DREAMM-2: SINGLE-AGENT BELANTAMAB MAFODOTIN IN RELAPSED/REFRACTORY MULTIPLE MYELOMA REFRACTORY TO PROTEASOME INHIBITORS, IMMUNOMODULATORY AGENTS, AND REFRACTORY AND/OR INTOLERANT TO ANTI-CD38 MABS

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Background

Investigational single-agent belantamab mafodotin (GSK2857916), a B-cell maturation antigen-targeting immunoconjugate, showed clinically meaningful activity and manageable safety in patients with heavily pretreated relapsed/refractory multiple myeloma (RRMM; DREAMM-2, NCT03525678, *Lancet Oncol* 2020). We report updated results (median follow-up 9 months).

Methods

DREAMM-2 is an ongoing single-agent belantamab mafodotin (2.5 or 3.4 mg/kg) study in patients with RRMM after ≥3 prior therapies and refractory to an immunomodulatory agent, a proteasome inhibitor, and refractory and/or intolerant to an anti-CD38 monoclonal antibody. Patients provided informed consent. Primary endpoint: overall response rate (ORR; ≥partial response per independent review committee).

Results

ORR was 31% in the 2.5 mg/kg (19% with ≥very good partial responses [VGPR]) and 35% (24% with ≥VGPR) in the 3.4 mg/kg groups (Table). The median duration of response (DoR) was not reached (NR) in the 2.5 mg/kg and 6.2 months in the 3.4 mg/kg groups; 1-year overall survival (OS) estimate was 53%. Common Grade 3/4 AEs (>10% in either group) were keratopathy (2.5: 29%; 3.5: 24%), thrombocytopenia (2.5: 21%; 3.4: 32%), anemia (2.5: 20%; 3.4: 27%), pneumonia (2.5: 6%; 3.4: 13%), and neutropenia (2.5: 11%; 3.4: 16%). AEs were managed with dose delays (2.5: 54%; 3.4: 62%) and reductions (2.5: 34%; 3.4: 43%); discontinuations due to AEs were uncommon (2.5: 9%; 3.4: 12%).

Table. Outcomes

	2.5 mg/kg (n=97)[a]	3.4 mg/kg (n=99)[b]
Median number of cycles (range)	3 (1–15)	3 (1–14)
ORR (97.5% CI), %	31 (20.8–42.6)	35 (24.8–47.0)
DoR,[c] m	NR (4.2–NR)	6.2 (4.8–NR)
Probability of DoR ≥6 m, % (95% CI)	70 (48–84)	58 (39–72)
Progression-free survival (PFS),[c] m	2.8 (1.6–3.6)	3.9 (2.0–5.8)
PFS: patients with ≥minimal response,[c] %	NR (7.5–NR)	8.4 (6.9–13.8)
Probability of OS at 12 m, % (95% CI)	53 (38–66)	53 (41–63)

[a]n=41 on study; n=17 on treatment; [b]n=47 on study; n=18 on treatment; [c]median (95% CI estimates)
CI, confidence interval; m, months.

Conclusion

Single-agent belantamab mafodotin was well tolerated, and clinically meaningful responses were sustained despite dose modifications with longer follow-up.

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Keyword(s): Clinical trial, Immunoconjugate, Multiple myeloma