

Long-Term Follow-Up from MajesTEC-1 China Cohort of Teclistamab in Patients with Relapsed/Refractory Multiple Myeloma: Efficacy Updates, Infection Profile and Immunoglobulin Usage

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Key Takeaway

With a longer-term follow-up (median 27.2 months), teclistamab continues to demonstrate deep and durable responses in Chinese pts with triple-class exposed myeloma, offering an effective treatment with a manageable safety profile and no new safety signals.

Conclusions

In the China cohort of MajesTEC-1 study, responses with teclistamab were deep with all responders achieving ≥VGPR and 75% of responders achieving ≥CR. Among pts who achieved ≥CR, 30-month DOR, PFS, and OS rates were favorable at 80.0%, 80.0% and 93.3%, respectively.

In this China cohort, there were no discontinuation due to AEs. A notable decrease in the incidence of new onset high grade infections over time may reflect increased Ig use to maintain IgG levels as well as a biweekly dosing interval.

These findings support TEC as a promising treatment option for triple-class exposed RRMM pts in China and emphasize the importance of infection management including Ig use.

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Poster
Narrated poster video
Supplementary material

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Disclosures
Zhen Cai, Yu-Jun Dong, Ai-Li He, Aijun Liao, Ting Niu, Yafei Wang, and Zhongjun Xia have no conflicts of interest to disclose. Juan Du and Weijun Fu conducted and completed this study at Shanghai Changzheng Hospital. Currently, they are working at Renji Hospital and Shanghai Fourth People's Hospital, respectively. Yang Song, Juanjuan Song, Katherine Chastain, Latisha Watkins, Xinchao Luo, Lin Huang, Rui Liu, Hongye Chen, Athena Zuppa, Wannan Chen, Angeline Zhu, and Xiaohong Wang are employees of, and may own stock/stock options in Johnson & Johnson. Bing Ning is contractor in Johnson & Johnson.

Introduction

- For patients (pts) with triple-class exposed relapsed/refractory MM (TCE RRMM), who have had prior exposure to a proteasome inhibitor (PI), an immunomodulatory drug (IMiD), and an anti-CD38 antibody, prognosis is particularly poor with median overall survival (OS) of 8–12 months (mos) and median progression-free survival (PFS) of less than 5 mos.¹⁻⁵
- Teclistamab (TEC) is the first approved B-cell maturation antigen (BCMA) and CD3, bispecific antibody in pts with TCE RRMM, using weight-based dosing.^{6,7}
- Recent clinical studies including the pivotal cohort and China cohort of MajesTEC-1, and Japan MMY1002 study had demonstrated rapid, deep and durable responses of TEC in pts with RRMM.^{8,9}
- This analysis aims to present the longer-term follow-up (>2 years) results of phase 2 MajesTEC-1 China cohort, focusing on efficacy, QoL, infection profile, and use of immunoglobulin (Ig).

Results

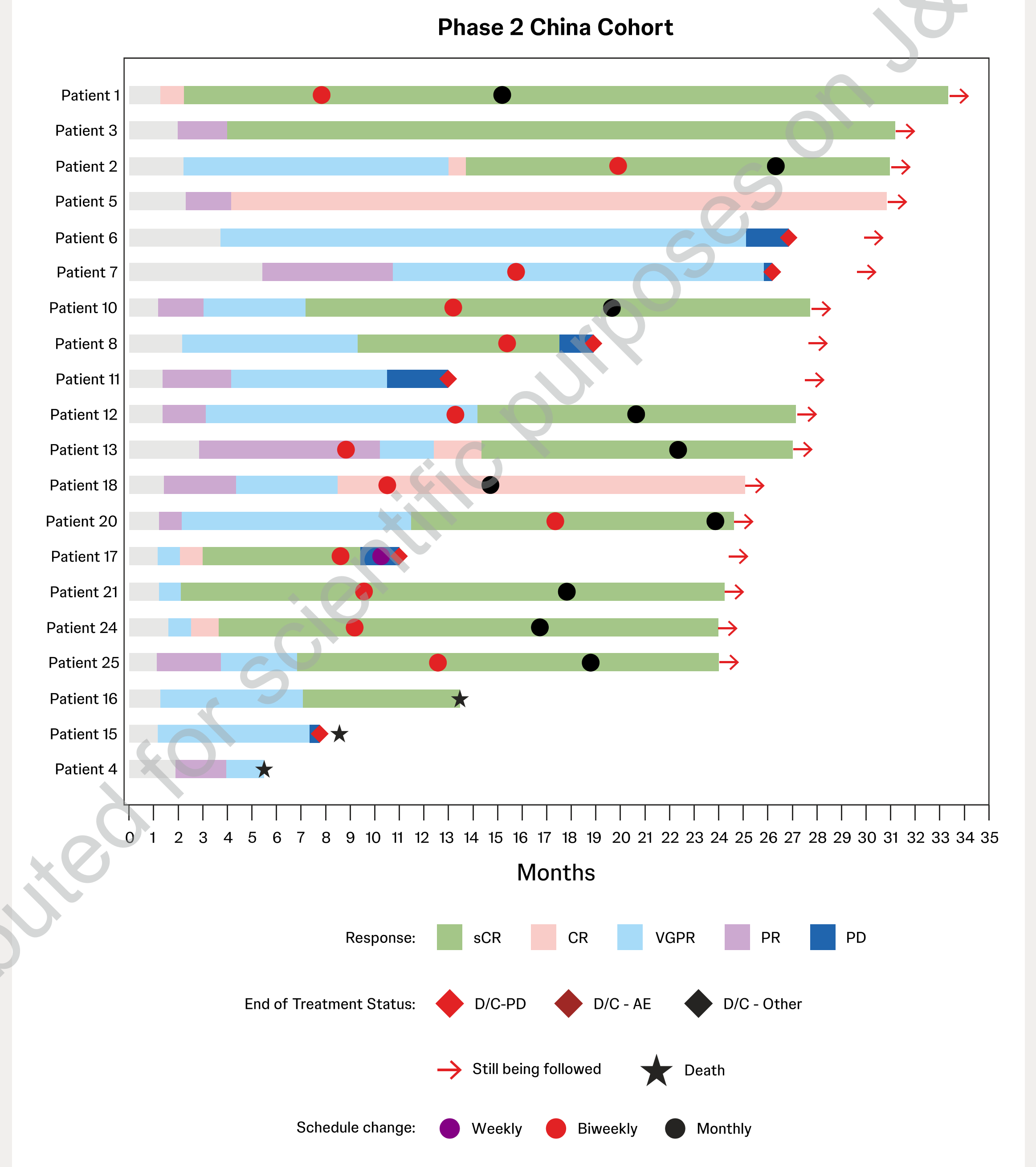
Baseline characteristics

- Median age, 66 years; 73.1% female; 57.7% high-risk cytogenetics; 34.6% ≥1 extramedullary plasmacytoma; 26.9% ISS stage III; median 5 prior line of treatment

Efficacy: Response Rates

- Median follow-up was 27.2 mos (range, 0.8 to 33.4) mos. Pts received a median of 10.1 mos of TEC (range: 0.7 to 31.9)
- ORR, ≥VGPR, ≥CR and sCR were 76.9%, 76.9%, 57.7% and 50%, respectively
 - The median time to first response was 1.4 mos (range, 1.1–5.5)
 - Among responders, 75.0% achieved CR or better
- Among 13 pts who had dose interruptions for >28 days, all remained in response, and 7/13 pts reported deepened responses
- Switching to less frequent dosing of TEC (Q2W/Q4W):
 - 13 pts (50.0%) switched from QW to Q2W, the median time to switch to Q2W dosing was 12.6 mos (range, 7.9–20.0)
 - 10/13 pts (83.3%) then switched from Q2W to Q4W dosing schedule and remained in response after switching

Figure 1: Response and Follow-up Based on Investigator Assessment; Responders in the All Treated Analysis Set



Note: Response was assessed by investigator, based on IMWG consensus criteria (2016). AE, adverse events; CR, complete response; D/C, discontinued; IMWG, International Myeloma Working Group; PD, progressive disease; PR, partial response; sCR, stringent complete response; VGPR, very good partial response.

Methods

MajesTEC-1 is an ongoing, phase 2, single-arm, open-label, multicenter study to evaluate the efficacy and safety of TEC in pts with triple-class exposed RRMM^{8,9}

- The current study analyzed the long-term efficacy (median follow-up of 27.2 mos) in pts from China cohort
- The eligible pts received TEC step-up doses of 0.06 and 0.3mg/kg followed by 1.5 mg/kg subcutaneously once-weekly (QW). Pts could switch to every-2-weeks (Q2W) dosing if complete response (CR) for ≥6 mos. Additionally, switching to every-4-weeks (Q4W) was permitted if pts achieved CR at Cycle 12, day 1 post Q2W dose for 6 mos
- Treatment of TEC was continued until disease progression, unacceptable toxicity, withdrawal of consent, or end of study
- Clinical cut-off date for this analysis was 27 September 2024

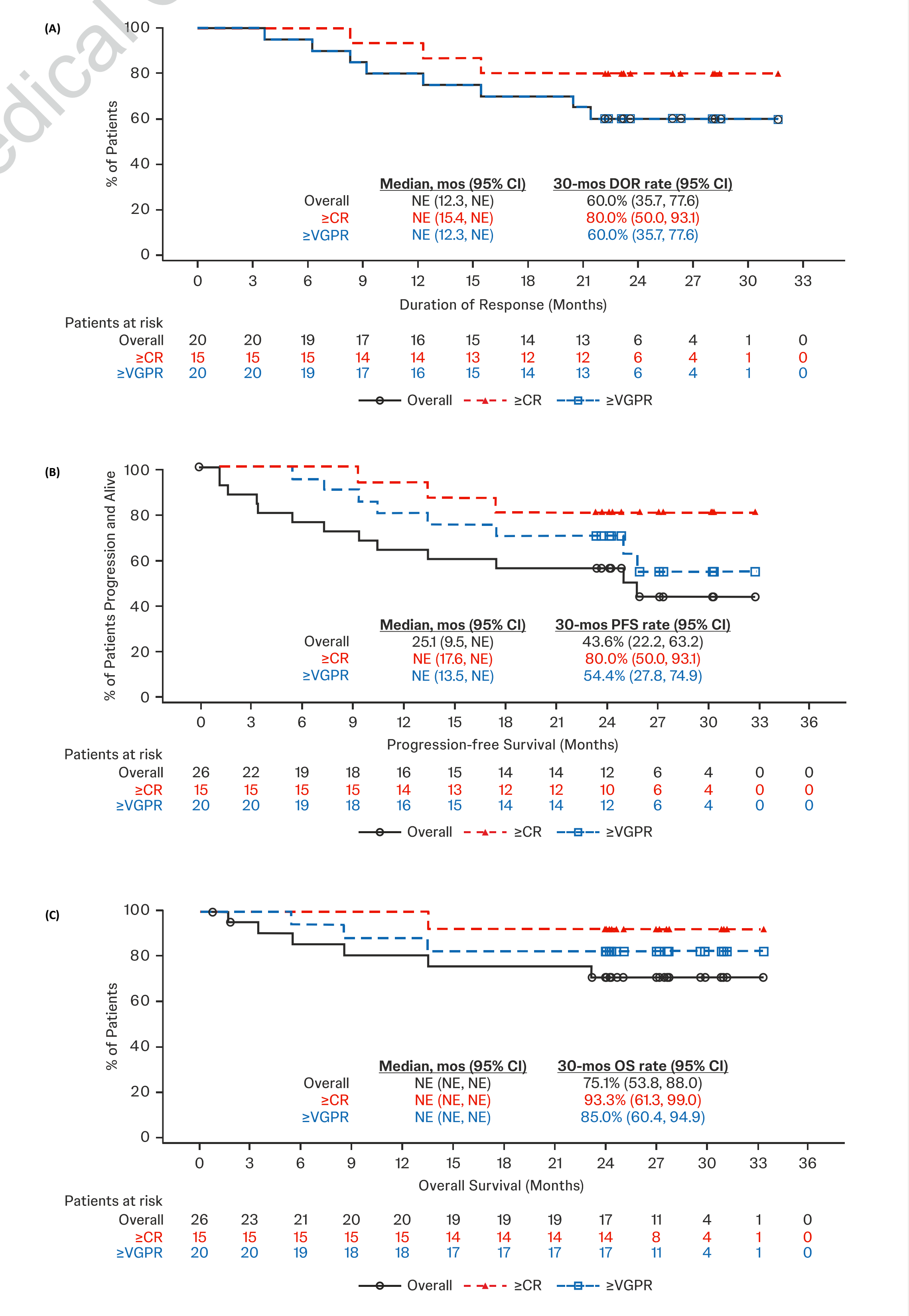
Study outcomes:

- Efficacy outcomes:**
 - Overall response rate (ORR), Very good partial response rate (VGPR), CR, Stringent CR (sCR), Time to response
 - Duration of response (DOR), PFS and OS
- European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 Item (EORTC-QLQ-C30) assessment**
- Infection profile:** Incidence rates
- IgG and Ig usage**

Efficacy: DOR, PFS and OS (Figure 2)

- Overall median DOR (95% CI) was not reached (12.3 to not estimable [NE]) after censoring 60.0% of pts. 30-mos DOR was 60.0% (95% CI: 35.7; 77.6) (Figure 2A)
- Overall median PFS was 25.1 mos (95% CI: 9.5 to NE) after censoring 50.0% of pts. 30 mos-PFS rate was 43.6% (95% CI: 22.2; 63.2) (Figure 2B)
- Overall median OS was not reached after censoring 76.9% of pts. 30 mos-OS rate was 75.1% (95% CI: 52.8; 88.0) (Figure 2C)
- Pts who achieved ≥CR had better DOR, PFS and OS: 30-mos rates were 80.0%, 80.0% and 93.3%, respectively

Figure 2: Kaplan-Meier plot for (A) Duration of response, (B) Progression-free survival, (C) Overall survival (All-treated analysis set)



Response and progression were assessed by investigator, based on IMWG consensus criteria (2016). Responders with schedule change are a subset of the China Cohort responders. CI, confidence interval; CR, complete response; mos, months; NE, not estimable; VGPR, very good partial response; PR, partial response; IMWG, International Myeloma Working Group.

Treatment with TEC was associated with a reduction in symptoms and a sustained improvement in EORTC-QLQ C30 scores

- Treatment with TEC was associated with a sustained improvement in all subscales of EORTC-QLQ C30, with median time to improvement ranging from 1.3 to 3.5 mos

Safety, Infection profile, IgG levels and Ig usage

No new safety findings were observed with the longer-term follow-up

- No pts discontinued TEC due to TEAEs

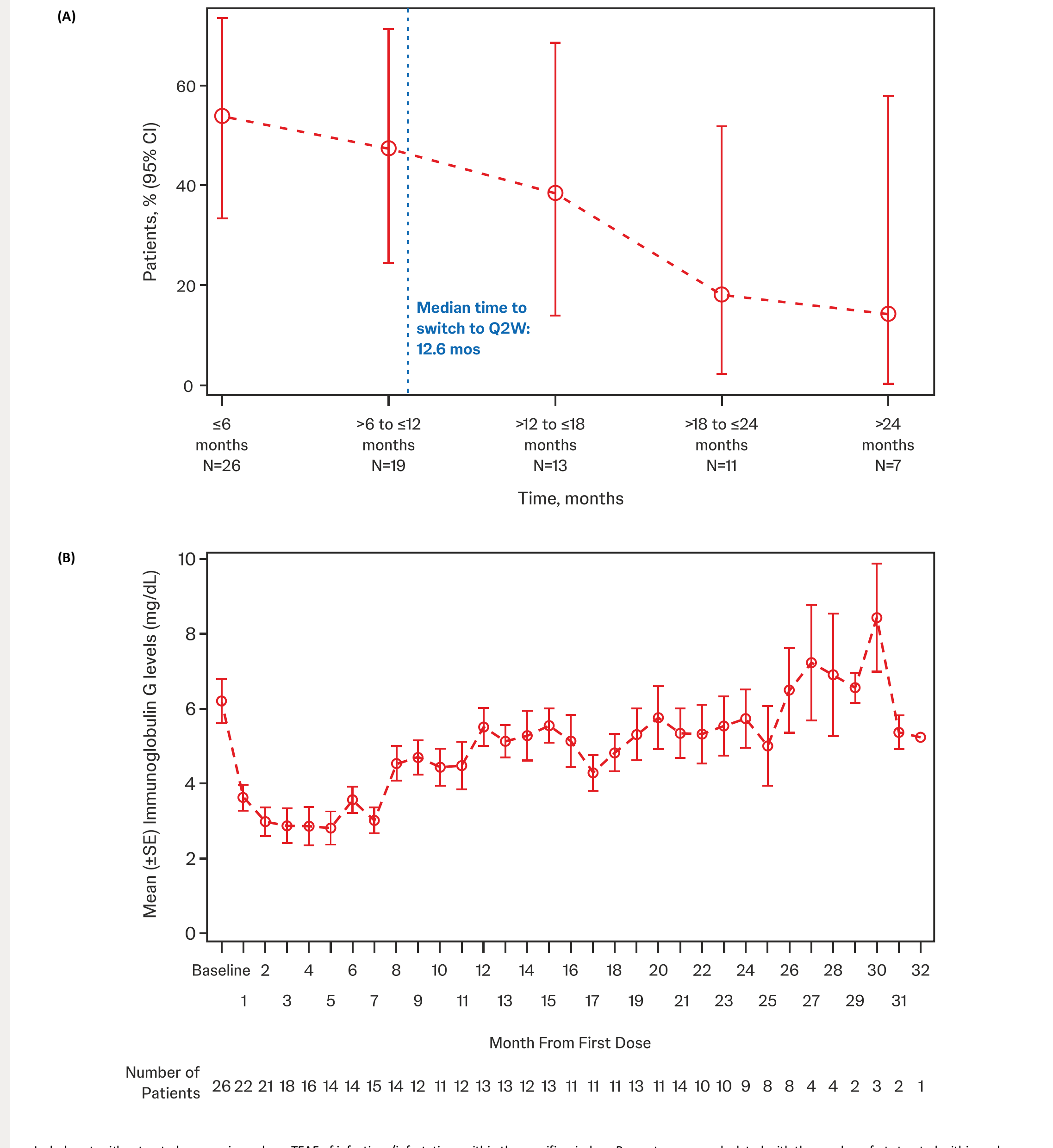
A decrease in new-onset grade ≥3 infections over time (Figure 3A):

- Within first 6 mos (53.8%, n=14/26); >6 to 12 mos (47.4%, n=9/19); >12 to 18 mos (38.5%, n=5/13); >18 to 24 mos (18.2%, n=2/11); >24 mos (14.3%, n=1/7)

IgG levels and Intravenous Ig (IVIg) Usage

- 24/26 pts (92.3%) had ≥1 postbaseline IgG level <400 mg/dL after TEC therapy; median (range) time to IgG level <400 mg/dL was 1.4 (1.1–4.8) mos
- 22/26 (84.6%) patients received ≥1 dose of Ig replacement
- Mean IgG level began to rise after 6 mos of tec therapy and remained consistently above 400 mg/dL after 8 mos with ongoing IVIg replacement (Figure 3B)

Figure 3: (A) New-onset grade ≥3 infections decreased over time in MajesTEC-1, (B) Mean (±SE) values for Immunoglobulin G (mg/dL) level over time (All-treated analysis set)



Includes pts either treated or experienced any TEAE of infections/infectious within the specific window. Percentages are calculated with the number of pts treated within each window as denominator. 95% exact CI is displayed. Adverse events are reported until 30 days after the last dose of teclistamab or until the start of subsequent anticancer therapy, if earlier. In cases of IgG myeloma, the M-spike component was subtracted from the total IgG level to approximate the amount of polyclonal and functional IgG. The highest IgG was presented within each month. CI, confidence interval; IgG, immunoglobulin G; mos, months; pts, patients; SE, standard error; TEAE, treatment-emergent adverse events.

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Multiple Myeloma