

Primary endpoint: Progression-free survival

Eligibility: Not refractory to anti-CD38 therapy; R/R MM with 1–3 prior lines of therapy; no previous carfilzomib; no primary refractory MM; ECOG ≤2

TRIAL DESIGN

Randomization in a 3:2 ratio

Treatment arm, n = 179 (Isatuximab + Carfilzomib + Dexamethasone)

Control arm, n = 123 (Carfilzomib + Dexamethasone)

Isatuximab

10 mg/kg

Cycle 1 days

1 8 15 22

Subsequent cycle days

1 15

Carfilzomib

Cycle 1 days

1 2 8 9 15 16

20 mg/m² 56 mg/m²

Subsequent cycle days

1 2 8 9 15 16

56 mg/m²

Dexamethasone

20 mg

All cycles days

1 2 8 9 15 16 22 23

or

28-day cycles; to PD or unacceptable toxicity

EFFICACY

Median progression-free survival

NR vs 19.15 months

HR, 0.53; 99% CI, 0.32–0.89; one-sided p = 0.0007

2-year progression-free survival rate

Treatment arm 68.9%

Control arm 45.7%

Very good PR or better

p = 0.0011

73% 56%

MRD negativity by NGS at 10⁻⁵

p = 0.0004

30% 13%

Complete renal response

52% 31%

SAFETY

Treatment arm

Control arm

77%

Patients with Grade ≥ 3 TAEs

67%

Patients with TAEs leading to treatment discontinuation

8% 14%

Most common TEAEs (any grade):

83% 74%

46% 3%

37% 31%

36% 29%

Respiratory infection

Infusion-related reactions

Hypertension

Diarrhea

Grade ≥3 hematologic AEs:

22% 20%

19% 7%

30% 24%

Anemia

Neutropenia

Thrombocytopenia

Moreau P, et al. *Lancet*. 2021;397(10292):2361-2371.
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