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Teclistamab in a Large Cohort of ~100 Asian Patients with Triple-Class Exposed Multiple Myeloma: Experience from Trial and Non-Trial Settings

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Key Takeaway

In this large cohort of Asian patients with TCE RRMM (N=99), teclistamab as a weight-based dosing regimen induced deep and durable responses in both trial and non-trial settings. The overall safety profile was consistent with the pivotal MajesTEC-1 study.

Conclusions

In Asian patients treated with teclistamab in clinical trials, ORR was 76.9% with 63.5% of patients achieving ≥CR; median DOR, PFS and OS were not yet reached after a median follow-up of 26.3 months. In Asian patients treated outside of the clinical trial setting, ORR/≥CR rates of 68.1%/44.7% were observed.

The incidence of new-onset grade ≥3 infections decreased over time in the trials, which may reflect increased immunoglobulin use to maintain IgG levels aligned with International Myeloma Working Group guidelines[8], as well as moving to a biweekly dosing interval.

These findings support the adoption of teclistamab as the new standard of care for patients with TCE RRMM and emphasize the importance of improving the feasibility and adoption of best practices for effective AE management in clinical practice, including Ig use.

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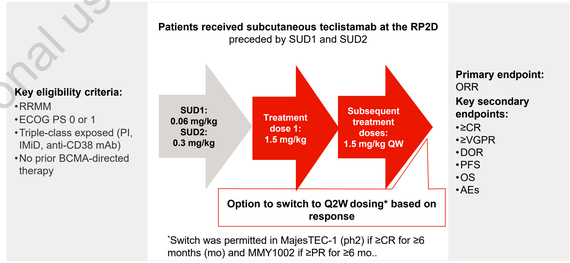
Introduction

- Teclistamab is the first B cell maturation antigen (BCMA)and CD3+ bispecific antibody (BsAb) approved for the treatment of patients (pts) with triple-class exposed (TCE = a proteosome inhibitor [PI], an immunomodulatory drug [IMiD], and anti-CD38 antibody) relapsed/refractory multiple myeloma (RRMM).[1,2]
- Teclistamab induced rapid, deep, and durable responses with a manageable safety profile in clinical trials.[3-5] Teclistamab has weight-based dosing and the most real-world experience (>20,800 patients).[6]
- Here, we present the efficacy and safety of teclistamab in large cohorts of Asian pts, including
  - 1) Asian clinical trial cohort: China cohort of MajesTEC-1 and phase 2 MMY1002 study in Japan
  - 2) outside trial experience from Asian pre-approval access (PAA) cohort from Korea and Singapore.

Methods

- The Asian clinical trial cohort (N=52) included:
  - 26 pts from the MajesTEC-1 China cohort (NCT04557098), enrollment period: December 2021–September 2022; and 26 pts from the Japan study (NCT04696809), enrollment period: July 2022–March 2023.
  - The MajesTEC-1 and Japan study designs have been previously described.[3,4]
- The Asian PAA cohort (N=47) included 42 patients from Korea (enrollment period: October 2022–March 2023) and 5 from Singapore (enrollment period: Jul 2023-Feb 2024).
  - Patients were eligible for treatment under the PAA if they had prior exposure to a PI, an IMiD, and an anti-CD38 antibody, and had exhausted all commercially approved and clinically appropriate treatment options.[7]

Figure 1: MajesTEC-1 and MMY1002 Japan study design



AE, adverse event; CR, complete response; DOR, duration of response; EGOG PS, Eastern Cooperative Oncology Group performance status; IMiD, immunomodulatory drug; mAb, monoclonal antibody; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; PR, partial response; Q2W, every other week; QW, weekly; SUD, step-up dose; VGPR, very good partial response.

Results

Study populations (Table 1)

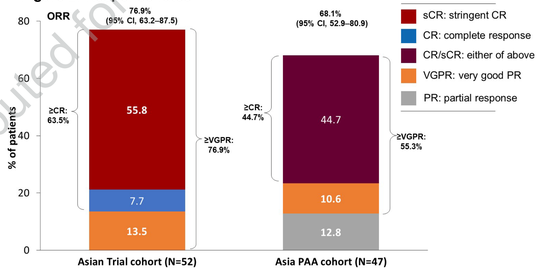
- Asian clinical trial cohort: median 5 prior lines of therapy (LOT), 38.5% had high-risk cytogenetics, 25.0% had soft-tissue extramedullary disease, and no prior BCMA exposure.
- Asian PAA cohort: 72.3% had ≥5 prior LOTs; 25.5% had high risk cytogenetics, 21.3% had soft-tissue EMD, 80.9% had prior penta-drug exposure.
  - Some pts in the Asian PAA cohort had features that would have made them ineligible for MajesTEC-1 inclusion: 29.8% with ECOG 2-3, 12.8% with CrCl <30 mL/min, and 6.4% with prior BCMA exposure.

Table 1: Baseline features of the Asian cohorts

Characteristic	Asian clinical trial cohort (N=52)	Asian PAA (N=47)
Male, n (%)	21 (40.4)	30 (63.8)
Age, years, median (range)	67 (42–84)	67 (48–84), 64 (53-74)**
Weight, kg, median (range)	58.0 (37.5–86.4)	-
Extramedullary plasmacytomas* ≥1, n (%)	13 (25.0)	10 (21.3)
ECOG PS at baseline, n (%)		
0	24 (46.2)	14 (29.8)
≥1	28 (53.8)	33 (70.2)
ISS stage at study entry, n (%)		
I	25 (48.1)	10 (21.3)
II	17 (32.7)	18 (38.3)
III	10 (19.2)	18 (38.3)
High-risk cytogenetics, n (%)	20 (38.5)	12 (25.5)
Number of prior LOT, median (range)	5 (2–12)	6 (3-10), 4 (3-4)**
Prior exposure, n (%)		
Triple-class	52 (100.0)	43 (91.5)
Penta-drug†	26 (50.0)	38 (80.9)

ISS, International Staging System; LOT, line of therapy.
* Extramedullary plasmacytomas: bone-independent soft tissue plasmacytoma.
** Korea and Singapore cohorts, respectively.
†Penta-drug exposure includes at least two IMiDs, at least two PIs, and at least one anti-CD38 antibody.

Figure 2: Response rates[a]

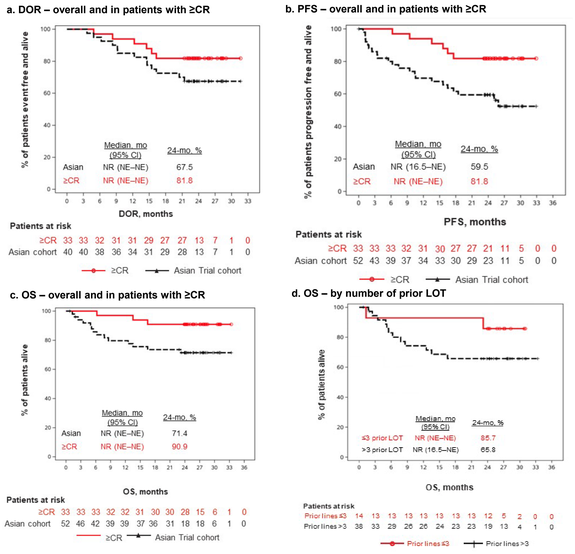


[a]Response assessed by independent review committee in the MajesTEC-1 study and by a computerized algorithm in the Japan study. Response in the Asian PAA cohort was assessed by physicians.

Asian Trial cohort (N=52): Efficacy

- Median follow-up: 26.3 mo. At the time of analysis, 28 pts (53.8%) switched from QW to Q2W (13 in China cohort, 15 in Japan cohort). Median time to switch was 9.3 mo (range: 7.1–26.0).
- ORR was 76.9% (95% CI 63.2–87.5), 63.5% achieved ≥CR and 76.9% achieved ≥VGPR (**Figure 2**).
- ORR/≥CR rates across subgroups were:
  - Triple-class refractory (n=33), 78.8%/60.6%;
  - Penta-drug refractory (n=9), 66.7%/55.6%;
  - Age ≥75 years (n=7), 85.7%/71.4%;
  - ECOG PS ≥1 (n=28), 64.3%/50.0%;
  - ISS-III (n=10), 60.0%/30%;
  - High-risk cytogenetics (n=20), 60.0%/30%;
  - EMD (n=13), 46.2%/23.1%.
- Median DOR, PFS, and OS were not reached. The 24-mo DOR, PFS, and OS were 67.5%, 59.5%, and 71.4%, respectively (**Figure 3a-c**).
- Pts who achieved ≥CR (n=33) had higher 24-mo DOR, PFS, and OS rates at 81.8%, 81.8%, and 90.9%, respectively.
- Pts who received ≤3 prior LOT (n=14) had higher ORR/≥CR rates (85.7%/85.7%), and higher 24-mo DOR, PFS and OS rates (91.7%, 78.6%, 85.7%, respectively) vs those with >3 prior LOT (**Figure 3d**).

Figure 3: DOR, PFS, and OS in the Asian clinical trial cohort (overall and in patients with ≥CR, and by numbers of prior LOT)

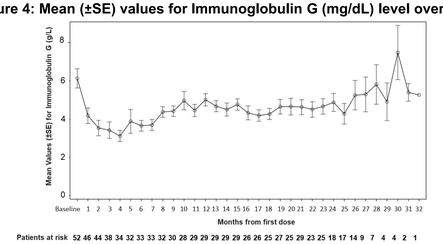


CR: complete response; LOT, lines of therapy; OS, overall survival; PFS, progression-free survival; DOR, duration of response; NE, not estimable; NR, not reached.

Asian Trial cohort (N=52): Safety

- The most frequent AEs were cytokine release syndrome, cytopenias, and infections, consistent with the known profile of BCMA BsAbs.
  - 2 (3.8%) pts discontinued due to AEs (including 1 due to infection)
- Infection profile, IgG level and Ig use:
  - The incidence of new-onset grade ≥3 infections was more frequent within the first 6 mo of teclistamab therapy and decreased over time: 32.7% (17/52) within first 6 mo, 26.3% (10/38) within >6 to 12 mo, 26.7% (8/30) within >12 to 18 mo, 14.8% (4/27) within >18 to 24 mo, 10.5% (2/19) >24 mo.
  - 46/52 pts (88.5%) had ≥1 postbaseline IgG level <400mg/dL after teclistamab therapy; median time to IgG <400mg/dL was 1.3 mo (range 0.2–5.7), and 43/52 pts (82.7%) received ≥1 dose of Ig replacement (either IV or SC). Mean IgG level began to rise after 6 mo of teclistamab therapy and remained consistently above 400 mg/dL after 8 mo (**Figure 4**).

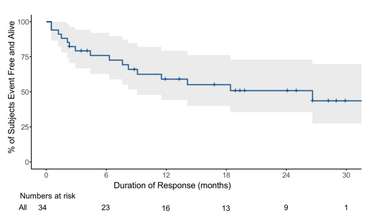
Figure 4: Mean (±SE) values for Immunoglobulin G (mg/dL) level over time



Asian PAA cohort (Non-trial setting, N=47)

- Median follow-up was 28.0 mo for Korean pts and 8.3 mo for Singapore pts.
- ORR was 68.1% and 44.7% achieved ≥CR (based on serologic response) and 55.3% achieved ≥VGPR (**Figure 2**).
- The estimated 12-mo DOR was 58% (**Figure 5**); the estimated 12-mo PFS and OS were 48.1% and 55.0%, respectively;
- 9 (19.1%) pts discontinued due to AEs.

Figure 5: DOR in the Asian PAA cohort (overall)



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