PA-356

Patient-Reported Outcomes (PROs) of Teclistamab-Based Treatment in Relapsed/Refractory Multiple Myeloma (RRMM) After 1-3 Lines of Therapy (LOTs)

Katja Weisel,[1] Eva G Katz,[2] Marguerite O'Hara,[2] Nina Kim,[2] Margaret Doyle,[3] Tzu-Min Yeh,[2] Maria Rubin,[2] Dai Wang,[2] Weili Sun,[4] Priya Shah,[5] Diogo F Ramos,[6] Susanne Huschens,[7] Michel Delforge[8]

[1]Department of Oncology, Hematology and Bone Marrow Transplantation, Section of Pneumology, University Medical Center Hamburg–Eppendorf, Hamburg, Germany; [2]Johnson & Johnson, Raritan, NJ, USA; [3]Johnson & Johnson, Dublin, Ireland; [4]Johnson & Johnson, Los Angeles, CA, USA; [5]Johnson & Johnson, High Wycombe, UK; [6]Johnson & Johnson, Madrid, Spain; [7]Johnson & Johnson, Neuss, Germany; [8]Department of Hematology, University Hospital Leuven, Leuven, Belgium

Key Takeaway

Tec+Dara and Tec-mono led to greater and more durable HRQoL benefits versus controls, reinforcing Tec-based treatment as a new standard of care in RRMM as early as first relapse

Conclusions

Tec+Dara and Tec-mono improved HRQoL in patients with highly refractory RRMM and 1 to 3 prior LOTs compared with control in the phase 3 MajesTEC-3 and MajesTEC-9 studies, respectively

Tec-based therapy improved PRO scores from baseline, with a greater proportion of patients experiencing meaningful improvement in scores and more durable HRQoL compared with controls

Building on transformative progression-free survival, overall survival, and safety data with Tec-based regimens, PROs demonstrate patient-relevant benefits, supporting improved patient experience with monthly dosing and steroid-sparing regimens

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Acknowledgments

This study was sponsored by Johnson & Johnson. Authors would like to acknowledge the patients who participated in the studies (MajesTEC-3 and MajesTEC-9) and their families and caregivers; the physicians, nurses, and staff members at each site; the members of the Study Safety Committee; and additional members who were involved in data collection and analysis. Medical writing and editorial support were provided by Laura Ganser, PhD, of Lumanity Communications Inc., and funded by Johnson & Johnson.

Disclosures

KW received research funding from AbbVie, Amgen, Bristol Myers Squibb, BeiGene, Janssen, GSK, and Sanofi; received consulting honoraria from AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, BeiGene, CellCentric, Janssen, GSK, Karyopharm, Oncopeptides, Pfizer, Regeneron, Roche Pharma, Sanofi, Stemline, and Takeda; and received speaker honoraria from AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, BeiGene, Janssen, GSK, Karyopharm, Novartis, Oncopeptides, Pfizer, Regeneron, Roche Pharma, Sanofi, Stemline, and Takeda.

Introduction

- RRMM is associated with impaired health-related quality of life (HRQoL), including high symptom burden and reduced functioning, that typically worsens with each subsequent LOT[1-6]
- Teclistamab (Tec), a first-in-class bispecific antibody that targets B-cell maturation antigen×CD3, is a standard of care with positive real-world experience in >30,700 patients[7,8]
- Tec in combination with daratumumab (Dara; Tec+Dara) and Tec monotherapy (Tec-mono) significantly improved progression-free and overall survival versus established controls in patients with RRMM and 1 to 3 prior LOTs in MajesTEC-3 and MajesTEC-9, respectively[9,10]
  - With Tec-based regimens, time to worsening of MM symptoms per the Multiple Myeloma Symptom and Impact Questionnaire (MySIm-Q) total symptom score was significantly longer than with control (Tec+Dara: hazard ratio [HR], 0.50; 95% confidence interval [CI], 0.34, 0.72; *P*=0.0002 and Tec-mono: HR, 0.50; 95% CI, 0.36, 0.71; *P*<0.0001)
  - Positive patient experience with Tec-based regimens is facilitated by monthly dosing, steroid-sparing regimens, and manageable safety profiles
- Here, we report expanded PRO results from MajesTEC-3 and MajesTEC-9

Methods

- MajesTEC-3 and MajesTEC-9 are phase 3, randomized, open-label studies[9,10]
- The following PRO questionnaires and select assessments were evaluated:
  - MySIm-Q (0- to 4-point scale), a multiple myeloma–specific assessment[11]
    - Includes 5 symptom domains (pain, neuropathy, fatigue, digestive, and cognitive) and 3 impact domains (activity, social, and emotional)
  - European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30; 0- to 100-point scale), a cancer-specific assessment[12]
    - Includes a global health status (GHS) scale, pain and fatigue symptom scales, and a physical function scale
  - EuroQoL 5-Dimension 5-Level (EQ-5D-5L; 0- to 100-point scale), a generic measure of health status[13]
    - Includes a visual analog scale (VAS) rating of overall health
- Results report on multiple time points from baseline to the latest Cycle (C)/Day (D) with adequate sample size to provide stable estimates; tables and figures display data only for this latest time point (MajesTEC-3: C37D1; MajesTEC-9: C20D1)
- Least squares (LS) mean change from baseline was analyzed using mixed-model for repeated measures
- Time to worsening/responder analyses used distribution-based (MajesTEC-9, MySIm-Q), anchor-based (MajesTEC-3, MySIm-Q), or literature-based (EORTC QLQ-C30) methods to define the minimally important differences
- Meaningful change from baseline was assessed with descriptive statistics
- Time to worsening was defined as the time interval from the date of randomization to the start date of sustained meaningful worsening of a PRO score and assessed using survival analysis

Results

Patients

- Patients who received Tec+Dara (N=291) and daratumumab plus dexamethasone and pomalidomide or bortezomib (DPd/DVd; N=296) in MajesTEC-3 and patients who received Tec-mono (N=293) and pomalidomide plus bortezomib and dexamethasone or carfilzomib plus dexamethasone (PVd/Kd; N=293) in MajesTEC-9 were evaluated
- Questionnaire compliance was >85% at baseline and >80% at most postbaseline time points across treatment groups in both studies
  - The most common reasons for noncompliance were technical failure, site forgot, and other
- Similar baseline values were reported for all PRO measures across treatment groups in both studies

MySIm-Q

- In both studies, LS mean change from baseline in the MySIm-Q total symptom and impact scores improved early with Tec-based treatment and improvements were sustained through all evaluable time points
  - Greater improvements were seen with Tec-based treatment versus control in both MajesTEC-3 (**Table 1**) and MajesTEC-9 (**Table 2**)
- A higher proportion of patients reported meaningful improvement in MySIm-Q total symptom and impact scores with Tec-based treatment versus control at most time points, with the majority of patients reporting stable or improved scores in MajesTEC-3 (**Figure 1**) and MajesTEC-9 (**Figure 2**)
- Time to worsening of the MySIm-Q total impact score was prolonged with Tec+Dara versus DPd/DVd (HR, 0.41; 95% CI, 0.29, 0.58) in MajesTEC-3 and with Tec-mono versus PVd/Kd (HR, 0.42; 95% CI, 0.30, 0.59) in MajesTEC-9, consistent with the MySIm-Q total symptom score results (see **Introduction**)

EORTC QLQ-C30

- In both studies, LS mean change from baseline in EORTC QLQ-C30 GHS, pain, fatigue, and physical function scores improved early with Tec-based treatment and improvements were sustained through all evaluable time points
  - Greater improvements were seen with Tec-based treatment versus control in both MajesTEC-3 (**Table 1**) and MajesTEC-9 (**Table 2**)
- A higher proportion of patients reported meaningful improvements in EORTC QLQ-C30 GHS, pain, fatigue, and physical function scores with Tec-based treatment versus control at most time points, with the majority of patients reporting stable or improved scores in both MajesTEC-3 (**Figure 1**) and MajesTEC-9 (**Figure 2**)
- Time to worsening of the EORTC QLQ-C30 GHS score was prolonged with Tec+Dara versus DPd/DVd (HR, 0.46; 95% CI, 0.32, 0.65) in MajesTEC-3 and with Tec-mono versus PVd/Kd (HR, 0.50; 95% CI, 0.36, 0.69) in MajesTEC-9
- Time to worsening of the EORTC QLQ-C30 pain, fatigue, and physical function scores was also prolonged for Tec-based treatments in both studies (HR≤0.50 for all)

EQ-5D-5L

- In both studies, LS mean change from baseline in EQ-5D-5L VAS score improved early with Tec-based treatment and improvements were sustained through all evaluable time points
  - Greater improvements were seen with Tec-based treatment versus control in both MajesTEC-3 (**Table 1**) and MajesTEC-9 (**Table 2**)

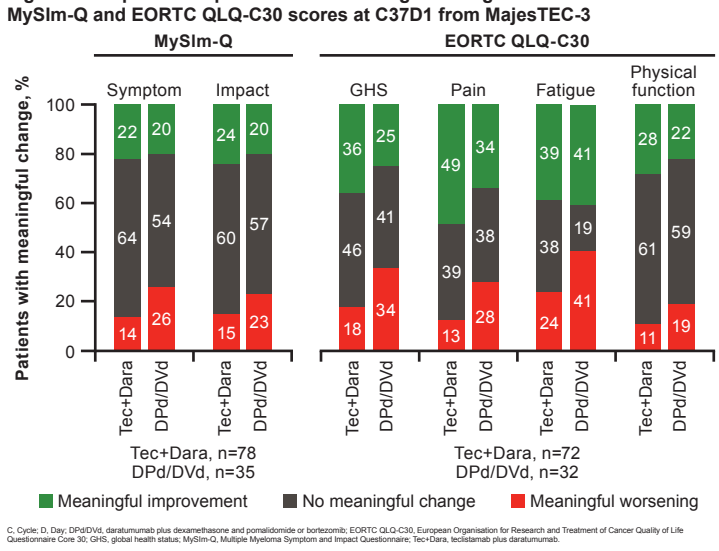
Table 1: LS mean change from baseline in PRO scores at C37D1 for Tec+Dara and DPd/DVd in MajesTEC-3

LS mean change (95% CI)	Tec+Dara	DPd/DVd
MySIm-Q (0- to 4-point scale)	**n=78**	**n=35**
Symptom[a]	−0.10 (−0.20, 0.01)	0.03 (−0.11, 0.17)
Impact[a]	−0.30 (−0.41, −0.19)	−0.14 (−0.29, 0.01)
EORTC QLQ-C30 (0- to 100-point scale)	**n=72**	**n=32**
GHS[b]	5.4 (2.6, 8.3)	0.26 (−3.7, 4.2)
Pain[a]	−9.7 (−13.8, −5.6)	−5.1 (−11.1, 0.8)
Fatigue[a]	−5.0 (−9.0, −0.9)	2.1 (−3.7, 7.9)
Physical function[b]	5.1 (2.5, 7.8)	−0.6 (−4.2, 3.0)
EQ-5D-5L (0- to 100-point scale)	**n=72**	**n=32**
VAS[b]	5.3 (3.0, 7.5)	2.9 (−0.1, 5.9)

Improvement Worsening

C, Cycle; CI, confidence interval; D, Day; DPd/DVd, daratumumab plus dexamethasone and pomalidomide or bortezomib; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; EQ-5D-5L, EuroQol 5-Dimension 5-Level; GHS, global health status; HRQoL, health-related quality of life; ISS, International Staging System; LOT, line of therapy; LS, least squares; MMRM, mixed-effects model with repeated measures; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; PRO, patient-reported outcome; Tec+Dara, teclistamab plus daratumumab; VAS, visual analog scale.
LS mean change from baseline was derived from a MMRM, with change from baseline as the dependent variable; independent variables were baseline score, visit, treatment, visit by treatment interaction, and randomization stratification factors (ISS stage [I vs II/III] and number of prior LOTs [1 vs 2/3]). The within-patient covariance between visits was estimated via an unstructured covariance matrix. The model was iteratively fit by removing the data of the last cycle until the model converged.
[a]A decrease from baseline indicates improved HRQoL.
[b]An increase from baseline indicates improved HRQoL.

Figure 1: Proportion of patients with meaningful change from baseline in MySIm-Q and EORTC QLQ-C30 scores at C37D1 from MajesTEC-3



C, Cycle; D, Day; DPd/DVd, daratumumab plus dexamethasone and pomalidomide or bortezomib; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; GHS, global health status; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; Tec+Dara, teclistamab plus daratumumab.

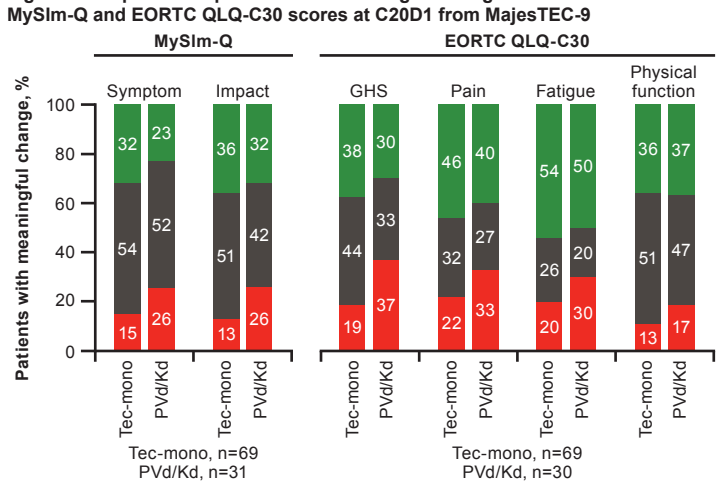
Table 2: LS mean change from baseline in PRO scores at C20D1 for Tec-mono and PVd/Kd in MajesTEC-9

LS mean change (95% CI)	Tec-mono	PVd/Kd
MySIm-Q (0- to 4-point scale)	**n=69**	**n=31**
Symptom[a]	−0.09 (−0.20, 0.03)	0.06 (−0.09, 0.22)
Impact[a]	−0.20 (−0.34, −0.05)	0.04 (−0.16, 0.23)
EORTC QLQ-C30 (0- to 100-point scale)	**n=69**	**n=30**
GHS[b]	3.8 (0.03, 7.5)	−1.2 (−6.5, 4.1)
Pain[a]	−12.8 (−16.7, −8.8)	−5.2 (−10.5, 0.2)
Fatigue[a]	−4.7 (−8.7, −0.7)	0.3 (−5.1, 5.8)
Physical function[b]	6.0 (2.7, 9.2)	1.9 (−2.5, 6.3)
EQ-5D-5L (0- to 100-point scale)	**n=69**	**n=30**
VAS[b]	4.9 (1.9, 7.9)	−1.5 (−5.5, 2.6)

Improvement Worsening

C, Cycle; CI, confidence interval; D, Day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; EQ-5D-5L, EuroQol 5-Dimension 5-Level; GHS, global health status; HRQoL, health-related quality of life; ISS, International Staging System; LOT, line of therapy; LS, least squares; MMRM, mixed-effects model with repeated measures; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; PRO, patient-reported outcome; PVd/Kd, pomalidomide plus bortezomib and dexamethasone or carfilzomib plus dexamethasone; Tec-mono, teclistamab monotherapy; VAS, visual analog scale.
LS mean change from baseline was derived from a MMRM, with change from baseline as the dependent variable; independent variables were baseline score, visit, treatment, visit by treatment interaction, and randomization stratification factors (ISS stage [I vs II/III], number of prior LOTs [1 vs 2/3], investigator's choice [PVd vs Kd], and anti-CD38 monoclonal antibody refractory status [yes vs no]). The within-patient covariance between visits was estimated via an unstructured covariance matrix. The model was iteratively fit by removing the data of the last cycle until the model converged.
[a]A decrease from baseline indicates improved HRQoL.
[b]An increase from baseline indicates improved HRQoL.

Figure 2: Proportion of patients with meaningful change from baseline in MySIm-Q and EORTC QLQ-C30 scores at C20D1 from MajesTEC-9



C, Cycle; D, Day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; GHS, global health status; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; PVd/Kd, pomalidomide plus bortezomib and dexamethasone or carfilzomib plus dexamethasone; Tec-mono, teclistamab monotherapy.

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Multiple Myeloma

Presented by K Weisel at the International Myeloma Society (IMS) Annual Meeting & Exposition; September 23-26, 2026; Glasgow, Scotland