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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

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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

Running head: Outcomes for Chinese patients with RRMM treated with talquetamab

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GA, JJ, ZC, HJ, CF, PH, ZX, XG, DZ, XL, and BS have no conflicts of interest to disclose.

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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 at http://yoda.yale.edu.

Disease burden of multiple myeloma (MM), a common malignant disease, tends to be higher in developed (e.g., United States) vs developing (e.g., China) countries; however, similar to developed countries, MM incidence in China has doubled over the past 3 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 (RRMM) setting include T-cell redirecting B-cell maturation antigen (BCMA)-targeted therapies such as chimeric antigen receptor (CAR)-T-cell therapies[2,3] and bispecific antibodies (BsAbs).[4,5] Despite these advances, patients with RRMM 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 BsAb targeting GPRC5D and CD3, was recently approved in the United States, European Union, and China for RRMM[8-11] based on results of the phase 1/2 global MonumenTAL-1 (NCT03399799/NCT04634552) study.[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 (ORRs; 74.1% and 69.5%, respectively) and durable responses (median duration of response [DOR]; 9.5 and 16.9 months, respectively), with low discontinuation rates due to adverse events (AEs; 4.9% and 9.1%, respectively).[13] 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 per International Myeloma Working Group criteria,[14] received ≥3 prior lines of therapy (≥1 proteasome inhibitor, ≥1 immunomodulatory drug, ≥1 anti-CD38 monoclonal antibody), an Eastern Cooperative Oncology Group performance status ≤2, and no prior exposure to T-cell redirection therapy. Patients received subcutaneous (SC) talquetamab 0.4 mg/kg QW or 0.8 mg/kg Q2W.[12] To mitigate risk of cytokine release syndrome (CRS), patients received pretreatment with dexamethasone, an antihistamine, and an antipyretic. The primary endpoint was ORR. Responses were calculated with two-sided 95% confidence intervals. The Kaplan-Meier method was used for DOR, progression-free survival (PFS), and overall survival (OS) analyses. CRS and immune effector cell–associated

neurotoxicity syndrome (ICANS) were graded by American Society for Transplantation and Cellular Therapy criteria; all other AEs were graded by Common Terminology Criteria for Adverse Events v4.03. Pharmacokinetic profiles and immunogenicity were evaluated in patients who received ≥1 dose of talquetamab and had ≥1 post-dosing sample. 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 receiving 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 (EMD), 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, ORR (69.0% and 66.7%) and rates of very good partial response or better (58.6% and 58.3%) were similar (Table 1). ORRs were generally consistent across clinically relevant subgroups with the exception of patients with EMD who had lower ORRs (33.3% in the QW cohort; 1 patient with EMD in the Q2W cohort died prior to disease evaluation). Median time to first response was 1.3 months in both cohorts. Median DOR was 15.7 months and not reached (NR) in the QW and Q2W cohorts, respectively; median PFS was 8.3 months and NR, respectively; median OS was NR in either cohort, with 72.4% (QW) and 91.7% (Q2W) of patients censored (Table 1).

In terms of safety, common AEs 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. AEs resulted in treatment discontinuation in one (3.4%; ventricular fibrillation) and two (16.7%; progressive multifocal leukoencephalopathy and peripheral neuropathy) patients in the QW and Q2W cohorts, respectively. Dose reductions occurred in three (10.3%; pyrexia, weight decreases, and dizziness) and two (16.7%; same as those who discontinued treatment) patients, respectively.

Serious AEs occurred in twenty (69.0%; QW) and four (33.3%; Q2W) patients. Grade 5 AEs 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 AEs 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 0 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 10 (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 AEs 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 AEs (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, 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 (6.9%) and one (8.3%) patient, respectively. No patients died due to infections. Hypogammaglobulinemia was reported in three (10.3%) and one (8.3%) patient, 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} 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* nonresponders (*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 novel BsAb talquetamab in Chinese patients demonstrated high, deep, and durable responses across the two dose cohorts, consistent with results from the global MonumenTAL-1 cohorts.[13] Both dose schedules appear equally effective in the China cohort and are supported by pharamcokinetics data, further validating selection of the 2 approved doses of talquetamab.

CRS was the most common AE, with a slightly higher incidence in the China cohort compared with 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; the latter was a patient with grade 5 ICANS who died before concurrent CRS resolved. Studies are ongoing assessing 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) AEs 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 AEs seen with talquetamab. Interestingly, rates of taste-related AEs in the China cohort (25.0–41.4%) were substantially lower than in the global MonumenTAL-1 study (71.4–72.0%); reasons for this are unclear, and further research is being conducted to understand taste-related AEs 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 BsAbs, with rates of 18–20% with talquetamab compared with

40–45% with BCMA BsAbs.[4,5,13] In the China cohort, grade 3/4 infection rates in the Q2W cohort (16.7%) were similar to 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 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 talquetamab in patients with RRMM from China, where MM disease burden is steeply rising. Rates of discontinuations due to AEs were low, and none were due to oral or dermatologic on-target, off-tumor AEs. These results were generally consistent with findings from the global MonumenTAL-1 study and show talquetamab as an important new treatment option in China.

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Tables

Table 1. Efficacy in the talquetamab QW and Q2W dosing cohorts from the MonumenTAL-1 China cohort.

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

[a]With two to three step-up doses.

[b]MRD was detected by NGF 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.

CI: confidence interval; CR: complete response; DOR: duration of response; MRD: minimal residual disease; NE: not estimable; NGF: next-generation flow cytometry; NR: not reached; ORR: overall response rate; OS: overall survival; PFS: progression-free survival; Q2W: every other week; QW weekly; SC: subcutaneous; VGPR: very good partial response.

Table 2. Hematologic and non-hematologic adverse events (AEs) in the talquetamab QW and Q2W dosing cohorts from the MonumenTAL-1 China cohort.

	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 decreased	15 (51.7)	0	6 (50.0)	0
Pyrexia	19 (65.5)	0	4 (33.3)	0
Non-rash skin-related AEs[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 AEs[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 AEs[f]	11 (37.9)	1 (3.4)	3 (25.0)	0
Decreased appetite	8 (27.6)	0	4 (33.3)	0
Nail-related AEs[g]	4 (13.8)	0	5 (41.7)	0
Insomnia	9 (31.0)	0	2 (16.7)	0
Increased C-reactive protein	0	0	4 (33.3)	0
Constipation	9 (31.0)	0	0	0
Diarrhea	9 (31.0)	0	0	0

AEs 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.

AE: adverse event; CRS: cytokine release syndrome; NA: not applicable; Q2W: every other week; QW weekly; SC: subcutaneous.

Table 3. Onset, duration, and outcomes of skin-, nail-, rash-, and taste-related adverse events (AEs) in the talquetamab QW and Q2W dosing cohorts from the MonumenTAL-1 China cohort.

	Talquetamab 0.4 mg/kg SC QW[a] (N=29)	**Talquetamab 0.8 mg/kg SC Q2W[a] (N=12)**
Non-rash skin-related AE[b]		
Total, 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, N (%)		
Events, N	25	5
Recovered or resolved	17 (68.0)	5 (100.0)
Not recovered or not resolved	6 (24.0)	0
Recovered or resolved with sequelae	0	0
Recovering or resolving	2 (8.0)	0
Unknown	0	0
Missing	0	0
Nail-related AE[d]		
Total, 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, N (%)		
Events, N	4	5
Recovered or resolved	2 (50.0)	1 (20.0)
Not recovered or not resolved	2 (50.0)	4 (80.0)
Recovered or resolved with sequelae	0	0
Recovering or resolving	0	0
Unknown	0	0
Missing	0	0

Rash-related AE[e]		
Total, 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, N (%)		
Events, N	14	3
Recovered or resolved	11 (78.6)	3 (100.0)
Not recovered or not resolved	3 (21.4)	0
Recovered or resolved with sequelae	0	0
Recovering or resolving	0	0
Unknown	0	0
Missing	0	0
Taste-related AE[f]		
Total, 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, N (%)		
Events, N	12	3
Recovered or resolved	7 (58.3)	1 (33.3)
Not recovered or not resolved	5 (41.7)	2 (66.7)
Recovered or resolved with sequelae	0	0
Recovering or resolving	0	0
Unknown	0	0
Missing	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 AE onset 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.

AE: adverse event; Q2W: every other week; QW weekly; SC: subcutaneous.

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Supplemental materials

Supplementary figures

Figure S1. Mean (SD) talquetamab serum concentration-time profiles after SC administration of talquetamab at 0.01/0.06 mg/kg step-up doses followed by 0.4 mg/kg SC QW or 0.01/0.06/0.3 mg/kg step-up doses followed by 0.8 mg/kg SC Q2W.

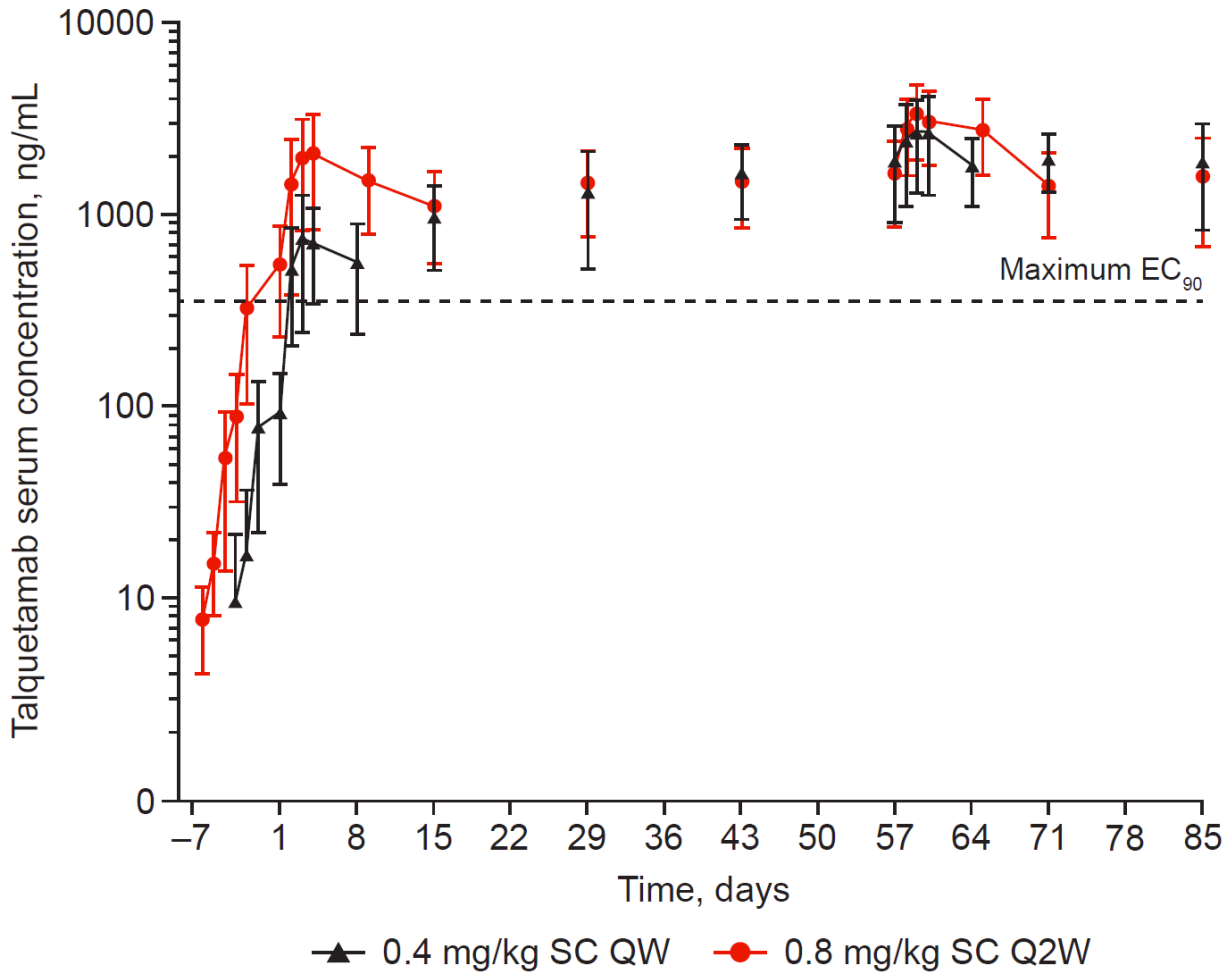
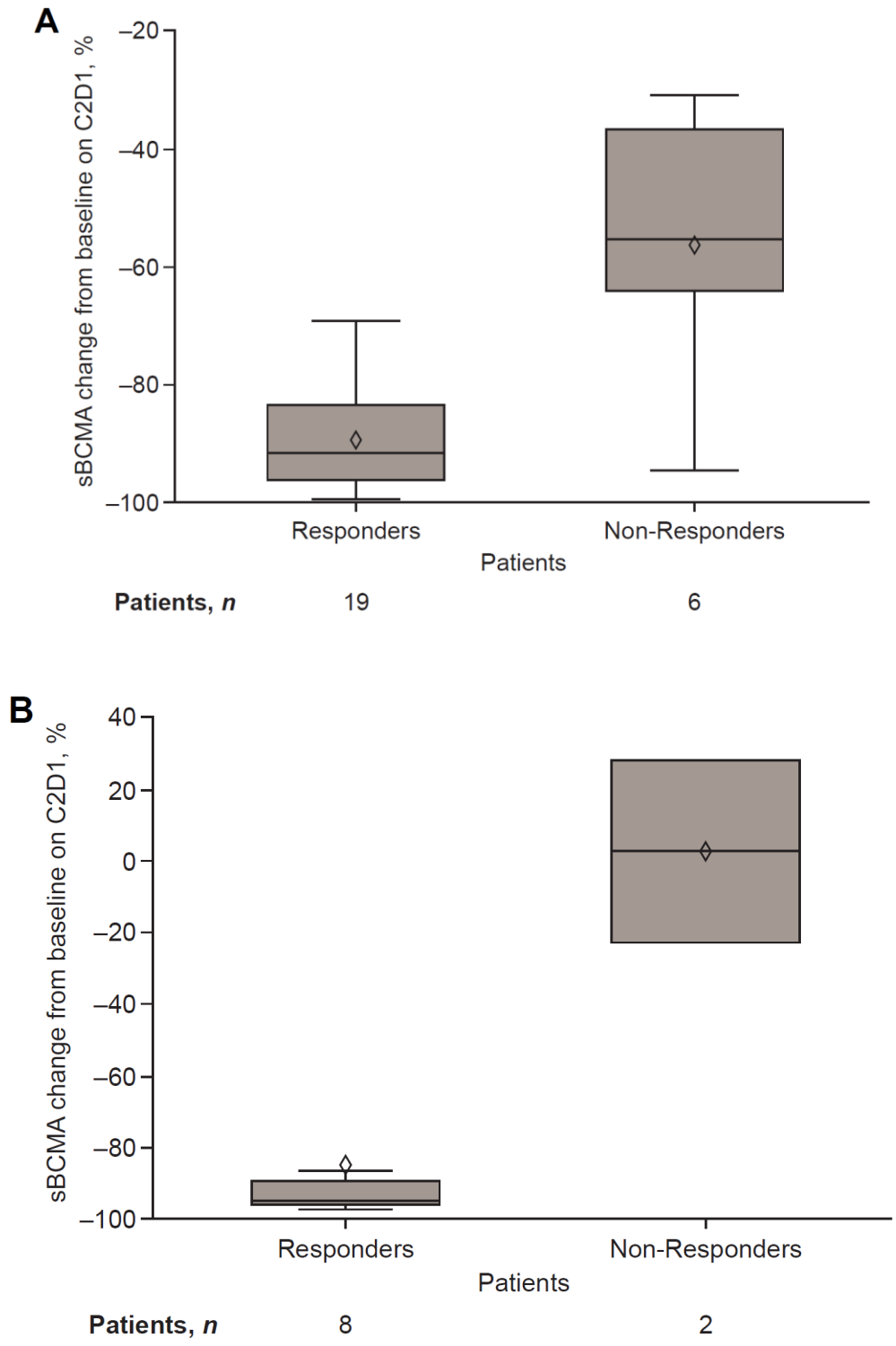


Figure S2. sBCMA percentage change from baseline at C2D1 for responders versus non-responders in (A) the 0.4 mg/kg SC QW cohort and (B) the 0.8 mg/kg SC Q2W cohort.



C: cycle; D: day; Q2W: every other week; QW: weekly; sBCMA: soluble B-cell maturation antigen; SC: subcutaneous.