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RESEARCH **REVIEW ARTICLE**

Real-World Use of Belantamab Mafodotin in Relapsed/Refractory Multiple Myeloma: A Systematic Review

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ABSTRACT

Belantamab mafodotin is an antibody drug conjugate directed against B-cell maturation antigen and was approved by the Food and Drug Administration under accelerated approval for use in the US in August 2020 for adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory drug. In November 2022 belantamab mafodotin was withdrawn from the US market after failure of a required confirmatory trial. In this article, we provide a systematic review on the efficacy and safety of the use of belantamab mafodotin in a real-world setting.

KEYWORDS - Multiple myeloma; belantamab mafodotin, Blenrep; real-world evidence.

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INTRODUCTION

The prognosis of multiple myeloma (MM) has continued to improve over the years; however, a significant proportion of patients develop relapsed/refractory (R/R) disease and require further treatment options for disease control [1, 2]. R/R MM is defined as a disease state that is either unresponsive or progressive to current therapy or therapy within the past 60 days in previously responsive patients [2]. The prognosis of R/R MM continues to be suboptimal [1, 3]. In so-called "triple-refractory" disease, which is refractory to an anti-CD38 antibody, a proteosome inhibitor, and an immunomodulatory drug, prognosis is poor and thus, new treatment options are needed [4–6].

Belantamab mafodotin, a monoclonal antibody targeting B-cell maturation antigen (BCMA), is a member of the antibody-drug conjugates (ADCs) that has been shown to have a single drug activity with an overall response of 31-34% at various dosing levels [7]. This resulted in an accelerated approval by the Food and Drug Administration (FDA) in August 2020 to use in adult patients with R/R MM who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory drug. In November 2022, belantamab mafodotin was withdrawn from the US market after failure of DREAMM-3 (NCT04162210), a required confirmatory trial comparing belantamab mafodotin vs pomalidomide and dexamethasone. In our systematic review, we

aimed to provide a comprehensive review on the use of belantamab mafodotin in real-world setting with focus on efficacy and safety.

METHODS

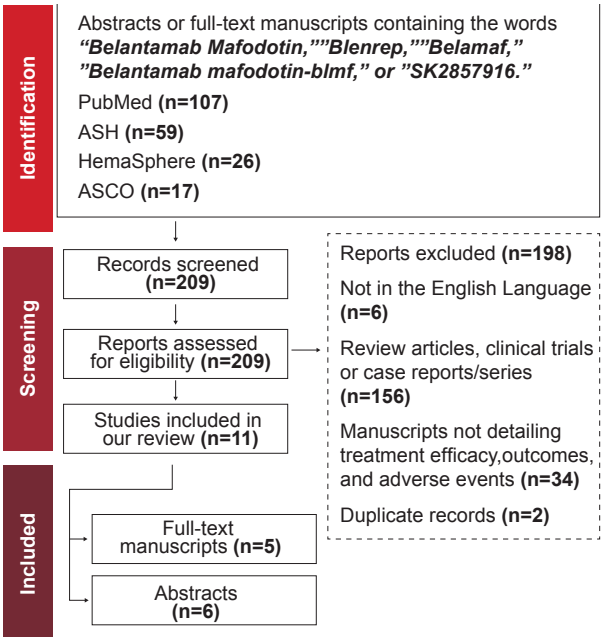
We performed a literature review within PubMed/Medline, as well as major oncology societies including the American Society of Hematology, American Society of Clinical Oncology, and HemaSphere to include all reported real-world use of belantamab mafodotin. The identification and reporting of the analyzed studies in this study were done in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [8].

We included all full-text manuscripts and/or abstracts that have the keywords *"belantamab mafodotin," "belamaf," "blenrep," "belantamab mafodotin-blmf,"* and/or *"GSK2857916"* (subsequently named as belantamab mafodotin) between January 2006 and December 2022. All search records were screened. We excluded all the following: reports not in the English language; reports not pertaining to treatment efficacy, outcome, and/or adverse effects; duplicate records (e.g., abstracts that were later published as full-text manuscripts); and manuscripts that did not describe "real-world" multiple patient experiences, thus excluding review articles, clinical trials, and case reports/series (Fig. 1). The records that met the criteria were then reviewed for their patient demographics, response rates, survival outcomes, and reported adverse events. Minimum endpoints included the report of overall response rates, median progression-free survival and overall survival, and a report of the incidence of adverse effects in the analyzed sample.

RESULTS

Our search initially included 209 manuscripts, of which 198 were excluded. Our final analysis included 11 manuscripts (6 abstracts and 5 full-text manuscripts). A total of 11 studies were analyzed and reviewed (Table 1). Of those, 3 studies reported the use of belantamab mafodotin exclusively as a single agent [9–11], 1 study included combination therapy with dexamethasone [12], and the remaining 7 studies included its use either as a single therapy or part of combination therapy [13–19]. Six studies were performed in the US [12, 14–18], 4 were done in Europe [10, 11, 13, 19], and 1 was done in the Middle East [9]. Eight studies were multicentered [9–11, 13, 14, 16, 17, 19], while 3 were single-center experiences [12, 15, 18].

Figure 1. Flow diagram describing the systematic review performed. This was performed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines. Abbreviations: ASH, American Society of Hematology; ASCO, American Society of Clinical Oncology.



When combined, a total of 851 patients were analyzed across all the reviewed studies. The median age at which belantamab mafodotin was initiated for each study ranged from 63 to 70 years [10, 19]. The median number of prior therapies before belantamab mafodotin initiation for each study ranged from 5 to 8 prior lines of therapy [11, 14]. The most frequent dosing reported was 2.5 mg/kg, and the most common dosing frequency, or cycle, was every 21 days, unless delayed due to adverse effects. The median number of cycles administered for each study varied, ranging from 2 to 4 cycles [15, 18].

Regarding outcomes, all studies reported data on median progression-free survival (median PFS), median overall survival (median OS), and response rates. When reported, the duration of follow up after belantamab mafodotin therapy ranged from 6 to 13 months [11, 14], and the duration of response ranged from 5 to 11 months [14, 18]. The response rates in all studies were done in accordance with the International Uniform Response Criteria for Multiple Myeloma [20]. The overall response rate ranged from 21.9% to 45.5% [9, 17]. Some studies reported the response rates strictly as part of the response criteria, while others categorized the response as greater or equal than a very good partial response (≥VPGR). When all studies are combined, a ≥VGPR has ranged from 3% in Becnel et al's study [15] to 33% in Hultcrantz et

al's study [18]. Stable disease was reported in 5 of 11 studies and ranged from 14% to 28% across the studies [10, 12, 14, 18, 19]. When progressive disease was reported in 4 studies, it ranged from 27% to 36% [12, 14, 18, 19]. Regarding survival analysis, all the studies reported data on median PFS, with the reported values ranging from 1.8 months (no confidence interval reported; n = 39 patients) [15] to 6 months (no confidence interval reported; n = 82 patients) [18]. Median OS ranged from 6.5 months to 14.5 months [9, 14], with 1 study not reaching a median OS [18].

Adverse events (AEs) were common, with the most common treatment-related AEs being keratopathy, affecting 442/831 patients (53.2%; Table 2). Grading of the keratopathy was done in 9 of 11 studies, with 8 studies grading based on the Keratopathy Visual Acuity Scale (KVAS) [9, 11–16, 18], while 1 study classified keratopathy as "mild or moderate/severe" [17]. Of the 243 patients with keratopathy of whom KVAS grading was performed, grade 1 keratopathy was noted in 52/243 patients (21.4%), grade 2 in 54/243 patients (22.2%), and ≥grade 3 in 137/243 patients (56.4%). Hematologic toxicity of belantamab mafodotin was also noteworthy, with the most reported hematologic AEs being thrombocytopenia. Its incidence varied, ranging from 13% to 80% among the reviewed studies [12, 19]. Of the 7 studies that reported data regarding thrombocytopenia [9–14, 16, 19], the cumulative incidence of thrombocytopenia was 114/523 (21.8%), although this may be underestimated as some studies only reported thrombocytopenia-related hospitalizations. Of the cases that reported thrombocytopenia grading, ≥grade 3 thrombocytopenia constituted 42/72 (58.3%) of the evaluable sample [9, 11, 12]. Other AEs included anemia, liver function test abnormalities, and infusion reactions or anaphylaxis. All studies reported AEs being a primary cause of treatment discontinuation; however, the effects were variable, with the incidence of treatment discontinuation due to AEs ranging from 3.8% to 33.8% in the respective sample sizes [9, 17]. Finally, dose delays or reductions were also commonly occurring because of treatment AEs, cumulatively affecting a range of 31% to 79.3% of patients in the respective studies [18, 19].

DISCUSSION

In 2016, a preclinical study revealed that GSK2857916, subsequently named as belantamab mafodotin, had demonstrated promising abilities to cause cytotoxicity in cells containing BCMA, which is expressed on normal and malignant plasma cells [21]. The first human trial, DREAMM-1, which was published in 2018, demonstrated that GSK2857916 was a potentially helpful treatment modality in patients with heavily pretreated R/R MM [22]. Subsequently, a phase II, randomized, open-label study [7] revealed promising response rates in cohorts that received either the 2.5 mg/kg or the 3.4 mg/kg doses with subsequent drug development at the 2.5 mg/kg dose every 3 weeks. AEs included keratopathy, which was ≥grade 3 in 29% of the 2.5 mg/kg cohort, anemia (≥grade 3 in 21%), and thrombocytopenia (≥grade 3 in 19%) [23]. In phase III of the DREAMM-3 trial, belantamab mafodotin was compared to pomalidomide and dexamethasone [24]. Most recently, on November 7, 2022, GlaxoSmithKline (GSK) had officially released an update on phase III trial, revealing that the targeted endpoint of PFS was not met for belantamab mafodotin in comparison to pomalidomide and dexamethasone. Shortly after, on November 22, 2022, GSK announced they will be withdrawing the use of belantamab mafodotin as per the request of the US FDA, based on the DREAMM phase III results.

In the DREAMM-2 trial, belantamab mafodotin was studied as a single agent on a total of 196 patients who were assessed in an intention-to-treat analysis, with 97 patients receiving the 2.5 mg/kg dose and 99 receiving the 3.4 mg/kg dose [7]. In the trial, an overall response rate was achieved in 31% of the 2.5 mg/kg cohort and 34% of the 3.4 mg/kg cohort. A ≥VPGR rate was achieved in 19% of the 2.5 mg/kg cohort and 20% of the 3.4 mg/kg cohort. In our review, only 3 of the reviewed studies reported the use of belantamab mafodotin as a single agent [10, 11, 16], and only 5 of the 11 reviewed studies achieved a VPGR rate as good as the one reported in the trial [11, 12, 16, 18, 19], while the remaining studies had lower response rates. In the DREAMM-2 trial, 97% of the 2.5 mg/kg cohort and 100% of the 3.4 mg/kg cohort had experienced at least one adverse event, with the most common being keratopathy, followed by thrombocytopenia and anemia [7]. While these findings are echoed in the real-life experiences of patients outside of clinical trials, the incidence of the findings have differed. For instance, the majority of the patients in the DREAMM-2 trial with keratopathy had grade 1-2 keratopathy, while the most prevalent keratopathy for patients in the nonclinical trial in our review was ≥grade 3 (Table 2). This discrepancy is important to point out because while both grade 2 and grade 3 keratopathy indicate a need to withhold treatment until ocular improvement, grade 3 keratopathy requires a dose reduction upon clinical improvement [25]. A possible explanation of the discrepancy of keratopathy gradings in the DREAMM-2 and the patients outside of the trial could be explained by

the exclusion of patients with corneal epithelial disease, excluding mild punctate keratopathy, in the DREAMM-2 trial. This is further evidenced as a recent study analyzing patients with newly diagnosed multiple myeloma revealed that 39% of patients had ocular comorbidities detected at baseline [26].

Furthermore, while keratopathy led to discontinuation of treatment in only 1% of the patients in the DREAMM-2 trial, our review shows higher numbers of treatment discontinuation due to adverse effects, ranging from 3.8% to 33.8% [9, 17]. In the DREAMM-2 trial, adverse events led to dose delays in 54% and dose reductions in 29% of the 2.5 mg/kg cohort. In contrast, dose delays ranged from 11.4% to 35.4% in the reviewed studies [18, 19], and dose reductions ranged from 19.6% to 43.9% [18, 19]. In both the DREAMM-2 trial as well as the reviewed studies, ocular toxicity was the most common AE leading to treatment interruption. Nonetheless, Mohan et al's real-life experience demonstrated that resuming belantamab mafodotin after resolution of keratopathy was associated with a better outcome when compared to permanent treatment discontinuation [16]. Nonetheless, the contrast in AE incidence, grading, and effect on treatment discontinuation between the DREAMM-2 trial and the reviewed studies is noteworthy for assessment of the risk of AEs during belantamab mafodotin therapy.

Ultimately, according to the most recent results of the DREAMM-3 trial, belantamab mafodotin did not reach its expected PFS and OS target, thus leading to cessation of its use as monotherapy for R/R MM at the time of writing this manuscript. However, its potential to be used in combination for R/R MM, as well as its utility in the management of light-chain amyloidosis and transplant-ineligible MM remains topics of ongoing research [27–34].

CONCLUSIONS

Belantamab mafodotin was associated with modest efficacy in reported real-world data with higher incidence of AEs when compared to the original clinical trial that resulted in its accelerated approval.

Table 1. Overview of the baseline characteristics and outcome measures of patients who received Belantamab Mafodotin outside of clinical trials.

Ref[a]	Author (study type)	Year of Publication	Location	Sample size	Median patient age (range)	Median prior therapies before Belamaf (range)	Median number of cycles (range)	Median follow up time	Response rates	Reported survival outcomes
[9]	Shragai et al (multicenter study)	2022	Israel	106	69.4 (36-88)	6 (2-11)	4 (2-17)	11.9 mo	ORR of 45.5% CR: 4.0% VGPR: 13.9% PR: 27.7%	Median PFS of 4.7 mo (95% CI 3.5-5.9) Median OS of 14.5 mo (95% CI 9.5-19.6) Median DoR 8.1 mo
[14]	Vaxman et al (multicenter study)	2021	USA	36	67 (IQR 59-74)	8 (IQR 7-1)	3 (1-6)	6 mo	ORR of 33% CR: 6% VGPR: 8% PR: 19% SD: 28% PD: 36%	Median PFS of 2 mo (95% CI 1–3) Median OS of 6.5 mo (95% CI 3-NR) Median DoR 5 mo
[15]	Becnel et al (single-center study)	2022	USA	39	66 (39-89)	7	2 (1-9)	10.1 mo	Best ORR of 27% ≥VGPR: 3% CBR: 35%	Median PFS of 1.8 mo Median OS of 9.2 mo Median DoR not reached
[10]	Lula et al (multicenter study)	2022	Italy	17	63 (51-77)	7 (4-14)	3 (1-18)	7 mo (0.5-18)	ORR of 43% CR: 7% PR: 36% SD: 14% CBR: 57%	Median PFS of 4 mo (range: 1-18) Median OS of 11 mo (range: 2-18) Median DoR not reached
[18]	Hultcrantz et al (single-center study)	2022	USA	82	68	6 (2-14)	4 (1-31)	N/A	ORR of 45% CR: 16% VGPR: 17% PR: 12% SD: 22% PD: 33%	Median PFS of 6 mo Median OS not reached Median DoR 11 mo
[19]	Roussel et al (multicenter study)	2022	France	184	70	N/A	3	7.8 mo	ORR of 35% ≥VGPR: 21% PR: 14% SD: 25% PD: 27% CBR: 39%	Median PFS of 2.7 mo (95% CI 1.9-3.3) Median OS of 9.5 mo (95% CI 7.2-11.9)

[11]	La Rubia et al (multicenter study)	2022	Spain	126	70 (39-89)	5 (1-10)	4 (1-31)	13 mo	ORR of 41.3% sCR: 5.6% CR: 8.7% ≥VGPR: 23.8%	Median PFS of 3.5 mo (95% CI 2.4-4.7) Median OS of 11.1 mo (95% CI 8.3-13.9) Median DoR 9.6 mo (95% CI 3.6-15.7)
[17]	Hultcrantz et al (multicenter study)	2022	USA	137	67.9[b]	64.2% had ≥ 5 prior therapies	N/A	3.1 mo (IQR 1.4-6)	ORR of 21.9% VGPR: 2.2% PR: 19.7%	Median PFS was 5.4 mo OS at 6 mo post index-date was 57.3%.
[13]	Alegre et al (multicenter study)	2021	Spain	33	70 (46-79)	5 (3-8)	3 (1-16)	11 mo	ORR of 42.2% ≥VGPR: 18.2%	Median PFS of 3 mo (95% CI 0.92-5.08) OS of 13.9 mo (95% CI 107-740 days)
[16]	Mohan et al (multicenter study)	2022	USA	56	66 (IQR 61-75)	5 (IQR 4-6.75)	7.7 mo[c] (6.7-NR	7.4 mo	ORR of 44.6% ≥ VGPR: 21%	Median PFS of 3.6 mo (95% CI 2.1-NR) Median OS of 10 mo (95% CI 8.8-NR
[12]	Atieh et al (single-center study)	2022	USA	35	66 (42-85)	5 (3-15)	N/A	10.7 mo (IQR 6.16-NA)	ORR: 43% sCR: 3% CR: 14% VGPR: 6% PR: 20% SD: 26% PD: 31%	Median PFS: 4.9 mo Median OS of 10.7 mo

[a] See References list
[b] mean
[c] median duration of therapy
Abbreviations: CBR, clinical benefit rate; CI; confidence interval; CR, complete response; DoR, duration of response; N/A, not available; NR, not reached; ORR, overall response rate; OS, overall survival; Ref, reference; PD, progression of disease; PFS, progression free survival; PR, partial response; sCR, stringent complete response; SD, stable disease; VGPR, very good partial response; NR, not reached.

Table 2. An overview of the reported adverse effects and their impact on the treatment course of belantamab mafodotin.

Refa	Author (study type)	Reported AEs			Effect of AEs on treatment coursen
[9]	Shragai et al (multicenter study)	**Ophthalmologic:** keratopathy in 68.4%: Grade 1 (11.6%), Grade 2 (16.8%), Grade 3 (38.9%) Grade 4 (1.1%)	**Hematologic:** thrombocytopenia in 27.4% (Grade ≥3: 17.9%), anemia in 11.3% (Grade ≥3: 3.8%), and neutropenia in 7.5% (Grade ≥3: 4.7%)	**Other:** infection in 11.3%, hypersensitivity reaction in 7.5%	**Discontinuation:** 3.8% due to keratopathy
[14]	Vaxman et al (multicenter study)	**Ophthalmologic:** keratopathy in 44%: Grade 1 (16.7%), Grade 2 (19.4%), and Grade 3 (8.3%)	**Hematologic:** thrombocytopenia-related hospitalization in 8.3%		**Discontinuation:** 8% due to keratopathy
[15]	Becnel et al (single-center study)	**Ophthalmologic:** keratopathy in 76%: Grade 1 (9%), Grade 2 (55%), and Grade 3 (12%)			**Discontinuation:** 9% due to AE
[10]	Lula et al (multicenter study)	**Ophthalmologic:** keratopathy in 21%	**Hematologic:** thrombocytopenia in 57%		**Discontinuation:** 11.7% due to keratopathy
[18]	Hultcrantz et al (single-center study)	**Ophthalmologic:** keratopathy in 68%: Grade 1 (31.7%), Grade 2 (18.3%), Grade 3 (14.6%), and Grade 4 (2.4%) Corneal microcysts in 31.7% of all patients			**Discontinuation:** 11% due to keratopathy **Dose Reductions:** 43.9% due to AE **Dose Delays:** 35.4% due to AE
[19]	Roussel et al (multicenter study)	**Ophthalmologic:** keratopathy in 38%	**Hematologic:** thrombocytopenia in 13.0%	**Other**: infusion reaction in 2.7%	**Discontinuation:** 12.5% discontinued treatment due to AE **Dose Reductions:** 19.6% due to ocular AE **Dose Delays:** 11.4% due to ocular AE
[11]	La Rubia et al (multicenter study)	**Ophthalmologic:** keratopathy in 50.8%: Grade ≥3 in 19.8%	**Hematologic:** thrombocytopenia in 14.3% (Grade ≥3: 10.3%)	**Other:** infection in 14.3%	**Discontinuation:** 5% due to AE
[17]	Hultcrantz et al (multicenter study)	**Ophthalmologic:** keratopathy in 40.9%: mild in 61.4% and moderate/severe in 38.6%			**Discontinuation:** 33.8% due to AE

[13]	Alegre et al (multicenter study)	**Ophthalmologic:** keratopathy in 51.5%, ≥ Grade 3 in 21.2 %	**Hematologic**: Grade ≥3 hematologic AE in 18.2%, thrombocytopenia in 21.2%		**Discontinuation:** 15.2% due to AE **Dose Reductions:** 30.3% due to AE **Dose Delays:** 36.4% due to AE
[16]	Mohan et al (multicenter study)	**Ophthalmologic:** keratopathy in 71.4%: ≥ Grade 3 in 54%	**Hematologic:** hematological toxicity in 16.10%	**Other:** abnormal liver enzymes in 1.79%, anaphylaxis in 1.79%	**Discontinuation:** 25% due to keratopathy **Dose Reductions:** 26.8% due to keratopathy **Dose Delays:** 30.4% due to keratopathy
[12]	Atieh et al (single-center study)	**Ophthalmologic:** keratopathy in 86% patients: Grade 1 (17%), Grade 2 (23%), Grade 3 (43%), Grade 4 (3%)	**Hematologic**: anemia in 83% (Grade 1-2 in 52%, Grade 3-4 in 48%), thrombocytopenia in 80% (Grade 1-2 in 57%, Grade 3-4 in 43%), and neutropenia in 34%	**Other:** abnormal liver enzymes in 51%	**Discontinuation:** 8.6% due to keratopathy **Dose Delays/Reductions:** 68.6% due to keratopathy

Abbreviations: Ref: Reference; AE: Adverse Event

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