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Elranatamab in Combination With Daratumumab and Lenalidomide in Transplant-Ineligible Patients With Newly Diagnosed Multiple Myeloma: Results From MagnetisMM-6 Part 1

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Objective

To report updated efficacy and safety data for EDR at the selected RP3D–DLG–in TI patients with NDMM

Conclusions

- In TI patients with NDMM, EDR at the RP3D demonstrated rapid and deep responses, with responses deepening with longer follow-up
- The safety profile was manageable and consistent with the known toxicities of the individual components, with no new safety signals observed
- These findings support further evaluation of EDR in part 2 of the MagnetisMM-6 study

Background

- MagnetisMM-6 (NCT05623020) is a phase 3, open-label, 2-arm randomized study evaluating the efficacy and safety of elranatamab in combination with daratumumab and lenalidomide (EDR) versus daratumumab, bortezomib, lenalidomide, and dexamethasone in transplant-ineligible (TI) patients with newly diagnosed multiple myeloma (NDMM)
- The dose-finding part 1 of the study showed early and promising efficacy of EDR with a predictable safety profile in TI patients with NDMM[1]
  - At dose level G (DLG), with a median follow-up of 4.6 (range, 1.2-6.2) months, investigator-assessed confirmed objective response rate (ORR) for EDR was 91.9% (95% CI, 78.1-98.3); 81.1% achieved very good partial response or better (≥VGPR)

Methods

- In DLG, eligible patients had
  - TI (defined as age ≥65 or <65 years with comorbidities impacting the possibility of transplant) NDMM per International Myeloma Working Group criteria
  - Eastern Cooperative Oncology Group performance status ≤2
  - Adequate liver, renal, and bone marrow function
- The DLG dosing schedule[1] is the recommended phase 3 dose (RP3D) for MagnetisMM-6
- Endpoints assessed included safety and preliminary efficacy
- Data cutoff for this analysis was March 16, 2026
  - Median duration of follow-up was 19.1 (range, 1.2-20.9) months

Results

PATIENTS AND TREATMENT

- In part 1 DLG of MagnetisMM-6, 40 TI patients with NDMM received ≥1 dose of elranatamab (**Table 1**)
  - Treatment was ongoing in 34 patients

Table 1. Patient demographics and disease characteristics

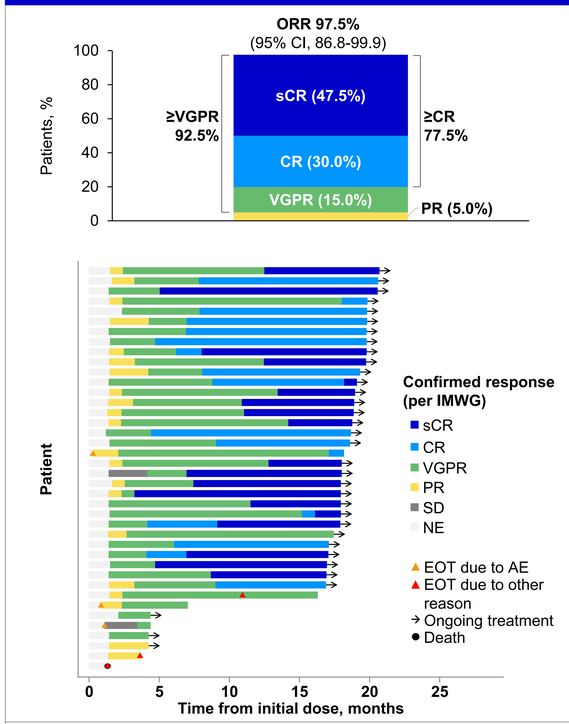
	DLG n=40
Age, median (range), years	75.0 (67-83)
Male, n (%)	15 (37.5)
Race, n (%)	
Asian	7 (17.5)
White	33 (82.5)
ECOG performance status, n (%)	
0	23 (57.5)
1	16 (40.0)
2	1 (2.5)
R-ISS disease stage, n (%)	
I	9 (22.5)
II	25 (62.5)
III	5 (12.5)
Unknown	1 (2.5)
IMWG risk, n (%)	
Standard	30 (75.0)
High	10 (25.0)
Extramedullary disease, n (%)	0
Baseline bone marrow plasma cells, n (%)	
<30%	16 (40.0)
30%-<50%	14 (35.0)
50%-<70%	7 (17.5)
≥70%	3 (7.5)
Frailty status, n (%)[a]	
Yes	10 (25.0)
No	30 (75.0)

[a] Assessed according to the simplified IMWG scale using scores for ECOG performance status, Charlson Comorbidity Index, and age.[2]
DLG=dose level G; ECOG=Eastern Cooperative Oncology Group; IMWG=International Myeloma Working Group; R-ISS=Revised International Staging System

EFFICACY

- Confirmed ORR by investigator was 97.5% (95% CI, 86.8-99.9; **Figure 1**)
  - 31 (77.5%) patients achieved complete response or better (≥CR)
  - 37 (92.5%) patients achieved ≥VGPR
- Median time to response was 1.5 (range, 0.3-4.2) months
  - Median time to ≥CR was 8.1 (range, 3.3-18.0) months
- Responses were durable (**Figure 1)**
- Minimal residual disease (MRD) negativity (10^{-5}) rate was 100% in patients with ≥CR who were evaluable for MRD (n=24)

Figure 1. Confirmed response[a] and swimmer plot



[a] By investigator.
AE=adverse event; CR=complete response; EOT=end of treatment; IMWG=International Myeloma Working Group; NE=not estimable; ORR=objective response rate; PR=partial response; sCR=stringent complete response; SD=stable disease; VGPR=very good partial response

SAFETY

- Treatment-emergent adverse events (TEAEs) were reported in 100% of patients (maximum grade 3/4, 95.0%; **Table 2**)
- Hematologic TEAEs were reported in 87.5%
- Cytokine release syndrome occurred in 62.5% (all grade ≤2)
- 1 case of immune effector cell–associated neurotoxicity syndrome (grade 2) was reported
- Any-grade infections were reported in 87.5% (grade 3/4, 25.0%; **Table 3**)
  - 1 case of grade 5 *Candida* pneumonia was reported in a patient who did not receive prophylactic immunoglobulin replacement
  - Infections of bacterial, viral, fungal, and unspecified origin were reported in 32.5%, 42.5%, 12.5%, and 60.0% of patients, respectively
- 37 (92.5%) patients received immunoglobulin replacement at least once during treatment

Table 2. Most frequent TEAEs[a]

	DLG n=40	
TEAE, n (%)[b]	Any grade	Grade 3/4
Any	40 (100)	38 (95.0)
Hematologic		
Neutropenia[c]	32 (80.0)	32 (80.0)
Anemia[d]	16 (40.0)	8 (20.0)
Thrombocytopenia[e]	7 (17.5)	5 (12.5)
Nonhematologic		
CRS	25 (62.5)	0
Diarrhea	15 (37.5)	3 (7.5)
Pyrexia	14 (35.0)	0
Cough	12 (30.0)	0
Rash	12 (30.0)	3 (7.5)
Injection site reaction	12 (30.0)	0
Hypogammaglobulinemia	12 (30.0)	1 (2.5)
Nausea	11 (27.5)	0
Constipation	10 (25.0)	0
Peripheral sensory neuropathy	9 (22.5)	2 (5.0)
Upper respiratory tract infection	9 (22.5)	0
Fatigue	9 (22.5)	0
Decreased appetite	8 (20.0)	2 (5.0)
Peripheral edema	8 (20.0)	0
Asthenia	8 (20.0)	4 (10.0)
Pneumonia	7 (17.5)	4 (10.0)

[a] Any grade in ≥20% or maximum grade 3/4 in ≥10% of patients. [b] TEAEs according to the Medical Dictionary for Regulatory Activities v28.0 and Common Terminology Criteria for Adverse Events v5; severity of CRS and ICANS was assessed according to the American Society for Transplantation and Cellular Therapy criteria.[3] [c] Including neutrophil count decreased, neutrophil percentage decreased, cyclic neutropenia, agranulocytosis, granulocytopenia, and granulocyte count decreased. [d] Includes hemoglobin decreased, red blood cell count decreased, hematocrit decreased, normochromic anemia, normocytic anemia, and normochromic normocytic anemia. [e] Includes platelet count decreased.
CRS=cytokine release syndrome; DLG=dose level G; ICANS=immune effector cell–associated neurotoxicity syndrome; TEAE=treatment-emergent adverse event.

Table 3. Most frequent infections[a]

	DLG n=40	
Infections, n (%)[b]	Any grade	Grade 3/4
Upper respiratory tract infection	9 (22.5)	0
Pneumonia	7 (17.5)	4 (10.0)
Escherichia coli tract infection	5 (12.5)	1 (2.5)
Viral upper respiratory tract infection	5 (12.5)	0
Bronchitis	5 (12.5)	0
Cytomegalovirus infection reactivation	5 (12.5)	0
Rhinitis	4 (10.0)	0
Nasopharyngitis	3 (7.5)	0
COVID-19	2 (5.0)	0
Campylobacteria bacteremia	2 (5.0)	1 (2.5)
Gastroenteritis	2 (5.0)	0
Infection	2 (5.0)	1 (2.5)
Influenza	2 (5.0)	0
Salmonellosis	2 (5.0)	1 (2.5)
Sinusitis	2 (5.0)	0
Urinary tract infection	2 (5.0)	0
Urosepsis	2 (5.0)	2 (5.0)

[a] Any grade in ≥5% of patients. [b] Infections include preferred terms in the system organ class of infections and infestations. TEAEs according to the Medical Dictionary for Regulatory Activities v28.0 and Common Terminology Criteria for Adverse Events.
DLG=dose level G; TEAE=treatment-emergent adverse event.

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