Received: 13 July 2023 | Revised: 9 August 2023 | Accepted: 12 August 2023

DOI: 10.1002/jha2.774

eJHaem

British Society for Haematology

RESEARCH ARTICLE

The real-world use and efficacy of pomalidomide for relapsed and refractory multiple myeloma in the era of CD38 antibodies

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Funding information
Holms Mindelegat; Kræftens Bekæmpelse, Grant/Award Number: R249-A14646-19-S70

Abstract

Pomalidomide-dexamethasone (Pd) has been a standard care treatment for relapsed and refractory multiple myeloma since 2013. However, the outcomes of Pd after exposure to CD38 antibodies are not known. Here we describe the real-world use and efficacy of pomalidomide in a Danish, nationwide cohort of daratumumab-exposed patients. We identified 328 patients that were treated with pomalidomide. Of these, 137 received Pd, 65 daratumumab-pomalidomide-dexamethasone (DPd), 43 pomalidomide-cyclophosphamide-dexamethasone (PCd), 19 carfilzomib-pomalidomide-dexamethasone (KPD), 11 pomalidomide-bortezomib-dexamethasone (PVd), and 52 pomalidomide in other combinations. Patients treated with Pd in this cohort had a partial response or better (≥ PR) rate of 35.8% and median time to next treatment (mTNT) of 4.9 months, almost identical to the results of previous prospective clinical trials. Although treatment with the various pomalidomide-containing triplet regimens resulted in higher ≥ PR rates (PCd: 46.5%, PVd: 63.6%, DPd: 55.4%, KPd: 63.2%), the mTNT achieved was not significantly better than with Pd in most cases (PCD: 5.4, PVD: 5.3, DPD: 4.7 months). The exception to this was KPd (mTNT 7.4 months), but this regimen was mainly used earlier in the course of the disease (median time from diagnosis 2.3 years vs. 3.7–4.3 years). The most important predictor of outcomes was not the choice of index regimen ($p = 0.72$), but prior exposure ($p = 0.0116$). Compared to CD38 antibody-naïve patients, triple-class-exposed patients achieved reduced ≥ PR rate (38.0% vs. 47.3%), shorter mTNT (4.0 vs. 5.9 months), and shorter median overall survival (12.4 vs. 24.2 months) with pomalidomide treatment.

KEYWORDS
immunomodulatory agent, myeloma, therapy

1 | BACKGROUND

Pomalidomide is a third-generation immunomodulatory drug approved by the Food and Drug Administration and the European Medicines Agency in 2013 for patients with relapsed and refractory multiple myeloma who have received at least two previous lines of therapy, including lenalidomide and bortezomib [1]. In the MM-002 study, which was the basis of this approval, patients who received pomalidomide with low-dose dexamethasone achieved an overall response rate of 33%, median progression-free survival of 4.2 months, and median overall survival (OS) of 16.5 months [2]. Pomalidomide-dexamethasone (Pd) has since been tested in triplet combinations with other antimyeloma agents and is currently approved for relapsed and refractory multiple myeloma in combination with bortezomib, daratumumab, isatuximab, or elotuzumab [3–7]. The outcomes of patients treated with Pd have been reported in several real-world studies performed in smaller populations [8–15]. Recently, two novel antimyeloma drugs, the peptide-conjugated alkylator melflufen in combination with dexamethasone, and the drug–antibody conjugate belantamab-mafodotin both failed to prove superior to Pd in their respective randomized phase III trials [16, 17]. Thus, for certain groups of patients, Pd remains a standard-of-care treatment option in 2023. Due to the current treatment algorithms, pomalidomide is mostly used in patients already exposed to a CD38 antibody [18]. However, none of the above studies were performed specifically in patients with previous CD38 antibody exposure, and the clinical performance of pomalidomide in the era of CD38 antibodies is unknown. We have previously reported results from a complete Danish, nationwide cohort of daratumumab-exposed patients [19, 20]. The aim of this current study was to describe the real-world use and efficacy of pomalidomide in this cohort.

2 | METHODS

The methods of data generation for this project have been previously described [19, 20]. In short, we conducted a nationwide retrospective review of the clinical course of all patients treated with a daratumumab-containing regimen prior to January 1, 2019. The project described 635 patients, who had received daratumumab either on or outside of a clinical trial at any time prior to this date. In Denmark, daratumumab had been approved as standard of care as monotherapy since September 2016 and in combination with either lenalidomide-dexamethasone or bortezomib-dexamethasone since April 2017. In this current study, we included only those daratumumab-treated patients, who at any time throughout the course of their disease had received pomalidomide. The first pomalidomide-containing line of therapy may thus have occurred either prior to, together with, or after daratumumab treatment. Information on daratumumab exposure was acquired from local pharmacy registers. Baseline characteristics and OS data were acquired from the Danish Multiple Myeloma Registry. Fluorescence in situ hybridization (FISH) data were reviewed and registered by experienced consultants in cytogenetic analysis. Lines of therapy, response rates, and causes of discontinuation were collected retrospectively from patient records by trained physicians working at the departments of hematology of nine Danish centers. Stringent complete response, complete response, and very good partial response were combined in the "very good partial response or better" category. This is because, in the daily clinic, bone marrow biopsies are rarely performed at "biochemical complete response," which results in underestimation of complete and stringent complete responses in real-world studies. Treatment data were updated until January 1, 2021. For the purposes of this current study, the first pomalidomide-containing line of therapy was called the index regimen. The date of initiation of the index regimen was called time 0 (t_0). When defining cytogenetic risk, the most recent FISH result prior to t_0 was used. Prior exposure status was defined based on previous treatment with a proteasome inhibitor (PI: bortezomib, carfilzomib, ixazomib), an immunomodulatory agent (IMiD: thalidomide, lenalidomide), and daratumumab (no other CD38 antibodies were used).

The methods of statistical analysis are presented in the Supporting Information.

3 | RESULTS

3.1 | Study population, index regimens, and prior exposure

We identified 328 patients who were treated with pomalidomide. Baseline characteristics for the study population are shown in Supplementary Table S1. The median age at t_0 was 71.3 years. The median time from diagnosis to t_0 was 3.8 years. The median number of lines of therapy prior to t_0 was 4. The most frequently used index regimens were Pd (n = 137), daratumumab-pomalidomide-dexamethasone (DPd; n = 65), pomalidomide-cyclophosphamide-dexamethasone (PCd; n = 43), carfilzomib-pomalidomide-dexamethasone (KPd; n = 19), pomalidomide-bortezomib-dexamethasone (PVD; n = 11) and pomalidomide in other combinations (P-other; n = 52), as shown in Supplementary Figure S1A. Three-hundred-and-four (92.7%) patients had been previously exposed to both a PI and an IMiD. Of these, 158 patients had been previously exposed to daratumumab (Supplementary Figure S1B). The prior exposure status of 24 (7.3%) patients not previously exposed to both a PI and an IMiD was categorized as "other." Key baseline characteristics by the index regimen group and prior exposure are shown in Table 1.

3.2 | Response

In the entire study population treated with the index regimen, 47 (14.3%) patients achieved a very good partial response or better, 97 (29.6%) partial response (PR), 30 (9.1%) minimal response, 77 (23.5%) stable disease, and 57 (17.4%) progressive disease, while responses were unmeasurable or unavailable in 20 (6.1%) patients. The PR or

TABLE 1 Key baseline characteristics by index regimen and prior exposure.

	Index regimen						Prior exposure		
Variable of interest	PD ($n = 137$)	DPD ($n = 65$)	PCD ($n = 43$)	KPD ($n = 19$)	PVD ($n = 11$)	P-other ($n = 53$)	PI, IMiD, -DARA	PI, IMiD, +DARA	other
Age at t_0; years; median (IQR)	72.1 (65.3–77.2)	70.4 (65.6–78.3)	72.9 (69.5–76.8)	62.7 (53.8–69.6)	70.6 (58.3–78.8)	66.6 (59.0–74.6)	70.7 (63.3–76.3)	71.4 (62.7–76.1)	72.9 (66.2–79.8)
Time from diagnosis to t_0; years; median (IQR)	4.3 (2.5–7.1)	3.7 (1.9–6.0)	3.7 (2.7–6.1)	2.3 (1.6–3.5)	3.8 (0.1–4.4)	3.7 (1.9–6.9)	3.7 (2.1–6.4)	4.2 (2.8–7.0)	1.0 (0.4–3.9)
Prior lines of therapy (median)	3	4	4	3	3	3	3	4	2
High-risk FISH	32%	31%	25%	40%	44%	32%	45%	26%	24%

Note: * Percentage in patients with available FISH results.

Abbreviations: DARA, daratumuma; DPD, daratumumab-pomalidomide-dexamethasone; FISH, Fluorescence in situ hybridization; high-risk FISH, at least one of *t*(4;14), *t*(14;16) or del17p; index regimen, the first pomalidomide-containing line of therapy; IMiD, immunomodulatory drug; IQR, interquartile range; KPD, carfilzomib-pomalidomide-dexamethasone; PCD, pomalidomide-cyclophosphamide-dexamethasone; PD, pomalidomide-dexamethasone; PI, proteasome inhibitor; PVD, pomalidomide-bortezomib-dexamethasone;P-other, pomalidomide in other combinations; t_0, date of initiation of the first pomalidomide-containing line of therapy.

better (≥ PR) rate was 43.9% in the entire study population. Based on the index regimen, the ≥ PR rate was 35.8% in Pd, 46.5% in PCd, 63.6% in PVd, 55.4% in DPd, 63.2% in KPd, and 37.7% in P-other (Supplementary Figure S2). Based on prior exposure, the ≥ PR rate was 47.3% in patients previously treated with a PI, an IMiD but not daratumumab, 38.0% in patients previously treated with a PI, an IMiD, and daratumumab, and 62.5% in patients with other prior exposure (Supplementary Figure S3).

3.3 | Reasons for discontinuation

The most frequent reasons for discontinuation in the entire study population were progressive disease ($n = 190$, 57.9%), toxicity ($n = 40$, 12.2%), and insufficient response ($n = 31$, 9.5%), as shown in Supplementary Figure S4. The reasons for discontinuation of pomalidomide treatment based on the index regimen are shown in Supplementary Figure S5.

3.4 | Time to next treatment

Based on the index regimen, the median (interquartile range [IQR]) time to next treatment (TNT) was 4.9 (2.8–8.9) months in Pd, 5.4 months in PCd (3.2–9.9), 5.3 (3.1–9.4) months in PVd, 4.7 (2.4–8.7) months in DPd, 7.4 (4.7–11.3) months in KPd, and 4.7 (2.1–9-2) months in P-other (Figure 1A). Based on prior exposure, the median (IQR) TNT was 5.9 (3.2–9.8) months in patients previously treated with a PI, an IMiD but not daratumumab, 4.0 (1.9–7.4) months in patients previously treated with a PI, an IMiD and daratumumab, and 4.0 (2.8–9.3) months in patients with other previous exposure (Figure 1B). Differences in the index regimen did not have a significant effect on TNT ($p = 0.72$), but differences in prior exposure did effect TNT significantly ($p = 0.016$).

3.5 | Overall survival

The median (95% confidence intervals [CI]) overall survival after t_0 in the entire study population was 19.1 (16.2–22.7) months (Supplementary Figure S6). Based on the index regimen, the median (95% CI) overall survival was 23.3 (20.1–32.8) months in Pd, 13.1 (8.9-not estimated) months in PCd, due to small group size not estimated in PVd, 16.4 (12.7–30.6) months in DPd, 14.4 (5.8-not estimated) months in KPd, and 15.2 (9.5–22.5) months in P-other (Figure 2A). Based on prior exposure, the median (95% CI) overall survival was 24.2 (22.2–34.2) months in patients previously treated with a PI, an IMiD but not daratumumab, 12.4 (9.6–15.8) months in patients previously treated with a PI, an IMiD, and daratumumab and due to small group size not estimated in patients with other previous exposure (Figure 2B). Based on cytogenetic risk status, the median (95% CI) overall survival was 10.1 (8.5–13.1) months in high-risk patients and 21.7 (17.9–32.6) months in non-high-risk patients (Supplementary Figure S7).

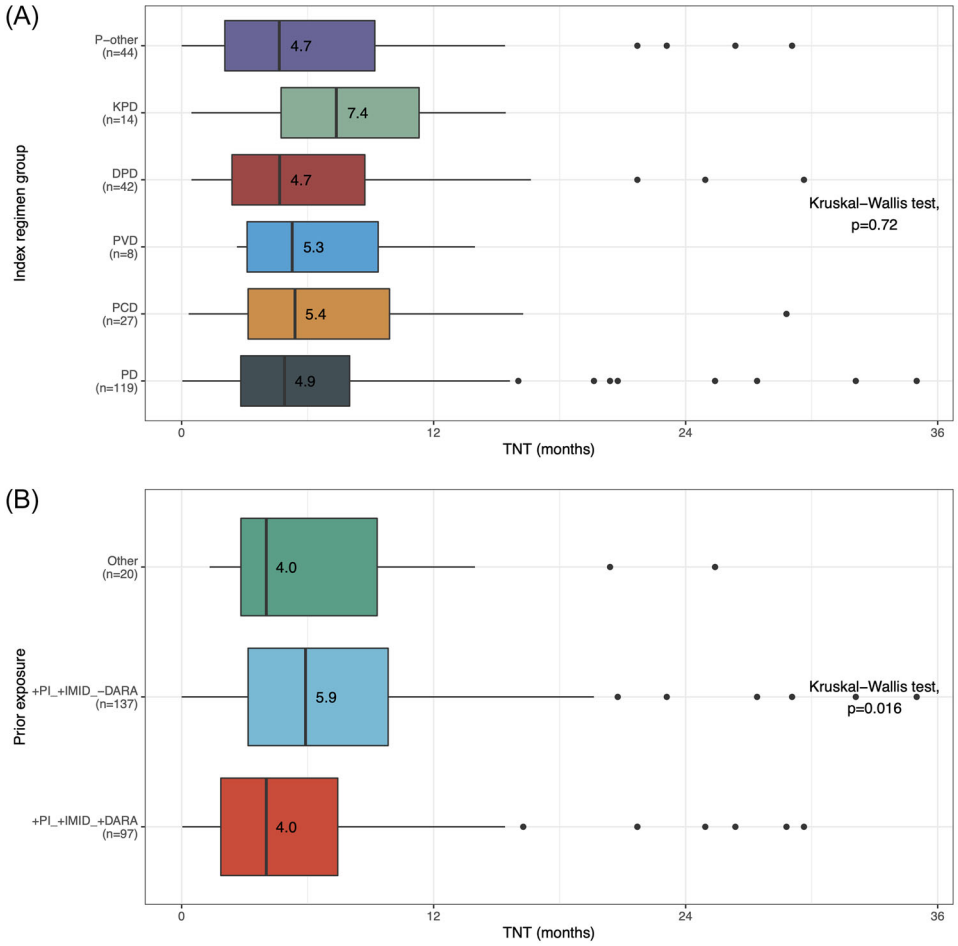

FIGURE 1 (A) Time to next treatment based on index regimen. (B) Time to next treatment based on prior exposure. Index regimen, the first pomalidomide-containing line of therapy; PD, pomalidomide-dexamethasone; DPD, daratumumab-pomalidomide-dexamethasone; PCD, pomalidomide-cyclophosphamide-dexamethasone; KPD, carfilzomib-pomalidomide-dexamethasone; PVD, pomalidomide-bortezomib-dexamethasone; P-other, pomalidomide in other combinations; PI, proteasome inhibitor; IMiD, immunomodulatory agent; DARA = daratumumab.

3.6 | Subsequent lines of therapy

After discontinuation of the index regimen, 77.4% of patients received one, 52.4% two, 40.0% three 24.4% four, and 17.1% five subsequent lines of therapy. The achieved response rates and TNT tended to worsen for each subsequent line of therapy (Supplementary Table S2).

4 | DISCUSSION

This is the largest real-world study to describe the use patterns and efficacy of pomalidomide in relapsed and refractory multiple myeloma. Moreover, ours is the only study to report the outcomes of pomalidomide treatment before and after exposure to CD38 antibodies.

We found that the outcomes of Pd, the ≥ PR rate of 35.8%, and the median TNT of 4.9 months were similar to those reported in previous studies [8–15]. Most notably, the clinical performance of Pd in our study was almost identical to that achieved in prospective clinical trials, which is typically not the case when prospective and real-world studies are compared [2, 16, 17, 19].

On the other hand, although direct comparisons are not possible in a retrospective study like this, the outcomes of the different pomalidomide-containing regimens were similar. Despite the higher response rates achieved with the triplet combinations, patients receiving DPd, PCd, and PVd, all achieved a median TNT around 5 months. The exception to this was KPd, associated with slightly longer median TNT, but this regimen was mainly used earlier in the course of the disease.

Instead of the different index regimens, the most important predictor of outcomes of pomalidomide treatment in our study was prior exposure. In comparison with patients previously treated with two classes of drugs (a proteasome inhibitor and an immunomodulatory agent), patients who had been exposed to a third class of drugs (a CD38 antibody) in the form of daratumumab, had worse ≥ PR rates, shorter TNT, and, most importantly, significantly shorter life expectancy on pomalidomide treatment. Triple-class-exposed patients had approximately a year shorter median OS (12.4 vs. 24.2 months)

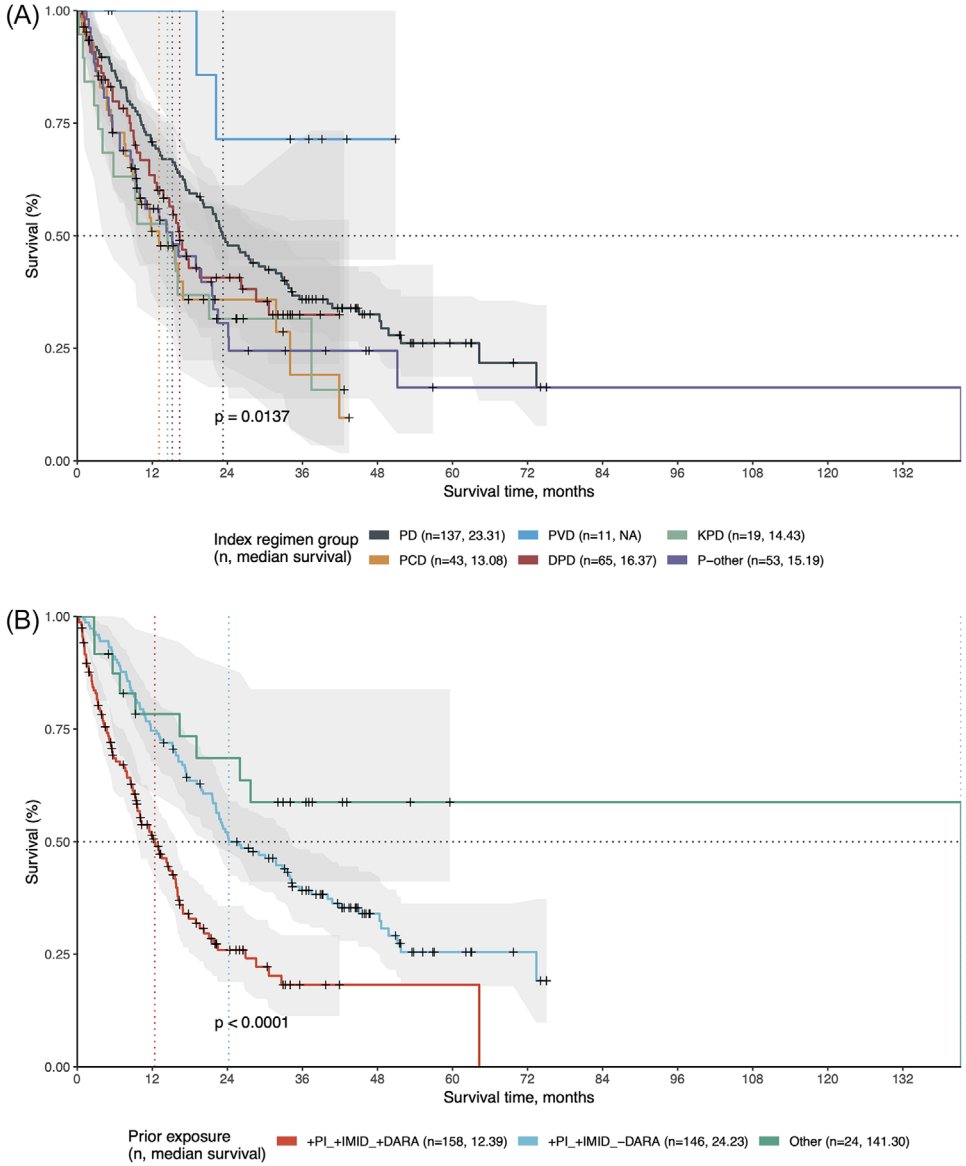

FIGURE 2 (A) Overall survival after t_0 based on index regimen. (B) Overall survival from t_0 based on prior exposure. Index regimen, the first pomalidomide-containing line of therapy; t_0, the date of initiation of the index regimen; PD, pomalidomide-dexamethasone; DPD, daratumumab-pomalidomide-dexamethasone; PCD, pomalidomide-cyclophosphamide-dexamethasone; KPD, carfilzomib-pomalidomide-dexamethasone; PVD, pomalidomide-bortezomib-dexamethasone; P-other, pomalidomide in other combinations; PI, proteasome inhibitor; IMiD, immunomodulatory agent; DARA, daratumumab.

after initiation of pomalidomide treatment than daratumumab-naïve patients.

A strength of our work is that it investigates a complete, population-based cohort of daratumumab-treated patients without referral bias. Among the limitations of our work are its retrospective nature and observational design, which resulted in a heterogenous cohort of patients treated with various pomalidomide containing regimens. The categorization into index regimen subsets is limited by the relatively low numbers of patients in the different treatment groups.

Patients with triple-class-exposed multiple myeloma have a poor prognosis and an unmet medical need. T-cell redirecting therapies like chimeric antigen receptor T-cells and bispecific antibodies have recently been shown to achieve unprecedentedly high response rates and progression-free survival in this group of patients [21–24].

5 | CONCLUSION

In this large real-world cohort, the clinical performance of pomalidomide-dexamethasone was almost identical to the results of prospective clinical trials. Although treatment with the various pomalidomide-containing triplet regimens resulted in higher response rates, the achieved TNT was not better than what was achieved with pomalidomide-dexamethasone. The exception to this was KPD, used

earlier in the course of the disease. The most important predictor of outcomes of pomalidomide treatment was previous exposure. Compared to CD38 antibody-naïve patients, triple-class-exposed patients achieved worse clinical outcomes with pomalidomide treatment.

AUTHOR CONTRIBUTIONS

AGS designed the study, established the study database, conducted a patient chart review, entered clinical data in the study database, created figures, and wrote the manuscript. JT carried out data analysis, and statistics, created figures, and participated in the writing of the manuscript. KFI, MBL, CH, NEH, STB, KN, EMT, MD, EK, and CS conducted patient chart reviews, entered clinical data in the study database, and participated in the writing of the manuscript. AJV conducted a patient chart review, entered clinical data in the study database, supervised the study, and participated in the writing of the manuscript.

ACKNOWLEDGMENTS

We thank the Department of Internal Medicine and the Hematological Clinical Research Unit at Vejle Hospital for providing the financial and logistical background for this study. Data management for this study was provided by the Open Patient Exploratory Network, University of Southern Denmark. The work was funded by the Danish Cancer Society R249-A14646-19-S70, and Holms Mindelegat.

CONFLICTS OF INTEREST STATEMENT

AGS: Consulting for Janssen, Sanofi, Takeda, Research funding from BMS, Takeda; AJV: Honoraria from Janssen and Celgene; consulting for Takeda, Sanofi, Oncopeptides; STB: unrestricted grant fra CSL Behring; KFI: research funding from Genmab; EH: Advisory board: Janssen, Honoraria: Amgen, BMS, Janssen, Sanofi, Takeda, Research cooperation: BMS, Janssen, Sanofi, Conference participation support: BMS, Pfizer, Roche, Takeda; MBL, CH, KN, EMT, MD, EK, CS: No conflicts of interest.

DATA AVAILABILITY STATEMENT

The datasets generated and analyzed during the current study are not publicly available due to the National and European Data Protection Regulation.

ETHICS STATEMENT

The authors have confirmed ethical approval statement is not needed for this submission.

APPROVAL STATEMENT

This study was approved on behalf of the Danish Data Protection Agency by The Region of Southern Denmark (Journal 19/52220) and the Danish Patient Safety Authority (Journal 3-3013-2047/1 and 3-3013-2047/2). The ethics committee waived the requirement for informed consent.

PATIENT CONSENT STATEMENT

The authors have confirmed patient consent statement is not needed for this submission

CLINICAL TRIAL REGISTRATION

The authors have confirmed clinical trial registration is not needed for this submission.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Szabo AG, Thorsen J, Iversen KF, Levring MB, Helleberg C, Hermansen E, et al. The real-world use and efficacy of pomalidomide for relapsed and refractory multiple myeloma in the era of CD38 antibodies. eJHaem. 2023;4:1006–1012. https://doi.org/10.1002/jha2.774