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REALiTEC-2 Subgroup Analysis: An International Observational Retrospective Study of Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma in the Real World

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Key Takeaway

Results from REALiTEC-2 show consistent effectiveness in patient subgroups of clinical interest, further supporting teclistamab as a standard-of-care in RRMM

Conclusions

REALiTEC-2 confirmed consistent response rates across subgroups in a real-world setting, regardless of disease biology

Achieving deep responses (≥VGPR) was the strongest predictor of DOR, PFS and OS in multivariate analysis, underscoring the importance of maintaining treatment intensity to optimise outcomes

Treatment in earlier lines was associated with improved outcomes, and these data underpin the importance of Tec+Dara (MajesTEC-3) treatment as the SoC for patients as early as 2L+

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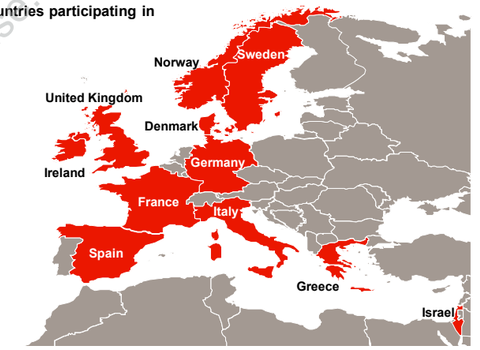
Introduction

- Teclistamab is the most widely used B-cell maturation antigen (BCMA) x CD3 bispecific antibody for triple-class-exposed (TCE) relapsed/refractory multiple myeloma (RRMM),[1-5] with more than 26,800 patients treated commercially worldwide
- REALiTEC (NCT06285318) is a multicohort, retrospective study aiming to describe the use of teclistamab in routine clinical practice
- In the first cohort, with 88.5% of the patients treated via pre-approval access programs, at median follow-up of 20.7 months[6]:
  - Overall response rate (ORR) was 60.2%, with most responses (52.2%) being very good partial response or better (≥VGPR)[6,7]
  - Median duration of response (mDOR), progression-free survival (mPFS), and overall survival (mOS) were in line with MajesTEC-1,[1-4] despite inclusion of a heavily pretreated patient population, and were consistent in patient subgroups with historically poor outcomes[6]
  - Safety profile was consistent with that previously reported, with no new safety signals identified[6]
- Here, we report the results of REALiTEC-2, the second cohort of REALiTEC, focusing on effectiveness outcomes in clinically relevant subgroups

Methods

- REALiTEC-2 is an international, non-interventional study that aims to describe the management and outcomes of patients treated with teclistamab in the real world
- Data were collected from patient medical records, including demographics, disease characteristics, prior therapies, effectiveness and safety
- Informed consent was obtained for all patients; for deceased patients, waivers were obtained as applicable based on country/site-specific requirements
- REALiTEC-2 included patients who received the first dose of teclistamab from January 1, 2023, to December 31, 2024, from 60 sites across 11 countries (**Figure 1**)

Figure 1: Countries participating in REALiTEC-2



Results

Patient disposition

- At data cut-off, 117 (45%) patients were still on treatment
- 139 (53.5%) patients had discontinued treatment, primarily due to progressive disease (n=83), adverse events (AEs; n=23), physician decision (n=13), deaths (n=8), other reasons (n=8), and patient decision (n=4)

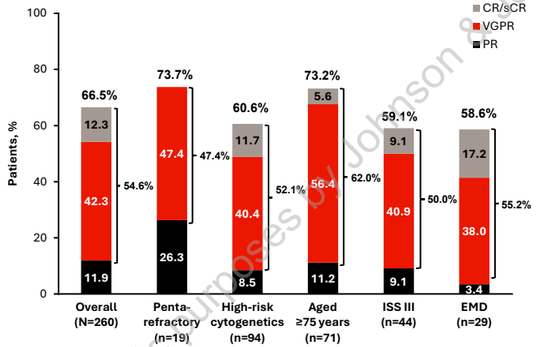
Baseline characteristics

- Patient baseline characteristics have previously been reported[8]
  - Briefly, median age was 68 years (range, 40–100). Patients received a median of 4 (2–14) prior lines of therapy (pLOT). 67.6% had high-risk cytogenetics, 19.1% had extramedullary disease (EMD), and 15.8% received prior BCMA

Effectiveness

- With a median follow-up of 12.7 months, ORR for the overall cohort was 66.5% with a ≥VGPR rate of 54.6%
- Response rates in subgroups were consistent with the overall patient population, with ORRs ranging from 58.6 to 73.7% and ≥VGPR rates from 47.4 to 62.0% (**Figure 2**)

Figure 2: Response rates in selected subgroups



CR, complete response; ISS, International Staging System; PR, partial response; sCR, stringent complete response; VGPR, very good partial response or better.

- In the overall cohort, mDOR was not reached (NR) (95% CI, 13.5–not estimable [NE]), mPFS was 15.2 months (95% CI, 10.8–NE), and mOS was NR (95% CI, 20.5 months–NE)
- 12-month estimates for DOR, PFS, and OS were 64.4% (95% CI, 54.3–72.8%), 53.7% (95% CI, 46.7–60.1%), and 69.8% (95% CI, 63.4–75.3%), respectively
- In patients achieving ≥VGPR, mDOR, mPFS, and mOS were all NR, with 12-month estimates of 73.8% (95% CI, 62.7–82.1), 83.6% (95% CI, 75.1–89.3), and 92.5% (95% CI, 85.9–96.1), respectively (**Figure 3A** and **B**)
- Prior BCMA, baseline thrombocytopenia, achieving ≥VGPR, and MajesTEC-1 ineligibility were significantly associated with DOR, PFS, and OS. Additional significant associations included age (DOR, PFS); Eastern Cooperative Oncology Group performance status (ECOG PS) ≥2 (DOR, OS); and baseline ISS III, prior CAR-T, and lactate dehydrogenase (LDH) >245 U/L (PFS, OS) (**Figure 4**)
- Nevertheless, in multivariate analyses, achieving a deep response (≥VGPR) was the only factor significantly associated with improved DOR (P<0.001), PFS (P<0.001), and OS (P=0.002)

Figure 3: PFS (A) and OS (B) in patients achieving ≥VGPR or <VGPR and the overall cohort

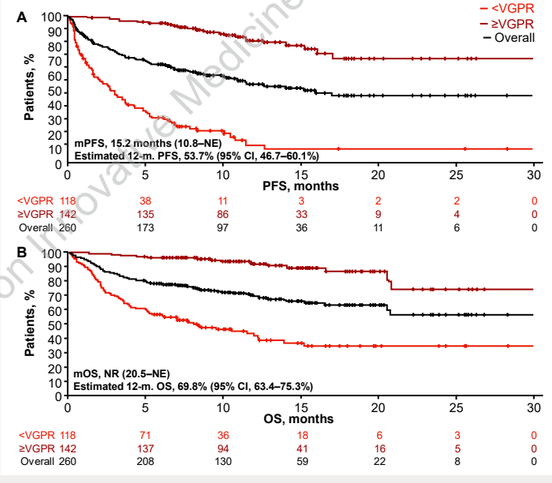
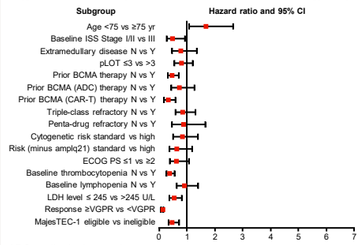


Figure 4: Forest plot of PFS in selected subgroups



	n1	n2	Med1	Med2	HR	LCL	UCL	LR pval
Age <75 vs ≥75 yr	189	71	11.53	NE	1.67	1.06	2.64	0.026
Baseline ISS Stage I/II vs III	53	44	NE	7.92	0.49	0.26	0.92	0.022
Extramedullary disease N vs Y	123	29	11.50	6.90	0.78	0.45	1.34	0.366
pLOT ≤3 vs >3	82	178	NE	12.71	0.80	0.53	1.19	0.268
Prior BCMA therapy N vs Y	219	41	NE	4.93	0.45	0.29	0.68	<0.001
Prior BCMA (ADC) therapy N vs Y	234	26	11.50	8.97	0.73	0.42	1.25	0.246
Prior BCMA (CAR-T) therapy N vs Y	246	14	16.03	2.15	0.31	0.16	0.57	<0.001
Triple-class refractory N vs Y	196	64	16.03	11.50	0.85	0.57	1.28	0.435
Penta-drug refractory N vs Y	241	19	15.24	7.16	0.86	0.45	1.64	0.636
Cytogenetic risk standard vs high	45	94	16.03	12.65	0.83	0.49	1.38	0.472
Risk (minus amplq21) standard vs high	45	39	16.03	7.03	0.64	0.35	1.17	0.147
ECOG PS ≤1 vs ≥2	91	30	NE	6.90	0.62	0.36	1.06	0.078
Baseline thrombocytopenia N vs Y	197	62	NE	3.55	0.37	0.25	0.54	<0.001
Baseline lymphopenia N vs Y	123	90	NE	17.05	0.92	0.61	1.38	0.686
LDH level ≤ 245 vs >245 U/L	124	69	17.05	6.70	0.53	0.35	0.80	0.003
Response ≥VGPR vs <VGPR	142	118	NE	2.79	0.08	0.05	0.13	<0.001
MajesTEC-1 eligible vs ineligible	104	156	NE	10.28	0.48	0.32	0.72	<0.001

ADC, antibody-drug conjugate.

- mDOR, mPFS, and mOS were also consistent in the clinically relevant subgroups as compared with the overall cohort (**Table 1**)

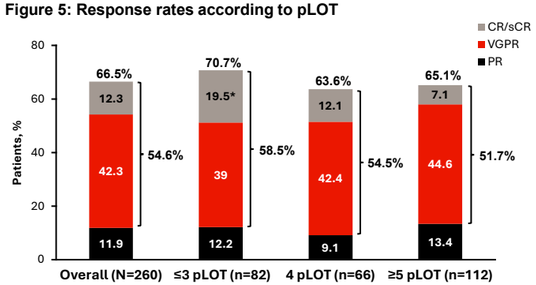
Table 1: Effectiveness in selected subgroups

	mDOR (months)	mPFS (months)	mOS (months)
Overall (N=260)	**NR**	**15.2**	**NR**
Penta refractory (n=19)	NR	7.2	16.6
High-risk cytogenetics (n=94)	NR	12.7	20.5
Aged ≥75 years (n=71)	NR*	NR*	NR
Baseline ISS III (n=44)	NR	7.9*	20.5*
EMD (n=29)	NR	6.9	12.8

*Statistically significant vs contrary in univariate analyses.

- Response rates were deeper and numerically higher in patients with ≤3 pLOT (**Figure 5**)

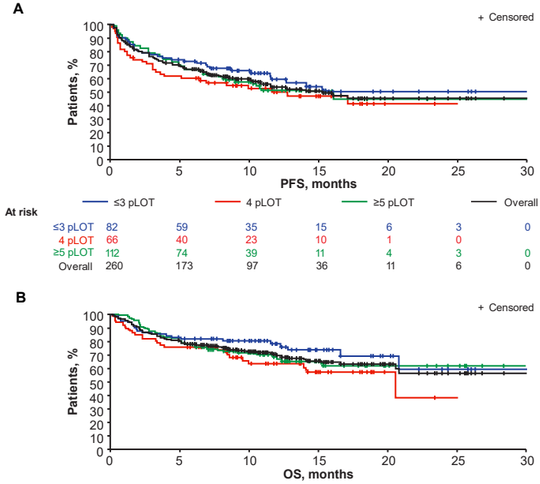
Figure 5: Response rates according to pLOT



*Statistically significant difference.

- A trend was observed in DOR, PFS, and OS favouring earlier line patients (≤3 pLOT; P=0.895, P=0.268, and P=0.158, respectively) (**Figure 6A** and **B**)

Figure 6: (A) PFS and (B) OS according to pLOT



- Overall, no differences were observed in safety outcomes considering pLOT. Treatment discontinuation due to adverse events was lower in patients with ≤3 pLOT (8.5% vs 10.7%)

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Multiple Myeloma

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