approved in the USA, European Union, and China for relapsed/refractory MM[8-11] based on results of the phase I/II global MonumenTAL-1 study (NCT03399799/NCT04634552).[12,13] At the recommended phase 2 doses of talquetamab 0.4 mg/kg weekly (QW) or 0.8 mg/kg every other week (Q2W),[9,10,13] patients demonstrated high overall response rates (74.1% and 69.5%, respectively) and durable responses (median duration of response 9.5 and 16.9 months, respectively), with low discontinuation rates due to adverse events (4.9% and 9.1%, respectively).[13] Here, we report the first results of talquetamab in Chinese patients enrolled as a separate phase 2 cohort in MonumenTAL-1 (China cohort), who were not included in the global MonumenTAL-1 analysis.

Patients enrolled in the China cohort of MonumenTAL-1 were required to have measurable MM as per International Myeloma Working Group criteria,[14] have received three or more prior lines of therapy (≥1 proteasome inhibitor, ≥1 immunomodulatory drug, ≥1 anti-CD38 monoclonal antibody), have an Eastern Cooperative Oncology Group performance status ≤2, and have had no prior exposure to T-cell redirecting therapy. Patients received subcutaneous talquetamab 0.4 mg/kg QW or 0.8 mg/kg Q2W.[12] To mitigate the risk of cytokine release syndrome (CRS), patients were pretreated with dexamethasone, an antihistamine, and an antipyretic. The primary endpoint was overall response rate. Responses were calculated with two-sided 95% confidence intervals. The Kaplan-Meier method was used for duration of response, progression-free survival, and overall survival analyses. CRS and immune effector cell-associated neurotoxicity syndrome (ICANS) were graded by American Society for Transplantation and Cellular Therapy criteria; all other adverse events were graded by Common Terminology Criteria for Adverse Events v4.03. Pharmacokinetic profiles and immunogenicity were evaluated in patients who received one or more doses of talquetamab and had one or more post-dose samples. The MonumenTAL-1 study was conducted in accordance with the Declaration of Helsinki and the International Council for Harmonisation Good Clinical Practice guidelines, with institutional review board approval; all patients provided informed written consent.

The results of the analysis were based on 29 and 12 patients who received the QW and Q2W talquetamab schedules, respectively, enrolled as two cohorts in the MonumenTAL-1 China cohort between February 2022 and September 2023. Baseline demographic and disease characteristics were generally similar between cohorts; in the QW and Q2W cohorts, respectively, 20.7% and 8.3% of patients had extramedullary disease, 37.0% and 30.0% had high-risk cytogenetics, and 6.9% and 8.3% had International Staging System stage III disease.

In terms of efficacy, with a median follow-up of 16.3 and 8.2 months for the respective cohorts, the overall response rates (69.0% and 66.7%) and rates of very good partial response or better (58.6% and 58.3%) were similar (Table 1). Overall response rates were generally consistent across clinically relevant subgroups with the exception of patients with extramedullary disease who had a lower overall response rates (33.3% in the QW cohort; 1 patient with extramedullary disease in the Q2W cohort died prior to disease evaluation). The median time to first response was 1.3 months in both cohorts. The median duration of response was 15.7 months and not reached in the QW and Q2W cohorts, respectively; the median progression-free survival was 8.3 months and not reached, respectively; the median overall survival was not reached in either cohort, with 72.4% (QW) and 91.7% (Q2W) of patients censored (Table 1).

With regard to safety, common adverse events included CRS (most common), on-target, off-tumor events, and infections (Table 2, described further below). Hematologic toxicities were the most common grade 3/4 events. Adverse events resulted in treatment discontinuation in

Table 1. Efficacy of talquetamab in the different dosing cohorts within the MonumenTAL-1 China cohort.

Outcomes	Talquetamab 0.4 mg/kg SC QW[a] N=29	Talquetamab 0.8 mg/kg SC Q2W[a] N=12
ORR, % (95% CI) ≥CR ≥VGPR	69.0 (49.2-84.7) 37.9 (20.7-57.7) 58.6 (38.9-76.5)	66.7 (34.9-90.1) 50.0 (21.1-78.9) 58.3 (27.7-84.8)
MRD negativity (10^{-5}),[b] % (95% CI) ≥CR,[c] % (95% CI)	79.3 (60.3-92.0) 100.0 (NE-NE)	58.3 (27.7-84.8) 100.0 (NE-NE)
Time to first response,[d] months, median (range)	1.3 (1.1-2.7)	1.3 (0.4-2.2)
Time to ≥VGPR,[e] months, median (range)	2.2 (1.1-5.4)	1.4 (1.2-2.1)
DOR,[d] months, median (95% CI) 6-month DOR rate, % (95% CI) 9-month DOR rate, % (95% CI)	15.7 (5.7-NE) 70.0 (45.1-85.3) 60.0 (35.7-77.6)	NR (2.8-NE) 85.7 (33.4-97.9) -[f]
PFS, months, median (95% CI) 6-month PFS rate, % (95% CI) 9-month PFS rate, % (95% CI)	8.3 (6.3-NE) 73.3 (52.0-86.3) 48.9 (28.6-66.4)	NR (2.3-NE) 61.4 (26.6-83.5) -[f]
OS, months, median (95% CI)	NR (14.5-NE)	NR (NE-NE)

[a]With two to three step-up doses. [b]Minimal residual disease was detected by next-generation flow cytometry in China. [c]N=11 (QW cohort); N=6 (Q2W cohort). [d]N=20 (QW cohort); N=8 (Q2W cohort). [e]N=17 (QW cohort); N=7 (Q2W cohort). [f]Data are not yet mature. SC: subcutaneous; QW weekly; Q2W: every other week; ORR: overall response rate; 95% CI: 95% confidence interval; CR: complete response; VGPR: very good partial response; MRD: minimal residual disease; NE: not estimable; DOR: duration of response; PFS: progression-free survival; NR: not reached; OS: overall survival.

Table 2. Hematologic and non-hematologic adverse events in the different talquetamab dosing cohorts within the MonumenTAL-1 China cohort.

Adverse events	Talquetamab 0.4 mg/kg SC QW[a] N=29		Talquetamab 0.8 mg/kg SC Q2W[a] N=12	
	Any grade	Grade 3 or 4	Any grade	Grade 3 or 4
Hematologic, N (%)				
Leukopenia	23 (79.3)	10 (34.5)	10 (83.3)	4 (33.3)
Lymphopenia	21 (72.4)	20 (69.0)	9 (75.0)	9 (75.0)
Anemia	22 (75.9)	8 (27.6)	8 (66.7)	3 (25.0)
Neutropenia	21 (72.4)	9 (31.0)	8 (66.7)	2 (16.7)
Thrombocytopenia	9 (31.0)	5 (17.2)	4 (33.3)	1 (8.3)
Non-hematologic, N (%)				
CRS	26 (89.7)	2 (6.9)	10 (83.3)	0
Infections[b]	23 (79.3)	15 (51.7)	5 (41.7)	2 (16.7)
Weight decrease	15 (51.7)	0	6 (50.0)	0
Pyrexia	19 (65.5)	0	4 (33.3)	0
Non-rash skin-related[c]	15 (51.7)	1 (3.4)	5 (41.7)	0
Hypokalemia	11 (37.9)	4 (13.8)	6 (50.0)	1 (8.3)
Taste-related[d,e]	12 (41.4)	NA	3 (25.0)	NA
Cough	11 (37.9)	0	3 (25.0)	0
Hypocalcemia	11 (37.9)	1 (3.4)	3 (25.0)	0
Rash-related[f]	11 (37.9)	1 (3.4)	3 (25.0)	0
Decreased appetite	8 (27.6)	0	4 (33.3)	0
Nail-related[g]	4 (13.8)	0	5 (41.7)	0
Insomnia	9 (31.0)	0	2 (16.7)	0
Increased CRP	0	0	4 (33.3)	0
Constipation	9 (31.0)	0	0	0
Diarrhea	9 (31.0)	0	0	0

The adverse events listed are those occurring in ≥30% of either cohort. [a]With two to three step-up doses. [b]Infections are reported at the System Organ Class level. [c]Includes skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome. [d]Includes dysgeusia, ageusia, hypogeusia, and taste disorder. [e]Per Common Terminology Criteria for Adverse Events v.4.03, the maximum grade for these events is 2. [f]Includes rash, maculopapular rash, erythematous rash, and erythema. [g]Includes nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, nail dystrophy, nail toxicity, and nail ridging. SC: subcutaneous; QW weekly; Q2W: every other week; CRS: cytokine release syndrome; NA: not applicable; CRP: C-reactive protein.

one patient (3.4%; ventricular fibrillation) and two patients (16.7%; progressive multifocal leukoencephalopathy and peripheral neuropathy) in the QW and Q2W cohorts, respectively. Dose reductions occurred in three patients (10.3%; pyrexia, weight decrease, and dizziness) and two patients (16.7%; same as those who discontinued treatment), respectively. Serious adverse events occurred in 20 (69.0%; QW) and four (33.3%; Q2W) patients. Grade 5 adverse events occurred in two (6.9%) patients in the QW cohort (ICANS [N=1; this was the only patient who experienced ICANS in both cohorts], attributed to talquetamab, and sudden cardiac death [N=1], not attributed to talquetamab). No grade 5 adverse events occurred in the Q2W cohort.

CRS events were generally grade 1 (62.1% and 75.0%) or 2 (20.7% and 8.3%) and occurred primarily during step-up and cycle 1 doses. Grade 3 CRS events occurred in two (6.9%) patients in the QW cohort and in no patients in the Q2W cohort. Recurrent CRS events occurred in 62.1% (17/18 grade 1/2) and 58.3% (all grade 1/2) of patients, respectively. Supportive measures were given to 26 (89.7%) and ten (83.3%) patients in the QW and Q2W cohorts, respectively. Corticosteroids were the most common supportive measure for CRS; tocilizumab was used in 25.0-41.4% of patients. All but one CRS event resolved, and no patients discontinued treatment due to CRS.

On-target, off-tumor adverse events included non-rash skin- (51.7% [QW] and 41.7% [Q2W]), nail- (13.8% and 41.7%), taste- ([e.g., dysgeusia] 41.4% and 25.0%), and rash- (37.9% and 25.0%) related adverse events (Table 3). Most were grade 1/2. No discontinuations or dose modifications were required (Table 3). Weight decrease was reported in 15 (51.7%) and six (50.0%) patients in the QW and Q2W cohorts, respectively. Initial weight loss and weight stabilization over time were observed in patients with and without dysgeusia; however, the small sample size in the China cohort limits conclusions about an association between weight loss and dysgeusia.

Infections occurred in 79.3% and 41.7% of patients in the QW and Q2W cohorts, respectively, and grade 3/4 infections occurred in 51.7% and 16.7%, respectively (Table 2). COVID-19 and pneumonia were the most common infections. Opportunistic infections occurred in two patients (6.9%) and one patient (8.3%), respectively. No patients died due to infections. Hypogammaglobulinemia was reported in three patients (10.3%) and one patient (8.3%), respectively. Intravenous immunoglobulin was used in four (13.8%) and three (25.0%) patients, respectively.

In terms of pharmacokinetics and immunogenicity analyses, mean talquetamab concentration-time profiles overlapped between the QW and Q2W cohorts and were maintained at or above the maximum EC_{90} (concentration required to achieve 90% inhibition of the maximum response) values identified in an *ex vivo* cytotoxicity assay (*Online Supplementary Figure S1*). Patients who responded to talquetamab had a greater reduction in soluble BCMA from baseline to cycle 2 day 1 *versus* non-responders (*Online Supplementary Figure S2*). Treatment-emergent anti-talquetamab antibodies were detected in 14/29 (48.3%) and 3/11 (27.3%) evaluable patients in the QW and Q2W cohorts, respectively. There was no apparent impact of anti-talquetamab antibodies on the pharmacokinetics, safety, or efficacy of talquetamab.

Together, these first results of the use of the novel bispecific antibody talquetamab in Chinese patients demonstrated high rates of deep and durable responses across the two dose cohorts, consistent with results from the global MonumenTAL-1 cohorts.[13] Both dose schedules appeared equally effective in the China cohort and the clinical findings were supported by pharamcokinetic data, further validating selection of the two approved doses of talquetamab.

CRS was the most common adverse event and its incidence was slightly higher in the China cohort than in the global cohorts (83-90% *vs*. 73-79%).[13] Nonetheless, most CRS events in the China cohort were grade 1/2, and all but one resolved; this last was a patient with grade 5 ICANS who died before concurrent CRS resolved. Studies are ongoing assessing the use of prophylactic tocilizumab to mitigate CRS with talquetamab, with initial promising results demonstrated in the global MonumenTAL-1 population.[15]

On-target, off-tumor (GPRC5D-related) adverse events were common, mainly grade 1/2, and did not require dose reductions or treatment discontinuations. GPRC5D has been found in malignant plasma cells, eccrine glands, hair follicles, keratogenous zones of nail beds, and filiform papillae on the tongue,[16] which may partially explain the GPRC5D-related adverse events seen with talquetamab. Interestingly, rates of taste-related adverse events in the China cohort (25.0-41.4%) were substantially lower than in the global MonumenTAL-1 study (71.4-72.0%); the reasons for this are unclear, and further research is being conducted to understand taste-related adverse events in the China cohort.

In the global MonumenTAL-1 study, rates of high-grade infections were lower than observed in published studies of BCMA-targeting bispecific antibodies, being 18-20% with talquetamab compared with 40-45% with BCMA bispecific antibodies.[4,5,13] In the China cohort, the rates of grade 3/4 infection in the Q2W cohort (16.7%) were similar to those in the global Q2W MonumenTAL-1 cohort (18.2%),[13] whereas grade 3/4 infection rates in the QW cohort (51.7%) were substantially higher than in the global QW MonumenTAL-1 cohort (20.3%).[13] These results likely reflect the peak of the COVID-19 pandemic during this cohort's study period (2022-2023). No fatal infections occurred in the China cohort.

In conclusion, despite limitations of the single-arm design of the MonumenTAL-1 study and small China cohort sample size, our results showed rapid and deep responses with

Table 3. Onset, duration, and outcomes of skin-, nail-, rash-, and taste-related adverse events in the different talquetamab dosing cohorts within the MonumenTAL-1 China cohort.

Adverse events	Talquetamab 0.4 mg/kg SC QW[a] N=29	Talquetamab 0.8 mg/kg SC Q2W[a] N=12
Non-rash skin-related adverse events[b]		
Total patients affected, N (%)	15 (51.7)	5 (41.7)
Leading to dose modification, N (%)	0	0
Onset, days, median (range)[c]	62.0 (14-496)	19.0 (14-313)
Duration, days, median (range)	40.0 (1-129)	28.0 (18-144)
Outcome		
Events, N	25	5
Recovered or resolved, N (%)	17 (68.0)	5 (100.0)
Not recovered or not resolved, N (%)	6 (24.0)	0
Recovered or resolved with sequelae, N (%)	0	0
Recovering or resolving, N (%)	2 (8.0)	0
Unknown, N (%)	0	0
Missing, N (%)	0	0
Nail-related adverse events[d]		
Total patients affected, N (%)	4 (13.8)	5 (41.7)
Leading to dose modification, N (%)	0	0
Onset, days, median (range)[c]	45.5 (17-154)	40.0 (35-145)
Duration, days, median (range)	223.0 (65-381)	117.0 (117-117)
Outcome		
Events, N	4	5
Recovered or resolved, N (%)	2 (50.0)	1 (20.0)
Not recovered or not resolved, N (%)	2 (50.0)	4 (80.0)
Recovered or resolved with sequelae, N (%)	0	0
Recovering or resolving, N (%)	0	0
Unknown, N (%)	0	0
Missing, N (%)	0	0
Rash-related adverse events[e]		
Total patients affected, N (%)	11 (37.9)	3 (25.0)
Leading to dose modification, N (%)	0	0
Onset, days, median (range)[c]	24.5 (11-247)	9.0 (2-173)
Duration, days, median (range)	17.0 (1-202)	23.0 (1-49)
Outcome		
Events, N	14	3
Recovered or resolved, N (%)	11 (78.6)	3 (100.0)
Not recovered or not resolved, N (%)	3 (21.4)	0
Recovered or resolved with sequelae, N (%)	0	0
Recovering or resolving, N (%)	0	0
Unknown, N (%)	0	0
Missing, N (%)	0	0
Taste-related adverse events[f]		
Total patients affected, N (%)	12 (41.4)	3 (25.0)
Leading to dose modification, N (%)	0	0
Onset, days, median (range)[c]	14.5 (6-64)	16.0 (5-18)
Duration, days, median (range)	231.0 (93-417)	160.0 (160-160)
Outcome		
Events, N	12	3
Recovered or resolved, N (%)	7 (58.3)	1 (33.3)
Not recovered or not resolved, N (%)	5 (41.7)	2 (66.7)
Recovered or resolved with sequelae, N (%)	0	0
Recovering or resolving, N (%)	0	0
Unknown, N (%)	0	0
Missing, N (%)	0	0

[a]With two to three step-up doses. [b]Including skin exfoliation, dry skin, pruritus, and palmar-plantar erythrodysesthesia syndrome. [c]Day of onset of the adverse event relative to initial step-up dose. [d]Including nail discoloration, nail disorder, onycholysis, onychomadesis, onychoclasis, nail dystrophy, nail toxicity, and nail ridging. [e]Including rash, maculopapular rash, erythematous rash, and erythema. [f]Including dysgeusia, ageusia, hypogeusia, and taste disorder. SC: subcutaneous; QW weekly; Q2W: every other week.

talquetamab in patients with relapsed/refractory MM from China, where MM disease burden is rising steeply. Rates of discontinuations due to adverse events were low, and there were no discontinuations due to oral or dermatological on-target, off-tumor adverse events. These results were generally consistent with findings from the global MonumenTAL-1 study and show that talquetamab is an important new treatment option in China.

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Contributions

GA, ZC, HJ, CF, PH, ZX, HX, LQ, and JJ contributed to the study design, study conduct, and data acquisition and interpretation. RL, LL, HZ, BWL, MC, TJM, TR, CH, IS, and DV contributed to the study design, study conduct, and data analysis and interpretation. LZ and BS contributed to data acquisition, analysis, and interpretation. DZ, XG, and XL contributed to data analysis and interpretation. All authors participated in drafting or revising the manuscript, and all approved the final version for submission. All authors had full access to all the data in the study and accept full responsibility for the decision to submit for publication.

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Data-sharing statement

The data sharing policy of Johnson & Johnson is available at *https://www.jnj.com/innovativemedicine/node/87*. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site *http://yoda.yale.edu*.

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