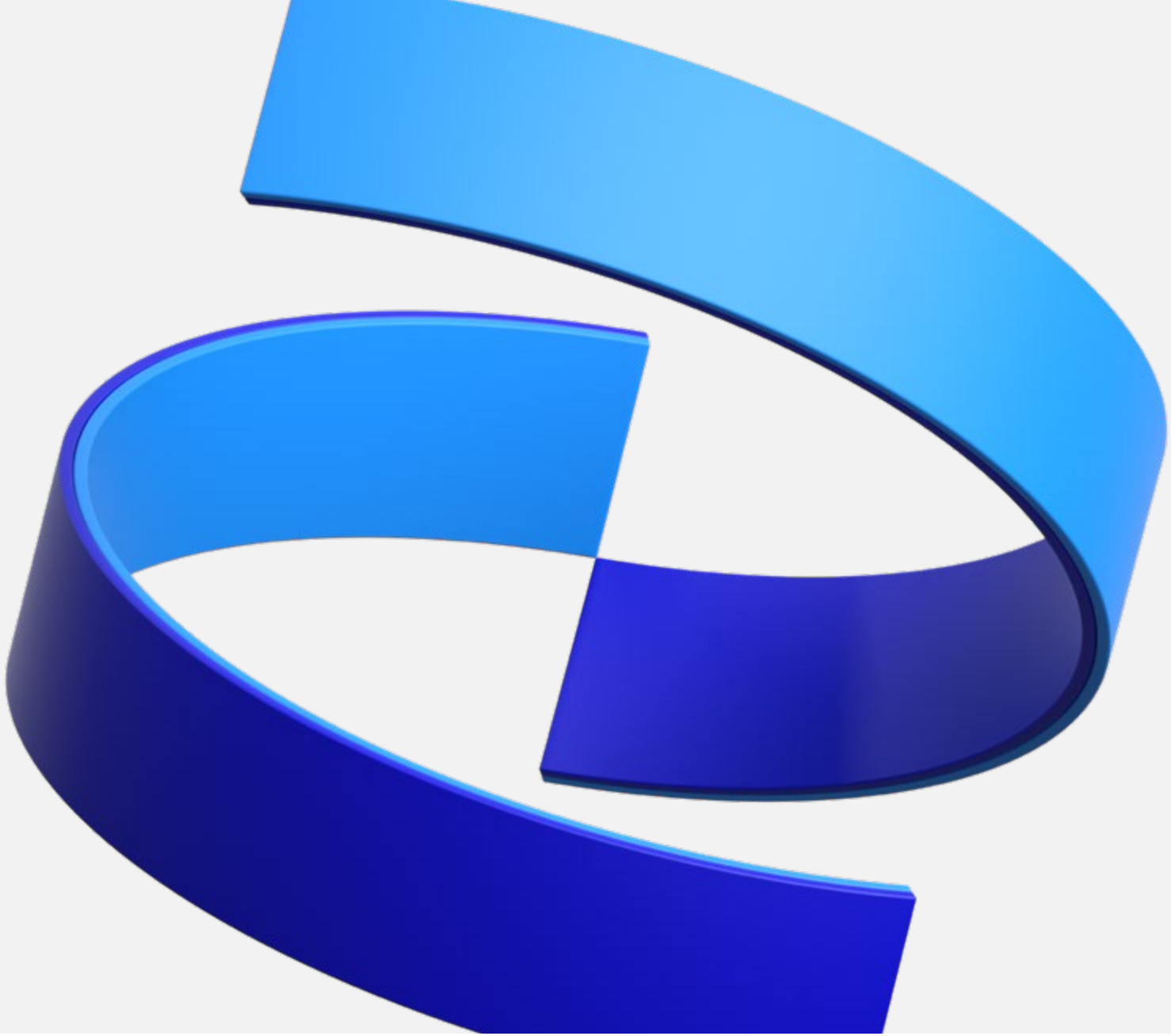
EHA 2024



European Hematology Association
Madrid, Spain

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Pfizer Medical Affairs

Long-Term Survival After Elranatamab Monotherapy in Patients With Relapsed or Refractory Multiple Myeloma: MagnetisMM-3

Mohty M et al. Poster Presentation at EHA 2024 (Abstract P932)

Pfizer-Sponsored Study

Long-Term Survival After Elranatamab Monotherapy in Patients With Relapsed or Refractory Multiple Myeloma: MagnetisMM-3

Background

- In the open-label, non-randomized, phase 2 MagnetisMM-3 registrational study (NCT04649359), elranatamab monotherapy induced deep and durable responses in BCMA-naïve patients with RRMM (N=123)[1,2]
  - OS data were immature at the last data cut (Sep 11, 2023), with >50% of patients censored, after a median follow-up (reverse KM method) of 22.0 (95% CI, 21.6-22.6) months[2]
- This presentation reports results obtained >2 years after the last patient was initially dosed on January 7, 2022

Objective

- To report updated efficacy and safety results from MagnetisMM-3, collected >2 years after the last patient was initially dosed

1. Lesokhin AM, et al. *Nat Med*. 2023;29:2259-2267.
2. Tomason M, et al. *Blood*. 2023;142(suppl 1):3385.

BCMA = B-cell maturation antigen; CI = confidence interval; KM = Kaplan-Meier; OS = overall survival; RRMM = relapsed/refractory multiple myeloma.

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Methods

- Eligible patients had disease refractory to ≥1 PI, ≥1 IMiD, and ≥1 anti-CD38 antibody
- Patients received sc elranatamab as 2 step-up priming doses followed by 76 mg QW
- Patients who received ≥6 months of QW dosing and achieved ≥PR for ≥2 months were transitioned to a Q2W dosing schedule and, subsequently, to a Q4W dosing schedule after ≥6 Q2W cycles
- **Primary endpoint:** ORR, assessed by BICR, per IMWG criteria[1]
- **Secondary endpoints:** DOR and PFS by BICR, OS, safety
- SPMs were determined by clinical review using the system organ class Neoplasms benign, malignant, and unspecified (including cysts and polyps)
- The data cutoff date was March 26, 2024; median follow-up by reverse KM method was 28.4 (95% CI, 28.0-29.0) months

BICR = blinded-independent central review; CD = cluster of differentiation; CI = confidence interval; DOR = duration of response; IMiD = immunomodulatory drug; IMWG = International Myeloma Working Group; KM = Kaplan-Meier; ORR = objective response rate; OS = overall survival; PFS = progression-free survival; PR = partial response; QW = once weekly; Q2W = once every 2 weeks; Q4W = once every 4 weeks; sc = subcutaneous; SPM = secondary primary malignancy.

1. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT04649359. Accessed April 26, 2024

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Patients and Treatment

Table: Demographics and Baseline Characteristics

	N=123
Age, median (range), years	68.0 (36.0-89.0)
Male, n (%)	68 (55.3)
Race, n (%)	
African American or Black	9 (7.3)
Asian	16 (13.0)
White	72 (58.5)
Unknown	1 (0.8)
Not reported[a]	25 (20.3)
ECOG PS, n (%)	
0	45 (36.6)
1	71 (57.7)
2	7 (5.7)
R-ISS disease stage, n (%)	
I	28 (22.8)
II	68 (55.3)
III	19 (15.4)
Unknown/missing	8 (6.5)
Cytogenetic risk, n (%)	
Standard	83 (67.5)
High[b]	31 (25.2)
Missing	9 (7.3)

Table: Demographics and Baseline Characteristics Cont'd

	N=123
Extramedullary disease by BICR, n (%)[c]	
Yes	39 (31.7)
No	84 (68.3)
Bone marrow plasma cells, n (%)	
<50%	89 (72.4)
≥50%	26 (21.1)
Missing	8 (6.5)
Patients with ≥1 poor prognosis feature, n (%)[d]	94 (76.4)
Prior lines of therapy, median (range)	5.0 (2.0-22.0)
Prior stem cell transplant, n (%)	87 (70.7)
Exposure status, n (%)	
Triple-class[e]	123 (100)
Penta-drug[f]	87 (70.7)
Refractory status, n (%)	
Triple-class[e]	119 (96.7)
Penta-drug[f]	52 (42.3)
Refractory to last line of therapy, n (%)	118 (95.9)

- Overall, 123 BCMA-naïve patients were treated with elranatamab. Patient demographics and disease characteristics are presented in the **Table**

[a]Includes patients recruited in countries where the collection of race is prohibited. [b]Includes t(4;14), t(14;16), del(17p) chromosomal abnormalities. [c]Extramedullary disease was defined as any plasmacytoma (extramedullary and/or paramedullary with a soft-tissue component). [d]Poor prognosis feature refers to ≥1 of the following: ECOG PS of 2, R-ISS stage III, EMD at baseline by BICR, high cytogenetic risk, BMPCs ≥50%, or penta-drug refractory disease. [e]Triple-class refers to ≥1 PI, ≥1 IMiD, and ≥1 anti-CD38 antibody. [f]Penta-drug refers to ≥2 PIs, ≥2 IMiDs, and ≥1 anti-CD38 antibody.

BICR = blinded independent central review; BMPC = bone marrow plasma cell; ECOG PS = Eastern Cooperative Oncology Group performance status; EMD = extramedullary disease; IMiD = immunomodulatory drug; PI = proteasome inhibitor; R-ISS = Revised International Staging System.

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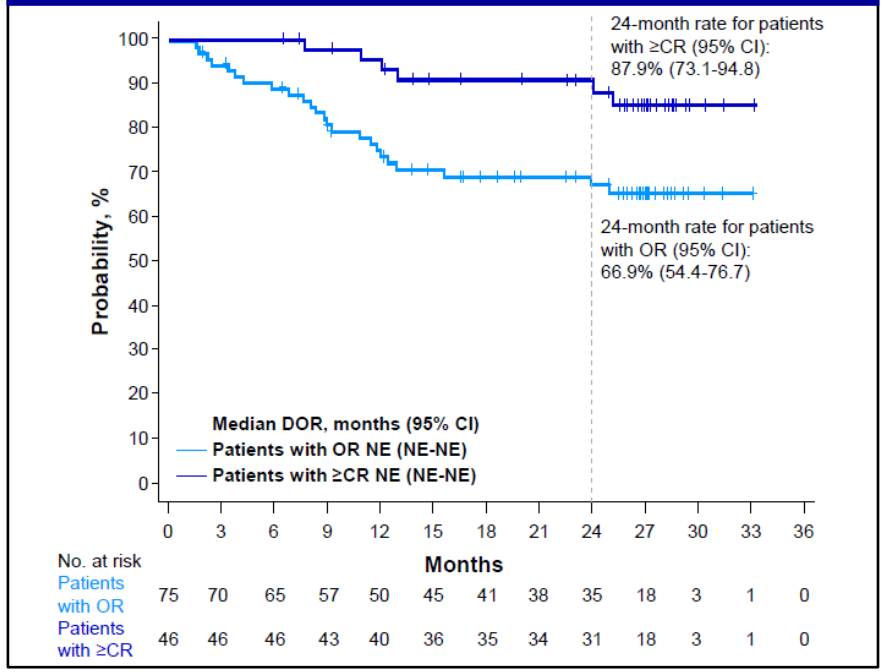
Efficacy: ORR, MRD-negativity, and DOR

- With extended follow-up, ORR per BICR remained at 61.0% (≥CR rate, 37.4%)
  - sCR, 16.3%; CR, 21.1%; VGPR, 18.7%; PR, 4.9%
- MRD negativity rate was 90.3% in patients with ≥CR who were evaluable for MRD (n=31) at the threshold of 10^{-5}
- Median DOR was not reached (**Figure**)
- The probability of maintaining a response at 2 years was:
  - 66.9% (95% CI, 54.4-76.7) among all responders, and
  - 87.9% (95% CI, 73.1-94.8) in patients with ≥CR

Figure: DOR



BICR = blinded-independent central review; CI = confidence interval; CR = complete response; DOR = duration of response; MRD = minimal residual disease; NE = not evaluable; OR = objective response; ORR = objective response rate.

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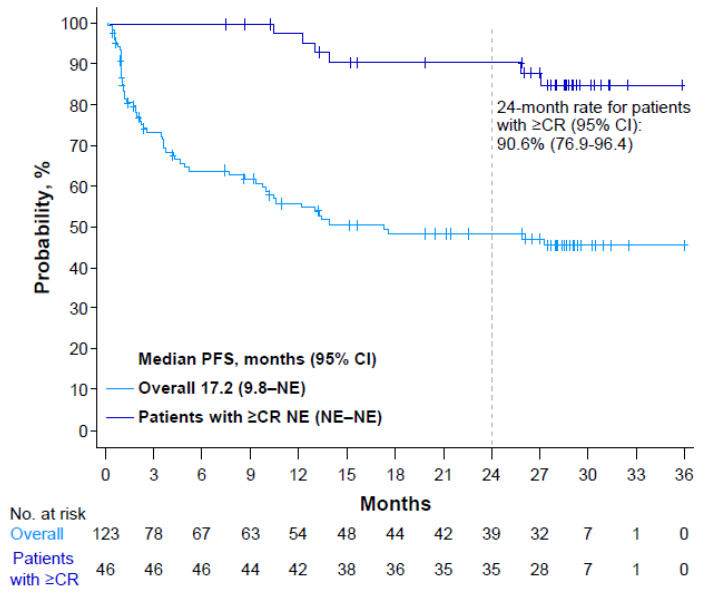
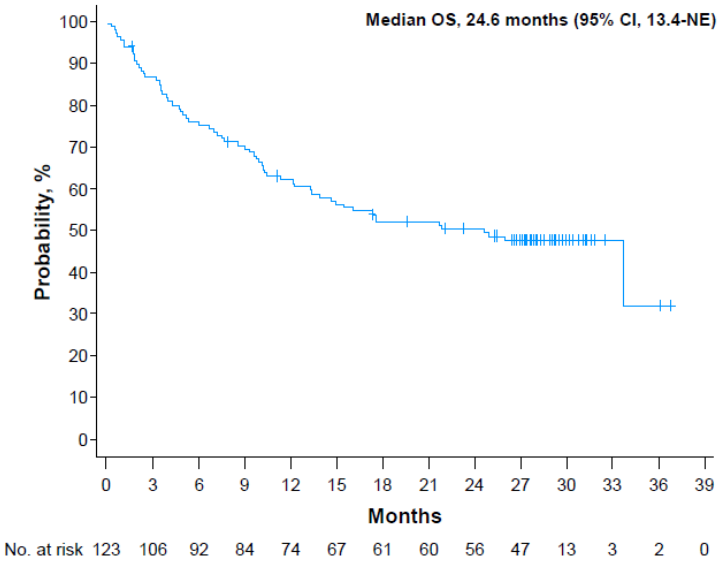
Efficacy: PFS and OS

Figure 1: PFS



- Median PFS was 17.2 (95% CI, 9.8-NE) months (**Figure 1)**
  - In patients with ≥CR, median PFS was not reached and the probability of being progression-free at 2 years was 90.6% (95% CI, 76.9-96.4)
- Median OS was 24.6 (95% CI, 13.4-NE) months (**Figure 2**)

Figure 2: OS



CI = confidence interval; CR = complete response; NE = not evaluable; OS = overall survival; PFS = progression-free survival.

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Safety

- No new safety signals were observed with extended follow-up
- With 6 more months of follow-up, there were 4 new deaths
  - 2 patients with disease under study and 1 patient each with unknown reason and septic shock
- 5 (4.1%) patients had SPMs, all of which were squamous cell carcinomas of the skin
  - No hematologic SPMs were observed
  - All 5 patients with SPMs had received prior lenalidomide and SCT

SCT = stem cell transplant; SPM, secondary primary malignancy

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Authors' Conclusions

- Elranatamab continued to demonstrate deep and durable responses in heavily pretreated (median 5 prior LOTs; 96.7%, TCR), BCMA-naïve patients with RRMM
  - MRD-negativity rate was 90.3% in evaluable patients with ≥CR
  - Median DOR was still not reached (2-year rate, 66.9% [95% CI, 54.4-76.7])
  - Median PFS was 17.2 (95% CI, 9.8-NE) months
  - Median OS was 24.6 (95% CI, 13.4-NE) months
- No new safety signals were observed. Although longer follow-up is needed, few SPMs were seen (<5%; all squamous cell carcinomas)
  - No hematologic SPMs were reported

BCMA = B-cell maturation antigen; CI = confidence interval; CR = complete response; DOR = duration of response; LOT = line of therapy; MRD = minimal residual disease; NE = nor evaluable; OS = overall survival; PFS = progression-free survival; RRMM = relapsed/refractory multiple myeloma; SPM = secondary primary malignancy; TCR = triple-class refractory.
Please note: The conclusions above represent the authors' conclusions only.

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ELREXFIO™ (elranatamab-bcmm)

INDICATION(S)

Elranatamab-bcmm is a BCMA-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with RRMM who have received at least four prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).

Please see **FULL PRESCRIBING INFORMATION**, including boxed warning.

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY
including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

- Cytokine Release Syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving ELREXFIO. Initiate treatment with ELREXFIO step-up dosing schedule to reduce the risk of CRS. Withhold ELREXFIO until CRS resolves or permanently discontinue based on severity.
- Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), and serious and life-threatening reactions, can occur in patients receiving ELREXFIO. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment. Withhold ELREXFIO until the neurologic toxicity resolves or permanently discontinue based on severity.
- Because of the risk of CRS and neurologic toxicity, including ICANS, ELREXFIO is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ELREXFIO REMS.

See full prescribing information for complete boxed warning.

BCMA = B-cell maturation antigen; CD = cluster of differentiation; CRS = cytokine release syndrome; ICANS = Immune Effector Cell-Associated Neurotoxicity Syndrome; REMS = Risk Evaluation and Mitigation Strategy; RRMM = relapsed or refractory multiple myeloma.

ELREXFIO™ (elranatamab-bcmm). Prescribing Information. New York, NY: Pfizer; 2023.

ELREXFIO™ REMS

ELREXFIO is available only through a restricted program under a REMS called the ELREXFIO REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Notable requirements of the ELREXFIO REMS include the following:

- Prescribers must be certified with the program by enrolling and completing training
- Prescribers must counsel patients receiving ELREXFIO about the risk of CRS and neurologic toxicity, including ICANS, and provide patients with ELREXFIO Patient Wallet Card
- Pharmacies and healthcare settings that dispense ELREXFIO must be certified with the ELREXFIO REMS program and must verify prescribers are certified through the ELREXFIO REMS program
- Wholesalers and distributers must only distribute ELREXFIO to certified pharmacies or healthcare settings

Further information about the ELREXFIO REMS program is available at www.ELREXFIOREMS.com or by telephone at 1-844-923-7845.

CRS = cytokine release syndrome; ICANS = immune effector cell-associated neurotoxicity syndrome; REMS = Risk Evaluation and Mitigation Strategy.

ELREXFIO™ (elranatamab-bcmm). Prescribing Information. New York, NY: Pfizer; 2023.