PA-300

Matching-Adjusted Indirect Treatment Comparison of Teclistamab Monotherapy (Tec) vs Belantamab With Pomalidomide and Dexamethasone (BPd) for Early-Line Relapsed or Refractory Multiple Myeloma (RRMM)

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Key Takeaway

Tec demonstrates substantial clinical benefit over BPd in patients with early-line RRMM per anchored MAIC

Conclusions

Tec monotherapy consistently demonstrated a high probability of clinical benefit relative to BPd, with probabilities of improved PFS ranging from 96.3% to 99.5% (HR <1, 0.434-0.438), improved OS from 82.7% to 93.4% (HR <1, 0.468-0.670), and higher ≥CR rates from 92.5% to 97.9% (RR range, 1.967-2.028)

Tec demonstrated a comparative benefit over BPd across PFS, OS, and response outcomes despite the marked imbalance between trials in regard to anti-CD38– and PI-refractory disease which favored BPd

These findings support Tec as a highly effective, steroid-sparing standard of care versus BPd, for use as early as first relapse

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Disclosure

KFS has nothing to disclose.

Introduction

- Teclistamab, a BCMA×CD3 bispecific antibody, is approved as monotherapy or in combination with daratumumab for the treatment of relapsed or refractory multiple myeloma as early as second-line onwards in ≥1 country[1-5]
- In the phase 3 MajesTEC-9 study (NCT05572515; median follow-up, 17.3 months), Tec significantly improved progression-free survival (PFS) and overall survival (OS) and deepened response versus pomalidomide plus bortezomib and dexamethasone or carfilzomib plus dexamethasone (PVd/Kd) in patients with RRMM and 1 to 3 prior lines of therapy (pLOTs), including an anti-CD38 monoclonal antibody and lenalidomide[6]
  - Despite 85% of Tec patients being anti-CD38 refractory, Tec still demonstrated a clinical benefit over PVd/Kd in this highly refractory population with high unmet need[6,7]
- Other off-the-shelf BCMA-directed therapies have improved efficacy in early-line RRMM, including belantamab mafodotin plus pomalidomide and dexamethasone (BPd)
  - In the phase 3 DREAMM-8 study (NCT04484623; median follow-up, 21.8 months), BPd significantly improved PFS versus PVd in patients with RRMM and ≥1 pLOT[8]
- Matching-adjusted indirect treatment comparisons (MAICs) can help contextualize comparative treatment efficacy across studies; however, relevant treatment effect modifiers (TEMs) must be adjusted for
  - In MajesTEC-9, PFS favored Tec regardless of anti-CD38 refractory status; PFS hazard ratio (HR) was numerically lower in anti-CD38 nonrefractory patients than in anti-CD38 refractory patients (HR, 0.16 vs 0.32), although the small sample size of the nonrefractory subgroup should be considered[6]
  - A similar trend was seen in DREAMM-8 (PFS HR, 0.48 vs 0.69)[8]
  - Consistent differences in PFS treatment effects by anti-CD38–refractory status across MajesTEC-9 and DREAMM-8 indicate that anti-CD38–refractory status is a TEM and should therefore be adjusted for
- We conducted an MAIC to compare the relative treatment effects of Tec versus BPd in early-line RRMM

Methods

Data sources

- Individual patient-level data (IPD) were leveraged from the MajesTEC-9 study, while aggregated data were sourced from the DREAMM-8 study (**Table 1**)

Table 1: Summary of data sources

MajesTEC-9 (N=593)[a]	DREAMM-8 (N=302)[b]
PFS/OS and ORR/≥VGPR/≥CR: Touzeau C, et al. *N Engl J Med* 2026[6] (median follow-up, 17.3 months)	**PFS and ORR/≥VGPR/≥CR:** Trudel S, et al. ASH 2025[9] (median follow-up, 35.8 months) **OS:** Dimopoulos MA, et al. *N Engl J Med* 2024[8] (median-follow-up, 21.8 months)

ASH, American Society of Hematology; BPd, belantamab mafodotin plus pomalidomide and dexamethasone; ≥CR, complete response or better; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; ≥VGPR, very good partial response or better.
[a]Total intent-to-treat population, which was composed of the teclistamab monotherapy group (n=296) and the control group (n=297).
[b]Total intent-to-treat population, which was composed of the BPd group (n=155) and control group (n=147).

Comparison

- An anchor-based MAIC was performed under a Bayesian framework, with frequentist approach shown alongside
  - The Bayesian framework enables a more informative interpretation of treatment effects in settings where the frequentist approach lacks sufficient statistical power to detect differences
- The primary anchor was pooled physician's choice (PVd or Kd), supported by a similar relative treatment effect of Tec versus PVd and Tec versus Kd[6]
- Propensity score weights were applied to MajesTEC-9 IPD to align baseline characteristics with aggregated DREAMM-8 data, adjusting for variables identified as potential TEMs
- Matching variables for adjustment were validated by clinical experts and included:
  - Base case (primary analysis): immunomodulatory drug/proteasome inhibitor (PI)/anti-CD38–refractory status, cytogenetic risk, International Staging System disease stage, extramedullary disease (defined per protocol), Eastern Cooperative Oncology Group performance status score, and age group
  - Full model (in addition to above): number of pLOTs, time since diagnosis, prior transplant status, race, sex, and type of MM

Statistical analysis

- Comparative effectiveness was estimated for PFS, OS, overall response rate (ORR), very good partial response or better (≥VGPR), and complete response or better (≥CR)
- HRs from the adjusted MajesTEC-9 cohort, reweighted to match DREAMM-8 baseline characteristics for treatment effect modifiers were compared with reported HRs from DREAMM-8 using a Bayesian framework
  - HRs and odds ratios (ORs)/risk ratios (RRs) were estimated with 95% credible intervals (CrIs), and Bayesian posterior probabilities for Tec to be more effective than BPd were estimated
- For frequentist analysis, HRs and ORs/RRs are also presented

Sensitivity analysis

- An anchored MAIC was also conducted within the PVd sub-cohort of MajesTEC-9

Results

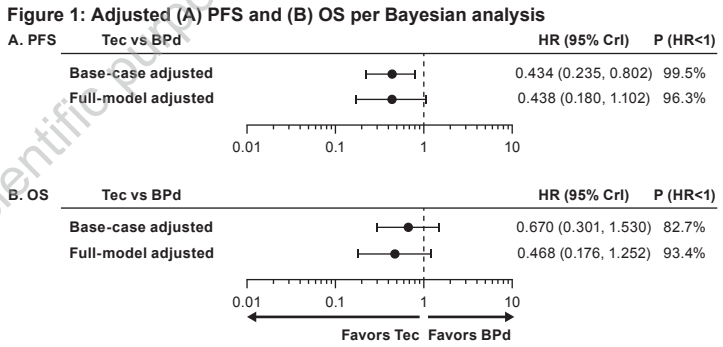
Patient demographic and baseline disease characteristics

- IPD and aggregated data were available for 593 MajesTEC-9 and 302 DREAMM-8 patients, respectively
  - Baseline characteristics differed between MajesTEC-9 and DREAMM-8 cohorts in regard to number of pLOTs (1: 22% vs 53%, respectively; 2: 45% vs 21%; 3: 33% vs 12%), PI-refractory status (42% vs 25%), and anti-CD38–refractory status (85% vs 24%)
- Effective sample size (ESS) of the MajesTEC-9 cohort was 129 and 74 after base-case and full-model adjustment, respectively
  - After adjustment, key baseline characteristics were well balanced across cohorts

Outcomes of Bayesian analyses

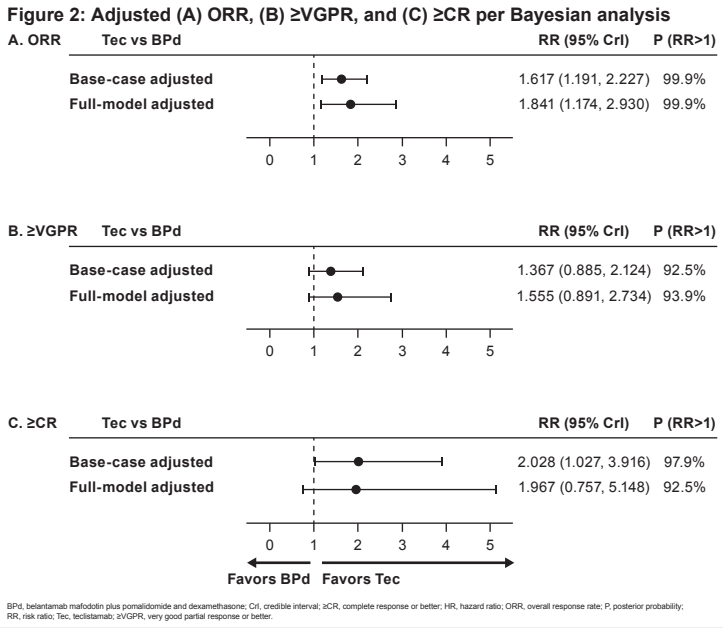
- Bayesian MAIC results suggest that Tec improves PFS relative to BPd, with a posterior probability of benefit of 99.5% and a HR of 0.434 (95% CrI, 0.235, 0.802; **Figure 1A**)
- Similarly, Tec improved OS relative to BPd, with a posterior probability of benefit of 82.7% and a HR of 0.670 (95% CrI, 0.301, 1.530; **Figure 1B**)
- Bayesian point estimates consistently favored Tec relative to BPd across all treatment responses (**Figure 2**), with a posterior probability of benefit for achieving a clinically meaningful, deep response of ≥CR with Tec versus BPd of 97.9% (RR, 2.028); respective ORs are presented in **Table 2**

Figure 1: Adjusted (A) PFS and (B) OS per Bayesian analysis



BPd, belantamab mafodotin plus pomalidomide and dexamethasone; CrI, credible interval; HR, hazard ratio; OS, overall survival; P, posterior probability; PFS, progression-free survival; Tec, teclistamab.

Figure 2: Adjusted (A) ORR, (B) ≥VGPR, and (C) ≥CR per Bayesian analysis



BPd, belantamab mafodotin plus pomalidomide and dexamethasone; CrI, credible interval; ≥CR, complete response or better; HR, hazard ratio; ORR, overall response rate; P, posterior probability; RR, risk ratio; Tec, teclistamab; ≥VGPR, very good partial response or better.

Table 2: Adjusted comparative analysis of ORR, ≥VGPR, and ≥CR per Bayesian analysis

	Tec vs BPd	
	OR (95% CrI)	P (OR>1)
ORR		
Base case	4.324 (1.638, 11.688)	99.7%
Full model	5.026 (1.199, 21.720)	98.5%
≥VGPR		
Base case	2.700 (1.088, 6.762)	98.4%
Full model	2.849 (0.792, 10.09)	94.6%
≥CR		
Base case	3.961 (1.540, 10.560)	99.8%
Full mode	3.285 (0.849, 12.583)	96.0%

BPd, belantamab mafodotin plus pomalidomide and dexamethasone; CrI, credible interval; ≥CR, complete response or better; OR, odds ratio; ORR, overall response rate; P, posterior probability; Tec, teclistamab; ≥VGPR, very good partial response or better.

Outcomes of frequentist analyses

- Frequentist MAIC results were comparable to that seen in Bayesian analyses, with Tec demonstrating a significantly longer PFS versus BPd (base-case: HR, 0.44; 95% confidence interval [CI], 0.23, 0.81) and a more favorable OS (base-case: HR, 0.67; 95% CI, 0.30, 1.50)
  - Full-model similarly favored Tec relative to BPd for PFS (HR, 0.44; 95% CI, 0.18, 1.07) and OS (HR, 0.47; 95% CI, 0.18, 1.25)
- Per unadjusted rates, 84.5% of Tec- versus 76.1% of BPd-treated patients achieved ORR, 80.1% versus 63.2% achieved ≥VGPR, and 65.9% versus 43.2% achieved a deeper, clinically meaningful ≥CR
- Per base-case RRs, Tec-treated patients were 1.62-, 1.37-, and 2.03-times more likely to achieve ORR, ≥VGPR, and ≥CR, respectively, relative to BPd; ORs similarly favored Tec (4.36-, 2.70-, and 3.97-times more likely to achieve ORR, ≥VGPR, and ≥CR)
  - While reduced ESS results widened CIs, results continued to favor Tec across full-model estimates for ORR (RR, 1.85; OR, 5.02), ≥VGPR (1.56; 2.83), and ≥CR (1.99; 3.29)

Sensitivity analysis

- In a sensitivity analysis using the PVd sub-cohort of MajesTEC-9 as an anchor, results were generally consistent with the primary analysis (base-case adjustment: MajesTEC-9 ESS=47)
  - Bayesian results suggest that Tec improves PFS relative to BPd (posterior probability of benefit, 91.8%; HR, 0.512; 95% CrI, 0.199, 1.334) and OS (posterior probability of benefit, 98.6%; HR, 0.312; 95% CrI, 0.112, 0.893)
  - Bayesian point estimates consistently favored Tec relative to BPd across all treatment responses, with a posterior probability of benefit for achieving a clinically meaningful, deep response of ≥CR with Tec versus BPd of 85.8% (RR, 1.559)

Strengths and Limitations

- Compared with DREAMM-8, MajesTEC-9 had a greater proportion of patients who were anti-CD38 (85% vs 24%) and PI refractory (42% vs 25%); while this imbalance favors the comparator, Tec demonstrated persistent comparative benefit over BPd following comprehensive anchored MAIC and adjustment
- Bayesian analyses were primarily presented, estimating the probability of treatment superiority and providing a more decision-relevant interpretation of available evidence; despite evidence of comparative benefit, anchored frequentist analyses were underpowered to detect statistically significant differences
- MajesTEC-9 is still ongoing and additional follow-up and future analyses will further inform these findings
- Results consistently favored Tec relative to BPd across base-case and full-model results, statistical analysis methods (Bayesian and frequentist), and across the anchor considered (PVd/Kd and PVd)

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Multiple Myeloma

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