PA-348

Phase 3 MajesTEC-9: Teclistamab Monotherapy vs Pomalidomide, Bortezomib, and Dexamethasone or Carfilzomib and Dexamethasone (PVd/Kd) in Chinese Patients With Relapsed/Refractory Multiple Myeloma

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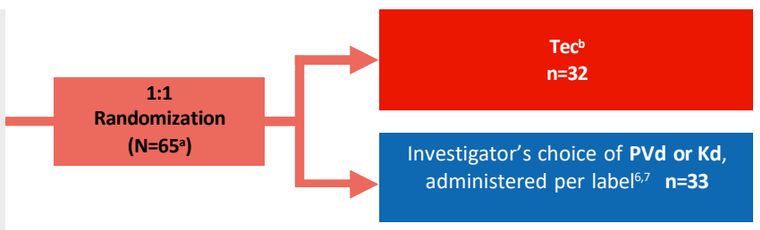
Introduction

- Despite improvements in the treatment of newly diagnosed multiple myeloma (MM), many patients (pts) become refractory/exposed to regimens containing anti-CD38 monoclonal antibodies and lenalidomide (Len), and outcomes in these pts are generally poor[1]
- Teclistamab (Tec) has demonstrated deep and durable responses for relapsed/refractory MM (RRMM) across clinical trials and real-world studies[2,3]
- In the phase 3 MajesTEC-3 trial, Tec plus daratumumab (Dara) significantly improved progression-free survival (PFS) and overall survival (OS) vs DPd (Dara, pomalidomide, dexamethasone) or DVd (Dara, bortezomib, dexamethasone) in pts with RRMM who had received 1-3 prior lines of therapy (LOT).[4] Based on these results, Tec-Dara received US and European approval for the treatment of RRMM with ≥1 prior LOT
- MajesTEC-9 (NCT05572515) is the first phase 3 study of Tec monotherapy in pts with 1-3 prior LOT
  - In the overall population of MajesTEC-9, Tec significantly improved PFS and OS when compared with PVd (pomalidomide, bortezomib, dexamethasone) or Kd (carfilzomib and dexamethasone)[5]
- Here, we report efficacy and safety results from the interim analysis of MajesTEC-9 in Chinese pts

Methods

Key inclusion criteria
- RRMM
- Received 1-3 prior LOT, including anti-CD38 and Len
- ECOG PS 0-2

Key exclusion criteria
- Prior BCMA-directed therapy



Primary endpoint[c]: PFS (per independent review committee)

Key secondary endpoints[c]
- Pts achieving a CR or better (sCR + CR)
- ORR
- OS
- DOR
- Safety

Exploratory endpoints
- MRD-negative CR rate

[a]In the China subgroup, 65 patients were randomized; a sample size of approximately 590 were planned (593 were randomized) for the global population. [b]Tec administered subcutaneously on a 28-day cycle (C) using a weight-based dosing schedule including 2 step-up doses (0.06 and 0.3 mg/kg) followed by a schedule of 1.5 mg/kg weekly in C1-2, 3 mg/kg every 2 weeks in C3-6, and 3 mg/kg every 4 weeks (Q4W) for C7 +, pts with confirmed ≥very good partial response could switch to Q4W dosing earlier than C7 per investigator's discretion. [c]Efficacy endpoints were assessed per International Myeloma Working Group 2016 criteria.

BCMA, B-cell maturation antigen; CR, complete response; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; MRD, minimum residual disease; ORR, overall response rate; sCR, stringent complete response.

Key Takeaway

Results from the phase 3 MajesTEC-9 study support the medical adoption of Tec monotherapy in Chinese pts as early as second-line therapy, regardless of prior anti-CD38 or Len exposure

Conclusions

At a median follow-up of 16.5 months, pts treated with Tec monotherapy had a clinically meaningful improvement in PFS, CR or better, and OS vs the current standard of care in China (PVd/Kd)

In Chinese pts, any-grade and grade 3/4 TEAEs were similar for Tec and PVd/Kd. CRS and infections were generally manageable with established protocols

Results from this China subgroup are in line with results from the overall population of MajesTEC-9, positioning Tec as a valuable option for the treatment of pts with RRMM in settings as early as the second line

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Poster
Narrated poster video
Supplementary material

https://www.congresshub.com/Oncology/IMS2026/Teclistamab/Liao

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Disclosures

AL, ZX, JL, JJ, WF, FJ, YW, CS, WC, GA, LB, ZC, BC, AH, XH, SJ, FL, XD, and YH report no conflicts of interest. **QW, XL, XW, JZ and HX** are employees of Johnson & Johnson and may own stock with Johnson & Johnson.

Results

Baseline characteristics

- 65 Chinese pts were enrolled (Tec, n=32; PVd/Kd, n=33; **Table 1**)
- Pts in both treatment groups received a median of 2 (range, 1-3) prior LOT
- Baseline characteristics were well balanced between the 2 groups, except that pts in the Tec group were older and had higher percentages of ECOG PS 2, extramedullary plasmacytomas, ≥60% bone marrow plasma cells, high cytogenetic risk, and were refractory to anti-CD38 treatment compared with the PVd/Kd group
- At the time of data cutoff (October 13, 2025), median treatment duration (range) was 13.0 (0.95-26.1) months in the Tec group and 7.6 (0.07-23.1) months in the PVd/Kd group; 62.5% of pts treated with Tec remained on treatment vs 28.1% of pts on PVd/Kd

TABLE 1: Pt demographics and baseline characteristics

Analysis set: ITT, n (%)	Tec (n=32)	PVd/Kd (n=33)
Median age, years (range)	65.5 (37-79)	61.0 (46-79)
Sex		
Female	19 (59.4)	18 (54.5)
Male	13 (40.6)	15 (45.5)
Baseline ECOG PS score		
0	15 (46.9)	14 (42.4)
1	14 (43.8)	18 (54.5)
2	3 (9.4)	1 (3.0)
ISS staging[a]		
I	21 (65.6)	18 (54.5)
II	5 (15.6)	9 (27.3)
III	6 (18.8)	6 (18.2)
Pts with extramedullary plasmacytomas[b]	4 (36.4)	2 (16.7)
≥60% bone marrow plasma cells[c]	3 (9.4)	2 (6.1)
Cytogenetic risk[d]		
Standard risk	16 (50.0)	19 (57.6)
High risk	16 (50.0)	13 (39.4)
Prior LOT[e]		
Median (range)	2 (1-3)	2 (1-3)
1	2 (6.3)	1 (3.0)
2	17 (53.1)	19 (57.6)
3	13 (40.6)	13 (39.4)
Prior exposure		
Any anti-CD38	32 (100)	33 (100)
Len	32 (100)	33 (100)
Refractory status		
Any anti-CD38	30 (93.8)	27 (81.8)
Len	27 (84.4)	27 (81.8)
Refractory to last LOT	32 (100)	31 (93.9)

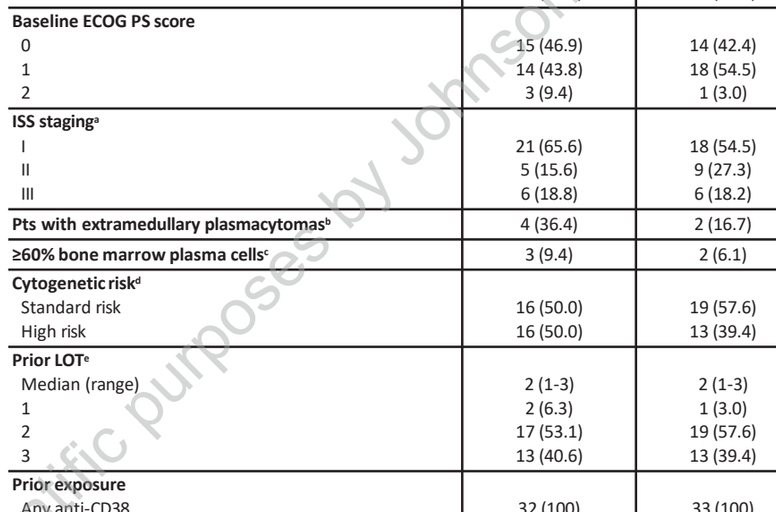
[a]ISS staging is derived based on serum β2-microglobulin and albumin. [b]A pt may have both extramedullary and bone-related plasmacytomas. Percentages calculated with the number of pts with ≥1 measurable soft-tissue plasmacytomas in each treatment group as the denominator. [c]Maximum value from bone marrow biopsy or bone marrow aspirate is selected if both the results are available. [d]Cytogenetic risk abnormalities are based on central fluorescence in situ hybridization (FISH) testing, or local FISH or karyotype testing if central FISH is not available. High risk is defined by FISH testing of subjects with abnormalities having t(4;14), t(14;16), or del(17p). [e]Based on data recorded on Prior Systemic Therapy electronic case report form page.

ISS, International Staging System; ITT, intent-to-treat.

Efficacy: response rate

- The ≥CR rate was markedly higher in the Tec (65.6%) vs the PVd/Kd group (15.2%) (odds ratio [OR], 10.69 [95% CI, 3.22-35.46])
  - More pts achieved an overall response with Tec (81.3%) vs PVd/Kd (48.5%) (including sCR + CR + partial response [PR] + very good PR [VGPR]) (OR, 4.60 [95% CI, 1.50-14.11]; **Figure 1**)

FIGURE 1: Response rates



Efficacy outcomes

- At a median follow-up of 16.5 months, Tec improved PFS vs PVd/Kd (hazard ratio [HR], 0.35 [95% CI, 0.16-0.73]; **Figure 2**) in this highly refractory population. Median PFS was not reached in the Tec-treated group and was 8.4 months with PVd/Kd
- Median DOR was not reached with Tec and was 14.3 months with PVd/Kd (**Figure 3**)
- OS showed a consistent improvement with Tec vs PVd/Kd (HR, 0.62 [95% CI, 0.24-1.64]). Median OS was not reached in either treatment group

FIGURE 2: Kaplan-Meier plot for PFS (ITT analysis set)

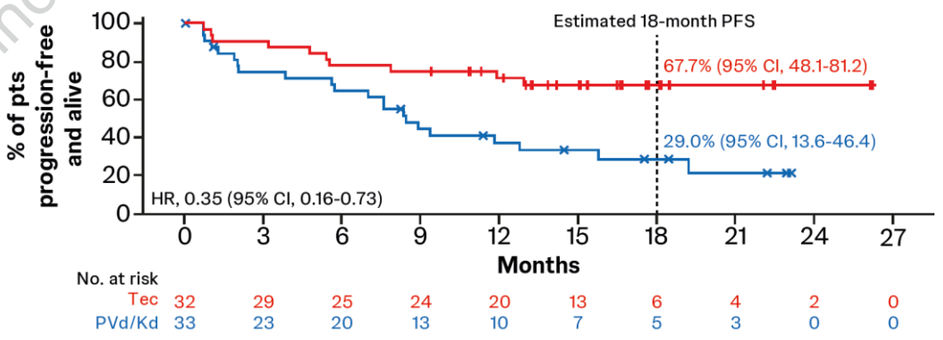
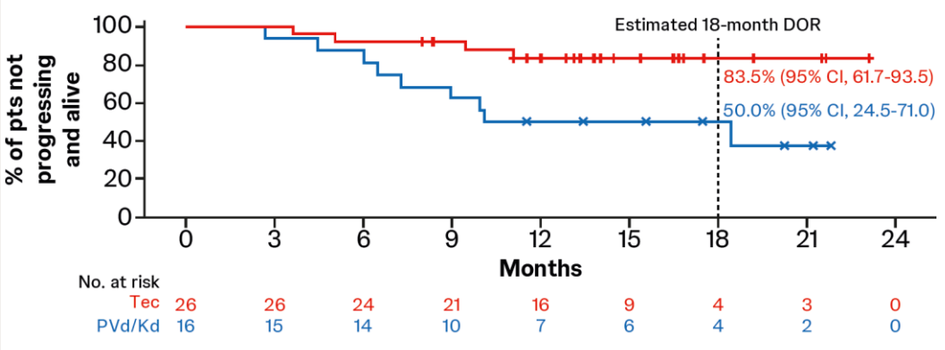


FIGURE 3: Kaplan-Meier plot for DOR (ITT analysis set)



Efficacy: MRD-negative CR rate

- In the ITT population, MRD-negative CR rate (next-generation flow [NGF], 10^{-5}) was achieved in 40.6% (13/32) of pts treated with Tec compared with 9.1% (3/33) of those treated with PVd/Kd (OR, 8.09; 95% CI, 1.67-39.22)
  - Among pts who had achieved CR/sCR and had an evaluable[a] MRD sample, MRD-negative CR rates were 92.9% (13/14) in the Tec group and 75.0% (3/4) in the PVd/Kd group

[a]Includes all randomized pts with ≥1 MRD sample collected after the date of randomization and prior to disease progression or subsequent antimyeloma therapy, resulting in either a positive MRD call or a negative MRD call if the sample contained a sufficient number of cells to meet the prespecified testing threshold.

Safety

- Any-grade and grade 3/4 treatment-emergent adverse events (TEAEs) were similar for Tec and PVd/Kd (**Table 2**)
- Grade 3/4 infections were reported in 65.6% of pts treated with Tec and 59.4% of pts treated with PVd/Kd. Any-onset grade ≥3 infections decreased over time in both groups. Most pts received ≥1 dose of intravenous immunoglobulin (Tec, 96.9%; PVd/Kd, 90.6%)
- Cytokine release syndrome (CRS) occurred in 24 pts (75.0%) receiving Tec, the majority of which were grade 1-2. Median duration of CRS was 1 day
- No cases of immune effector cell–associated neurotoxicity syndrome were reported
- Zero grade 5 TEAEs were reported with Tec vs 2 (6.3%) with PVd/Kd

TABLE 2: Most common TEAEs (safety population)

Analysis set: Safety, n (%)	Tec (n=32)		PVd/Kd (n=32)	
	AG[a]	G3/4[b]	AG[a]	G3/4[b]
Any TEAE	32 (100)	31 (96.9)	32 (100)	30 (93.8)
Hematologic				
Neutropenia	29 (90.6)	21 (65.6)	10 (31.3)	4 (12.5)
Anemia	20 (62.5)	6 (18.8)	26 (81.3)	10 (31.3)
Lymphopenia	18 (56.3)	15 (46.9)	13 (40.6)	9 (28.1)
Thrombocytopenia	17 (53.1)	6 (18.8)	27 (84.4)	10 (31.3)
Nonhematologic				
CRS	24 (75.0)	2 (6.3)	0	0
Diarrhea	17 (53.1)	4 (12.5)	8 (25.0)	0
URTI	16 (50.0)	5 (15.6)	14 (43.8)	4 (12.5)
Pneumonia	16 (50.0)	13 (40.6)	14 (43.8)	11 (34.4)
Cough	15 (46.9)	1 (3.1)	9 (28.1)	0
Hypogammaglobulinemia	13 (40.6)	0	5 (15.6)	0
Injection site erythema	4 (12.5)	0	0	0
Hypertension	2 (6.3)	1 (3.1)	9 (28.1)	6 (18.8)

[a]Any-grade TEAEs occurring in at least 20% of pts in either treatment group in the overall population. [b]G3/4 TEAEs occurring in at least 10% of pts in either treatment group in the overall population.

AG, any grade; G3/4, grade 3/4; URTI, upper respiratory tract infection.

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