Isatuximab, pomalidomide, and dexamethasone as salvage therapy for patients with multiple myeloma: the Italian, multicenter, retrospective clinical experience with 270 cases outside of controlled clinical trials

This real-world multicenter study aimed to evaluate the efficacy and tolerability of the isatuximab, pomalidomide, and dexamethasone (IsaPd) combination in relapsed/refractory multiple myeloma (RRMM). Our results confirm the safety and efficacy of IsaPd, in line with findings from the pivotal ICARIA-MM clinical trial.[1,2]

Isatuximab and daratumumab, both anti-CD38 antibodies, have demonstrated high response rates and improved survival in RRMM patients when used with agents like pomalidomide, lenalidomide, carfilzomib, and dexamethasone.[3-8] The pivotal ICARIA-MM trial, demonstrated a significant improvement in progression-free survival (PFS) of IsaPd, compared to pomalidomide-dexamethasone (Pd) with a median PFS of 11.5 months *versus* 6.5 months in the control group.[1] Extended follow-up confirmed the outcome benefit, with a median overall survival (OS) of 24.6 months compared to 17.7 months in the control arm.[2]

Our study analyzed 270 RRMM patients treated with IsaPd across 51 Italian centers between January 2021 and June 2024. This study was approved by the ethics committee at all participating hospitals. It adhered to the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. All patients received prophylactic antibacterial, antiviral, and antithrombotic therapy. PFS, OS, and time-to-next treatment (TTNT) were evaluated as time-to-event endpoints. Safety and treatment responses were also assessed.[9,10]

At baseline, 13.7% of patients were in stage III according to the International Staging System (ISS), and 26.7% had refractory disease (Table 1). About 29.3% of patients showed a creatinine clearance (CrCl) <60 mL/min. Cytogenetic evaluations performed at IsaPd initiation classified 104 out of 147 evaluable cases as standard-risk and 43 as high-risk (Table 1). Furthermore, 23% of cases showed a gain/amplification of 1q21 (1q21+). About 64% had received two lines of therapy and most cases were refractory to lenalidomide; in addition, 51 patients had been exposed to daratumumab, with 98% refractory to this therapy. Twelve patients received IsaPd immediately after a daratumumab-containing regimen, while 39 patients received other schedules in between. Median time between IsaPd and daratumumab-containing regimen was ten months (range: 0.5-41 months).

Compared to the ICARIA-MM trial,[1] our cohort had a lower incidence of renal impairment (29.3% *vs*. 39%), a higher proportion of high-risk cytogenetics (29.3% *vs*. 16%) and daratumumab-refractory patients (20% in our study *vs*. none in the trial), but similar distribution in ISS stage and lenalidomide-refractory patients. Two other studies have been reported on IsaPd use in a real-world setting (*Online Supplementary Table S1*).[11,12] Notably, our study has the longest median follow-up (23.5 months *vs*. 12.1 and 14.2 of the British and French studies, respectively). Our findings align with both the British and French studies, though they provide unique insights thanks to their scope and duration.[11,12] In comparison, the UK study reported a higher median number of prior therapies (N=3), but a lower rate of daratumumab-exposed patients (4.7%). The IMAGE study included more ISS stage III patients (36.4%) and daratumumab-exposed cases (26.5%). Finally, our cohort encompassed a greater number of high-risk cytogenetic patients (29.3%) (*Online Supplementary Table S1*).

At the last follow-up, the overall response rate (ORR) was achieved in 74.1% of patients, including 14.8% attaining a complete remission (CR) and 29.6% a very good partial response (VGPR). The response rate surpassed those of the ICARIA-MM trial (ORR 60%, CR 4.5%).[1,2] The English real-world study similarly reported an ORR of 66.4%, whereas the French study observed that 46.3% of patients achieved >VGPR.[11,12] In our cohort, the median time to response was 1.9 months.

A higher ORR has been observed in patients with CrCl >60 mL/min (74% *vs*. 65.8%; *P*=0.047), with ISS stage I and II (78.6% *vs*. 74.5% *vs*. 56.8%; *P*=0.027), with normal lactate dehydrogenase (LDH) levels (78.4% *vs*. 54.2%; *P*=0.001), and in those not exposed to daratumumab (78.1% *vs*. 56.9%; *P*=0.002). Age, gender, prior therapy lines, previous autologous stem cell transplation (ASCT), and disease status at IsaPd initiation did not significantly affect response rates. No differences in ORR were observed based on the time (<12 *vs*. >12 months and <6 *vs*. >6 months) or the sequencing (immediately after *vs*. other schedules in between) of IsaPd after daratumumab-containing regimens.

After a median follow-up of 23.5 months, 57.8% of patients experienced disease progression or death and 31.5% had died. Median PFS was 15.7 months, with a 2-year PFS probability of 38.8% (Figure 1A). This is higher than the 11.5 months in the pivotal study,[1] and the 12.4 and 10.9 months observed in the IMAGE study and in the UK-wide dataset, respectively.[11,12] Differences may be attributed to the num-

ber of prior therapies in the ICARIA-MM trial and the higher proportion of advanced ISS stages in the latter studies.

In univariable analyses, CrCl <60 mL/min, ISS stage II and III, abnormal LDH value, and previous daratumumab exposure (Figure 1B) were significantly associated with lower PFS (*Online Supplementary Table S2A*).

However, no significant differences in PFS were observed based on the time or the sequencing of IsaPd after daratumumab-containing regimens. In multivariable analysis, ISS stages II (Hazard Ratio [HR]=1.47; *P*=0.035) and III (HR=2.44; *P*=0.001), abnormal LDH value (HR=1.51; *P*=0.04), and previous daratumumab exposure (HR=1.87; *P*=0.002) were independent predictors of worse PFS (*Online Supplementary Table S2A*).

The lower PFS in patients previously treated with daratumumab is in line with real-world data. In the IMAGE study, daratumumab-refractory patients had a median PFS of three months, while daratumumab-exposed but not refractory patients experienced a median PFS of 8.4 months. Daratumumab-naïve patients had a median PFS of 16.6 months,[11] highlighting the negative impact of prior daratumumab treatment in IsaPd-treated patients. There was no significant difference in PFS between age groups (<70 *vs*. >70 years), consistent with the ICARIA-MM trial, which demonstrated that IsaPd was effective regardless of age.[13]

The median OS was not reached, with a 2-year OS probability of 64.2% (Figure 1C). In comparison, the ICARIA-MM trial reported a median OS of 24.6 months.[9] The IMAGE study also reported an OS not reached, whereas in the UK-wide real-world study OS was 18.8 months.[11,12] Univariable analyses showed that CrCl <60 mL/min, ISS stage II and III, abnormal LDH, more than two previous lines of therapy, and previous daratumumab exposure (Figure 1D) were significantly associated with shorter OS (*Online Supplementary Table S2B*). In the multivariable analysis, ISS stages II (HR=1.77; *P*=0.029) and III (HR=2.23; *P*=0.02), and abnormal LDH value (HR=2; *P*=0.006) were independent predictors of shorter OS (*Online Supplementary Table S2B*). Since prior daratumumab exposure showed a trend toward significance (HR=1.52; *P*=0.088), a longer follow-up is desirable to confirm these data. Again, no differences in OS were observed based on the time or the sequencing of IsaPd after daratumumab-containing regimens.

After discontinuing the IsaPd regimen, 38.5% of patients received subsequent treatment, with a median TTNT of 17.7 months, and a 2-year retreatment probability of 39% (Figure 1E). A total of 21 different salvage therapy regimens were used after IsaPd discontinuation or failure (*Online Supplementary Table S3*).

At the last update, the median number of IsaPd courses was 11 with 61.9% of patients discontinuing treatment mainly due to disease progression (50%). Other discontinuation reasons included toxicity (19 infections, 3 severe neutropenia, and 2 acute myocardial infarctions), therapy-unrelated deaths (N=4), second ASCT (N=2), and patient decision (N=1).

Table 1. Main characteristics of patients at the time of initiation of isatuximab, pomalidomide, and dexamethasone therapy.

Characteristic	N of patients (%)
Age in years	
Median (range)	69 (38-88)
<70	159 (58.9)
≥70	111 (41.1)
Sex	
Male	147 (54.4)
Female	123 (45.6)
Paraproteins, isotype	
Immunoglobulin G	159 (58.9)
Immunoglobulin A	57 (21.1)
Immunoglobulin D	2 (0.7)
Immunoglobulin M	1 (0.4)
Light chain only	51 (18.9)
Creatinine, mg/dL	
Median (range)	0.92 (0.38-8.47)
Creatinine clearance, mL/min	
Median (range)	70 (3-172)
≥60	191 (70.7)
<60	79 (29.3)
ISS stage (%)	
I	131 (48.5)
II	102 (37.8)
III	37 (13.7)
LDH serum level	
Median (range)	197 (112-1125)
Normal	222 (82.2)
Elevated°	48 (17.8)
Previous lines of therapy	
Median (range)	2 (2-7)
2	172 (63.7)
3	67 (24.8)
≥4	31 (10.5)
Previous ASCT	
No	107 (39.6)
Yes	163 (60.4)
Previous daratumumab	
No	219 (81.1)
Yes	51 (18.9)
Lenalidomide refractory	
No	4 (1.5)
Yes	266 (98.5)
Disease status	
Biochemical relapse	57 (21.1)
Symptomatic relapse	141 (52.2)
Refractory to last treatment	72 (26.7)
Cytogenetic analysis available	
Standard-risk	104/147 (70.7)
High-risk*	43/147 (29.3)

°Elevated: higher-than-normal lactate dehydrogenase (LDH) levels. *High-risk: patients with either t(4;14) or t(14;16) or del(17p). N: number; ISS: International Staging System; ASCT: autologous stem cell transplatation.

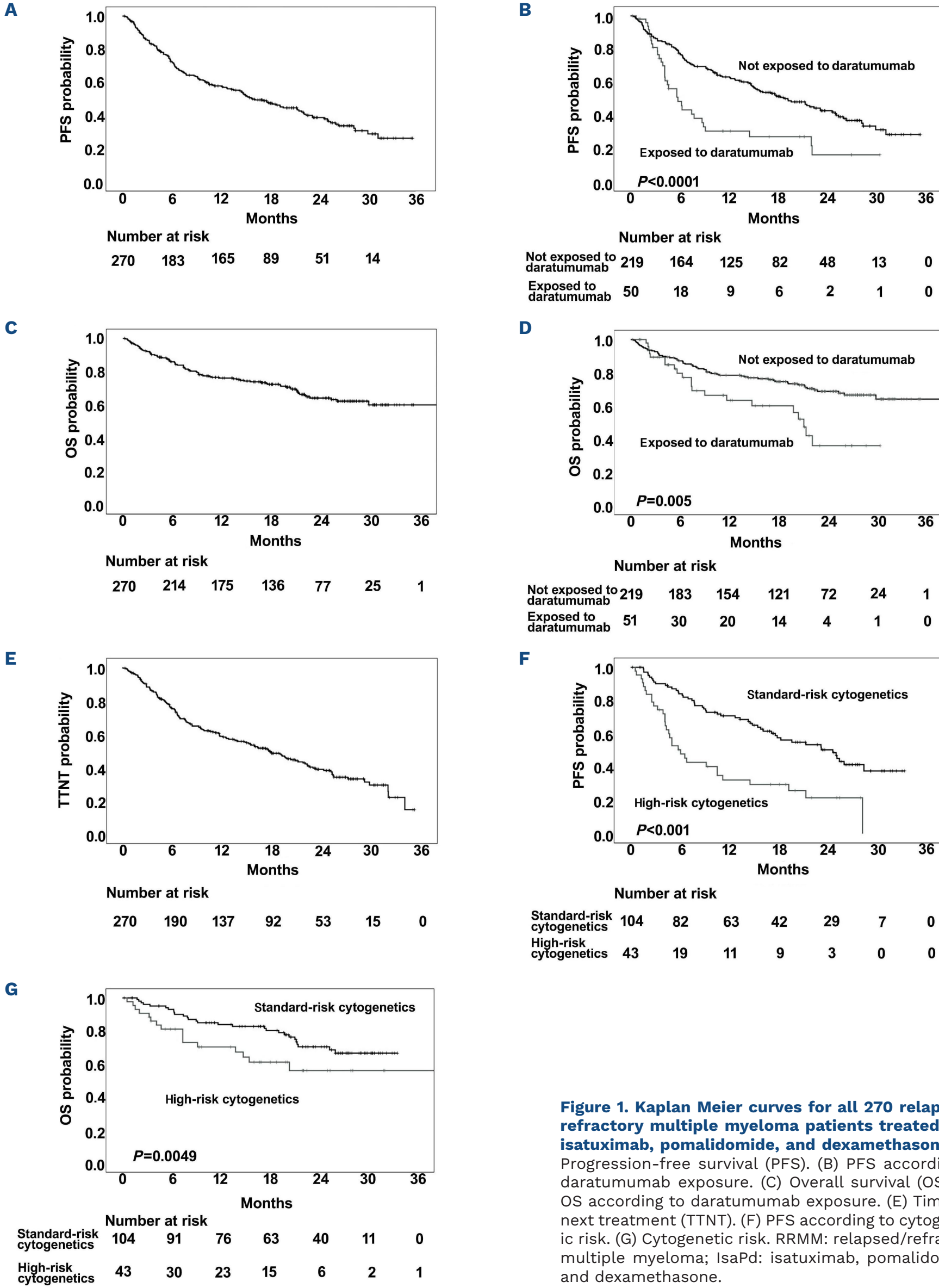

Figure 1. Kaplan Meier curves for all 270 relapsed / refractory multiple myeloma patients treated with isatuximab, pomalidomide, and dexamethasone. (A) Progression-free survival (PFS). (B) PFS according to daratumumab exposure. (C) Overall survival (OS). (D) OS according to daratumumab exposure. (E) Time-to-next treatment (TTNT). (F) PFS according to cytogenetic risk. (G) Cytogenetic risk. RRMM: relapsed/refractory multiple myeloma; IsaPd: isatuximab, pomalidomide, and dexamethasone.

Table 2. Incidence of adverse events.

Adverse event	IsaPd, N=270	
	All grades N (%)	Grade 3-4 N (%)
Hematologic toxicities		
Anemia	230 (85.2)	37 (13.7)
Thrombocytopenia	205 (75.9)	43 (15.9)
Neutropenia	265 (98.1)	152 (56.3)
Non-hematologic toxicities		
Infection	175 (64.8)	129 (47.8)*
Pneumonia	84 (31.1)	72 (26.7)
Fatigue	78 (28.9)	44 (16.3)
Gastrointestinal toxicity	92 (34.1)	17 (6.3)

IsaPd: isatuximab, pomalidomide, and dexamethasone therapy; N: number. *Grade 3-4 infections: pneumonia N=72; genitourinary tract infection N=22; bronchitis N=17; upper respiratory tract infection N=15; sepsis N=2.

Infusion reactions occurred in 11.8% of patients, mostly mild, with only one patient discontinuing therapy. Major adverse events (AE) included grade 3/4 neutropenia (56.3%), thrombocytopenia (15.9%), and anemia (13.7%) (Table 2). The incidence of grade 3-4 neutropenia and thrombocytopenia was seen to be lower than that reported in the ICARIA-MM trial (*Online Supplementary Table S1*), possibly attributed to the more diverse population and under-reporting of AE in real-world settings. The all grade infection rate was 47.8%, with 26.7% developing pneumonia. The lack of significant differences in the AE observed between patients based on age or renal function (*data not shown*) supports the feasibility of IsaPd in elderly and renally impaired patients, aligning our study with other real-world analyses.[11,12]

Cytogenetic data were available for 54.4% of cases. The similarity in features between patients with and without available FISH data, apart from a higher rate of refractoriness to the last therapy in those in whom FISH was not available, suggests that these findings are likely representative of the entire patient cohort. Indeed, our findings underscore the prognostic significance of cytogenetic risk stratification. The analysis revealed a significantly higher ORR in the standard-risk group compared to the high-risk group (82.7% *vs*. 62.8%; *P*=0.009).

Furthermore, patients with high-risk cytogenetics exhibited significantly shorter PFS (HR 2.57, 95% Confidence Interval [CI]: 1.64-4.03; *P*<0.0001) (Figure 1F), with a 2-year PFS of 21.6% in the high-risk group compared to 50.4% in the standard-risk group. Additionally, OS was poorer in the high-risk group (Figure 1G), with a 2-year OS of 56% *vs*. 70.4% in the standard-risk group (HR 1.86, 95% CI: 1.01-3.46; *P*=0.049), underscoring the prognostic value of cytogenetic profiling. Moreover, in line with the ICARIA-MM trial,[14,15] IsaPd appeared to overcome the negative impact of 1q21^{+}, with similar outcomes (ORR 82.4% *vs*. 75.2%; 2-year PFS 44.8% *vs*. 41.4%; 2-year OS 69% *vs*. 65.2%) in patients with and without this abnormality.

In conclusion, IsaPd is effective and safe in a real-world setting for RRMM patients who received two prior lines of therapy. Alternative therapeutic strategies, i.e., bispecific antibodies and chimeric antigen receptor T-cell therapy are needed for the high-risk and daratumumab-exposed patients.

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No conflicts of interest to disclose.

Contributions

EAM, MG, FDR, VDS, AN, FM and PM designed the study. MG and FM performed the statistical analysis. DD, ER, ST, GR, PS, JM, SM, EZ, MO, AF, GB, FL, CL, AL, RDP, GB, EB, CC, CDM, LDP, VB, AMC, AM, PB, CCe, CB, EA, NS, SA, GM, GBa, SP, OA, RB, MAF, GMC, AR, RF, FF, EV, AB, KM, DN, SM, ER, CCa, AA, DR, AL, AC, GU, RZ, AM, SN, MM, AG, VM, MB, EC, GP, AMQ, VA, NDR, MC, Mga and MTP analyzed and interpreted data. EAM, MG, FDR, VDS, AN, FM, and PM wrote the manuscript. All authors approved the final manuscript for publication.

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Data-sharing statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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