Management of Ocular Toxicity in Patients Receiving Belantamab Mafodotin

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Abstract

While significant strides have been made in the treatment of multiple myeloma, treatment options remain limited and definite, and most patients ultimately succumb to their disease. The urgency for more treatment modalities remains, as patients who are refractory to proteasome inhibitors, immunomodulatory agents, and anti-CD38 monoclonal antibodies have a median survival of only 5.8 to 13 months. Belantamab mafodotin, a first-in-class antibody-drug conjugate, was approved by the US Food and Drug Administration in 2020 for patients with relapsed or refractory myeloma who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. It produced an overall response rate of 31%, and the median progression-free survival was 2.9 months when administered as a single agent. While generally well tolerated, ocular toxicities were a notable adverse event reported. In this article, we discuss the response data, toxicity profile including ocular toxicities, and treatment management.

Multiple myeloma is a malignancy of the plasma cell characterized by the production of monoclonal immunoglobulins, bone marrow infiltration of malignant plasma cells, anemia, lytic bone lesions, hypercalcemia, and renal failure. In 2023, it is estimated that approximately 35,730 new cases of multiple myeloma will be diagnosed, and 12,590 deaths are expected to occur (American Cancer Society, 2023). In the past 20 years, a plethora of agents have been approved for the treatment of myeloma, resulting in an improvement in overall survival (Gulla & Anderson, 2020). Despite the advancements of treatment modalities, the median survival for patients with penta-refractory disease remains low, from 5.8 to 13 months (Mikhael, 2020), prompting further develop-

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ment of novel therapies to fulfill the unmet need for more effective treatment options in this patient subgroup.

As a first-in-class antibody-drug conjugate (ADC) targeting B-cell maturation antigen (BCMA), belantamab mafodotin (belamaf; Blenrep) was granted accelerated approval by the US Food and Drug Administration (FDA) as monotherapy for patients with relapsed or refractory myeloma who have received at least four prior lines of therapy, including an immunomodulatory agent (IMiD), proteasome inhibitor (PI), and an anti-CD38 monoclonal antibody (FDA, 2020a). This article will discuss the profile of this drug, including efficacy and safety data from the phase I dose expansion study and the phase II open-label, two-arm study (DREAMM-2), with a particular focus on keratopathy on the cornea and/or changes to the corneal epithelium.

MECHANISM OF ACTION

Belamaf targets BCMA, which is found on the surface of myeloma cells. BCMA belongs to the tumor necrosis factor family and is highly expressed on the surface of both normal and malignant plasma cells. One advantage of BCMA is that nonhematopoietic cells do not express BCMA and are minimally expressed on hematopoietic stem cells. In vitro, studies have shown that BCMA is universally detected on the surface of myeloma cells and that blocking BCMA on myeloma cells induces apoptosis through inhibition of cell growth (Shah et al., 2020).

Belamaf is a humanized IgG1 monoclonal ADC containing a microtubule disrupting agent, monomethyl auristatin F (MMAF), that when bound to BCMA delivers MMAF into the myeloma cell leading to apoptosis. Belamaf also induces antibody-dependent cellular cytotoxicity, antibody-dependent cellular phagocytosis, and immunogenic cell death.

PATHOPHYSIOLOGY OF OCULAR TOXICITY

The eye is an incredibly vascular organ with numerous cell receptors on the cell surface and rapidly and continuously dividing cell populations that make it highly susceptible to injury (Eaton et al., 2015). Ocular adverse events are well documented in ADCs and are widely seen in patients who received belamaf. They are predominately related to issues with the ocular surface, which can cause a multitude of symptoms that range from mild to moderate symptoms of discomfort and irritation like blurred vision, foreign body sensation, photophobia, and dry eyes, to serious vision-threatening events. The cornea is the transparent, protective structure covering the anterior portion of the eye, functioning to focus light onto the retina (Sridhar, 2018). It is the primary affected eye structure for patients who encounter ocular toxicity while receiving treatment with ADCs.

The MMAF is a microtubule-targeting agent that is carried to BCMA-expressing myeloma cells by the ADC and triggers apoptosis (Lonial et al., 2020a). It is directly associated with the corneal changes or microcyst-like epithelial changes (MECs) and seems to be related to the increased concentration of drug in the cells (Farooq et al., 2020). Keratopathy is often used interchangeably with MECs and when observed in the setting of ADC is a distinct entity different than what is typically observed by ocular specialists (Lonial et al., 2021). These corneal abnormalities are observed under high magnification during slit-lamp examination (Lonial et al., 2021). While the exact mechanism that causes corneal events is unknown, it is believed that there is a certain degree of uptake of the ADCs in the epithelial cells (Zhao et al., 2018). Ocular toxicities are commonly seen in other tubulin targeting ADCs such as brentuximab vedotin used to treat Hodgkin and anaplastic large cell lymphoma (Vankemmelbeke & Durrant, 2016).

OVERVIEW OF SAFETY AND EFFICACY DATA OF BELAMAF

In the initial phase I study of belamaf, a total of 35 patients were enrolled in the study and of those enrolled, 32 were refractory to proteasome inhibitors and immunomodulators. Of note, patients with a prior history of corneal disease were excluded (Trudel et al., 2019). In this dose escalation study, the maximum tolerated dose was established as 3.4 mg/kg IV every 21 days. The overall response rate (ORR) was 60% (95% CI = 42.1%–76.1%) with a very good partial response (VGPR) rate of 40%. In patients who were

refractory to both a PI and an IMiD, the ORR was 56.3% (95% CI = 37.7%–73.6%). Patients who were refractory to both a PI and an IMiD with prior daratumumab exposure had an ORR of 38.5% (95% CI = 13.9%–68.4%). Progression-free survival (PFS) was 12 months for the entire treatment group. The median PFS for patients without prior daratumumab exposure was 15.7 months vs. a median of 6.8 months in patients who were daratumumab exposed. Daratumumab-exposed patients who were PI and IMiD refractory had a median PFS of 6.2 months. The adverse events observed in the phase I study included thrombocytopenia (63%), blurred vision (51%), and cough (40%). The most common grades 3 or 4 adverse events included thrombocytopenia (35%), anemia (17%), pneumonia (9%), lung infection (6%), and infusion-related reactions (6%; Trudel et al., 2019).

Based on the results observed in the phase I study, belamaf moved on to a phase II study (DREAMM-2) enrolling a total of 196 patients who were refractory to a PI, IMiD, and were refractory or intolerant to an anti-CD38 monoclonal antibody (Lonial et al., 2020a). Patients were randomized to either the 2.5 mg/kg or 3.4 mg/kg cohort. In this trial, the ORR was 31% in the 2.5 mg/kg arm and 35% in the 3.4 mg/kg arm, with 19% vs. 24% achieving a VGPR in both arms (Lonial et al., 2020a, 2020b). The median PFS was similar in both groups, with 2.8 months in the 2.5 mg/kg arm vs. 3.9 months in the 3.4 mg/kg arm. The estimated overall survival (OS) at 12 months was the same in each arm at 53%.

The main grades 3 or 4 adverse events excluding ocular findings included thrombocytopenia (20% vs. 33%), anemia (20% vs. 25%), neutropenia (9% vs. 15%), decreased lymphocyte count (12% vs. 8%), infusion-related reactions (3% vs. 1%), increased aspartate aminotransferase (AST) (2% vs. 6%), fatigue (2% vs. 5%), increased creatinine (3% vs. 1%), increased gamma-glutamyl transferase (1% vs. 8%), hypertension (2% vs. 6%), hypophosphatemia (5% vs. 4%), hyponatremia (2% vs. 4%), lung infection (2% vs. 2%), pneumonia and (4% vs. 11%; Lonial et al., 2020a). Corneal toxicities are further discussed in the following section. Belamaf is currently undergoing investigation in combination with other antimyeloma agents (Trudel et al., 2021).

SAFETY DATA WITH AN EMPHASIS ON OCULAR TOXICITY

Corneal epithelium changes (keratopathy) were found in patients treated with belamaf at both dose levels in the DREAMM-2 study and led to the majority of dose adjustments (23% of 95 patients and 27% of 99 patients), treatment delays (47% of 95 patients and 48% of 99 patients), and discontinuations (1% of 95 patients and 3% in 99 patients; Lonial et al., 2020a). Patients who underwent dosing delays were usually able to re-initiate treatment with a median treatment initiation time of 83 days (2.5 mg/kg cohort) and 63 days (3.4 mg/kg cohort).

Patients underwent corneal evaluation every 3 weeks prior to each treatment cycle under the care of an ophthalmologist or optometrist (Lonial et al., 2020a). All patients underwent slit-lamp examinations and best corrected visual acuity (BCVA) scores to evaluate corneal and visual disturbance changes (Farooq et al. 2020). Investigators found that grade 1 to 2 keratopathy, with or without symptoms, was the most reported adverse event at both the 2.5 mg/kg (43%) and 3.4 mg/kg (54%) dose level. While grade 3 keratopathy was seen in 27% (2.5 mg/kg) and 20% (3.4 mg/kg) of cases, there were no grade 4 or 5 keratopathies noted in the 2.5 mg/kg cohort, while only 1% of grade 4 keratopathy was noted in the 3.4 mg/kg cohort (Lonial et al., 2020a). Microcyst-like epithelial changes often led to dose reductions and was the most common reason for permanent discontinuation. Of note, patients with baseline keratopathy statistically developed more ocular side effects than patients without baseline ocular conditions (Farooq et al., 2020). Microcyst-like epithelial changes were reported as adverse events any time the ophthalmologist or optometrist documented a corneal finding from the ocular exam (Farooq et al. 2020). Time to first ocular effect occurred by the fourth dose in 69% of patients, and dose modifications occurred based upon corneal and visual acuity grading (Farooq et al., 2020).

The study also found that while corneal symptoms were less frequently reported, symptom-driven complaints occurred more commonly in patients with epithelial changes to the cornea. Other common ocular findings were grade 1 or 2 blurred vision seen in 18% of patients (2.5

mg/kg) and 28% (3.4 mg/kg), and grade 1 or 2 dry eyes in 12% (2.5 mg/kg) and 23% (3.4 mg/kg), respectively. Of note, dry eye was used as a general term that encompassed symptoms such as ocular discomfort, pruritus, or sensation of a foreign body in the eye (Lonial et al., 2020a).

Despite the widespread occurrence of corneal toxicities, these events were found to be sufficiently managed with treatment breaks and frequent use of preservative-free artificial tears. Of note, prophylactic corticosteroid eye drops were not found to be effective in the prevention of corneal epithelial changes (Lonial et al., 2020a). Although DREAMM-2 data regarding ocular adverse events for follow-up patients was limited, the study did show resolution of ocular events in 36% of patients (2.5 mg/kg cohort) and in 28% of patients (3.4 mg/kg cohort), with median resolution times of 71 days and 96 days, respectively (Lonial et al., 2020a). Dry eyes and blurred vision were the most common follow-up corneal complaint. While visual acuity changes were observed, 85% (2.5 mg/kg cohort) and 77% (3.4 mg/kg cohort) saw improvement in visual acuity with vision returning to baseline or near baseline (Lonial et al., 2020a).

OCULAR SIGNS AND SYMPTOMS

Keratopathy seen in the context of treatment with ADC is unique with broad and varying characteristics. Although it has the potential to be severe, it is expected to resolve with appropriate treatment and management (Lonial et al., 2021). The median time it took for MECs to resolve was 86.5 days (Lonial et al., 2021). They accounted for most of the symptoms that patients experienced such as blurred vision and dry eyes, but may not cause symptoms at all, which underscores the importance of corneal examinations and noting visual acuity changes by ocular specialists (Lonial et al., 2021). Corneal adverse events were characterized by microcystic lesions that were often diffuse, occurring simultaneously in both eyes (Figure 1). The microcystic lesions typically started in the periphery and would spread toward the central cornea. The location and density of the microcysts correlated with the symptoms the patients experienced as well as the severity (Lonial et al., 2021). For instance, patients who were found to have centrally occurring microcysts were more likely to have symptoms including blurred vision and decreased visual acuity (Farooq et al., 2020). These microcysts were generally more severe, graded as a grade 3 corneal toxicity, and were more confluent (higher density; Lonial et al., 2021). Peripherally occurring microcysts or lower density microcysts conferred with lower grade corneal events. While ocular discomfort and changes in visual acuity are important symptoms of great focus, corneal damage may also increase the patient's risk for infection (Lonial et al., 2021).

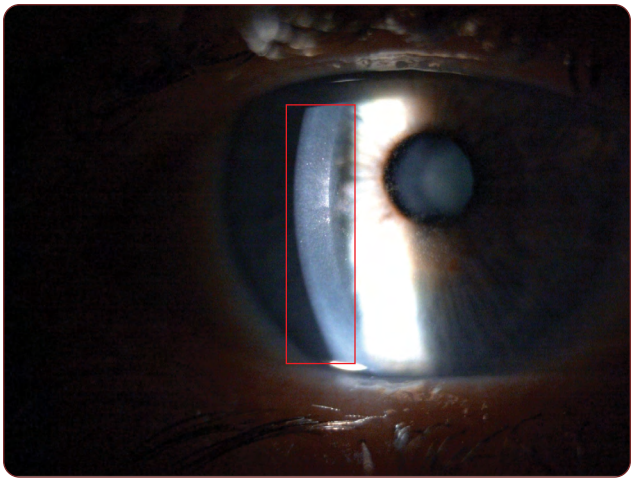

Figure 1. Retro-illumination of sparse diffuse microcysts. Grade 1 treatment is artificial tears every 2 hours in both eyes. Did not decrease in best corrected vision. Used with permission from A. Razmandi, MD Anderson Cancer Center, slit-lamp photography (2021).

When managing patients receiving belamaf, it is important to assess and educate patients to regularly monitor for ocular symptoms such as trouble reading or difficulty driving at night in order to identify vision changes early. While the patient is on treatment, it is imperative that clinicians maintain close communication with the eye care specialist for continuity of care to ensure that the patient receives timely and appropriate care for any ocular conditions. Per DREAMM-2 study protocol, patients should be evaluated by an ophthalmologist or optometrist at baseline and prior to subsequent doses using the keratopathy and visual acuity (KVA) scale, which is further discussed in the following section (Lonial et al., 2021).

DOSE MODIFICATIONS BASED ON OCULAR FINDINGS

During the DREAMM-2 study, although dose interruptions and reductions occurred most frequently for patients experiencing some degree of MECs, they were generally well tolerated and rarely led to treatment discontinuation. Patients were graded utilizing the KVA scale that combines both subjective corneal exam findings and BCVA to determine the grade of keratopathy. For patients who develop ocular toxicities, dose adjustments are made using an ocular exam as well as visual acuity (Table 1; Lonial et al., 2020a).

PATIENT EDUCATION

Patient education is key to minimizing and preventing complications associated with belamaf. To minimize the risk of ocular toxicity, it is imperative that patients see an eye specialist for baseline assessment prior to starting treatment and prior to each subsequent dose to monitor for worsening eye symptoms (dry eyes, blurred vision, deteriorating vision, and open sores on the cornea). To help reduce the incidence of ocular events, the provider should educate the patient on the use of preservative-free ophthalmic lubricants at least four times daily starting prior to the first treatment and continuing to the end of treatment. Since patients with preexisting corneal disease are at higher risk to develop keratopathy, contact lens are prohibited while on therapy since this too may adversely affect the cornea (Lonial et al., 2021). Due to the risk of decreased visual acuity that may impair patients' ability to operate motor vehicles, the provider should caution the patient when operating heavy machinery or driving. The provider should ensure that patients have adequate support and discuss the need for a potential caregiver to assist in activities of daily living in the event of corneal toxicities (Lonial et al., 2021). In order to improve compliance with the use of preservative-free eye drops, patients may self-enroll in a patient assistance program to potentially receive preservative-free eye drops at no cost (GSK, 2020). While patients may feel anxious about the risk for ocular toxicities, the provider may assure them that typically these toxicities will resolve with treatment cessation (Lonial et al., 2021).

Since corneal toxicities may not be accompanied by any symptoms at all, it is important for the provider to continually remind the patient to report any visual symptoms or changes. The clinician should ask patients focused questions that may help to elucidate any visual symptoms patients may have. These questions may include inquiring if the patient has difficulty reading fine print as in the newspaper, difficulty driving at night, or has experienced changes in activity levels due to frustrations with their eyesight (Lonial et al., 2021). Comprehensive patient education may help to quickly identify corneal events as they occur and can result in timely intervention, which may ultimately decrease treatment interruptions.

REMS PROGRAM

The belamaf Risk Evaluation and Mitigation Strategy (REMS) is a safety program that manages associated ocular toxicity risks (GSK, 2020).

Table 1. Dose Modifications for Ocular Toxicities

Grade	Keratopathy findings on cornea	Snellen change	Dose modification
1	Mild superficial keratopathy	Worsening vision by one line	Continue treatment.
2	Moderate superficial keratopathy	Worsening vision by 2–3 lines and not worse than 20/200	Hold treatment until keratopathy returns to grade 1 and visual acuity returns to grade 1. Resume at prior dose.
3	Severe superficial keratopathy	Worsening visual acuity by more than 3 lines	Hold treatment until keratopathy returns to grade 1 and visual acuity returns to grade 1 or better. Reduce dose by one dose level (1.9 mg/kg).
4	Corneal epithelial defect	Visual acuity worse than 20/200	Consider permanent discontinuation. If treatment continues, hold until corneal exam and visual acuity return to baseline. Reduce dose by one dose level.

Note. Information from US Food and Drug Administration (2020b).

As part of the REMS program, prescribers agree to counsel patients on the ocular toxicity risk, required ophthalmic exams, and ocular symptoms (GSK, 2020). For the patient to receive treatment, the prescriber and the health-care setting must be registered through the REMS program, and the patient must be cleared to receive treatment, with the appropriate documents submitted to the REMS program. Once the patient receives treatment, a post-infusion checklist must be submitted to the REMS program.

UPDATE

Belamaf received accelerated approval in 2020 for the treatment of patients with relapsed/refractory myeloma based on the reported response rate. However, in the DREAMM-3 phase III confirmatory study of belamaf vs. pomalidomide (Pomalyst) and dexamethasone, the approval was withdrawn. In the study, the ORR was 41% vs. 37% with a similar median PFS of 11 months vs. 7.1 months. Furthermore, the OS was similar between the two arms (GSK, 2022) At the time of the withdrawal, patients receiving belamaf standard of care who were continuing to derive benefit from treatment were transitioned to the belamaf compassionate use program. Providers are required to enroll patients through the GSK compassionate use website. Upon approval by GSK, the patients were enrolled in an investigational new drug study.

There is ongoing investigation into belamaf through DREAMM-7 (belamaf, bortezomib, and dexamethasone vs. daratumumab, bortezomib, and dexamethasone), DREAMM-8 (belamaf, pomalidomide, and dexamethasone vs. bortezomib, pomalidomide, and dexamethasone), and DREAMM-9 (belamaf, bortezomib, lenalidomide, and dexamethasone in newly diagnosed multiple myeloma patients who are transplant ineligible; GSK, 2020).

CONCLUSION

Belamaf demonstrates similar response rates compared with other novel agents and represents a first-in-class drug in the treatment of relapsed/refractory myeloma. While this drug has produced exciting results in efficacy and overall response, it is important that patients are aware of the associated ocular toxicities and are monitored closely. Advanced practitioners are well positioned to coordinate care with eye care providers to ensure correct eye exams are performed and ocular toxicities are graded accurately. They are on the front lines of patient care and may offer keen insight into the patient's case, uncovering potentially concerning symptoms or compliance issues. As such, they serve as an important link in the multidisciplinary care team in facilitating the communication between the patient, physician, and ocular specialists, which is fundamental to ensuring patient safety. Furthermore, the advanced practitioner is heavily relied upon to provide comprehensive patient education and ensure compliance with treatment requirements. With close monitoring, patients demonstrate tolerance and significant response, making belamaf a considerable treatment option for the patient with relapsed/refractory myeloma. ●

Disclosure

Ms. Lu has served as a consultant for GSK. The other authors have no conflicts of interest to disclose.

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