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Updated Analysis of Daratumumab Plus Lenalidomide and Dexamethasone (D-Rd) versus Lenalidomide and Dexamethasone (Rd) in Patients with Transplant-Ineligible Newly Diagnosed Multiple Myeloma (NDMM): the Phase 3 MAIA Study

Aurore Perrot[1], Thierry Facon[2], Saad Z. Usmani[3], Torben Plesner[4], Robert Z. Orlowski[5], Cyrille Touzeau[6], Supratik Basu[7], Nizar J. Bahlis[8], Hartmut Goldschmidt[9], Michael O'Dwyer[10], Christopher P. Venner[11], Katja Weisel[12], Cyrille Hulin[13], Lionel Karlin[14], Meir Preis[15], Annemiek Broijl[16], William Renwick[17], Markus Hansson[18], Maria Krevvata[19], Jianping Wang[20], Rian Van Rampelbergh[21], Jon Ukropec[22], Clarissa M. Uhlar[19], Rachel Kobos[20], Shaji K. Kumar[23]

[1]CHU de Toulouse, IUCT-O, Université de Toulouse, UPS, Service d'Hématologie, Toulouse, France; [2]University of Lille, CHU Lille, Service des Maladies du Sang, Lille, France; [3]Levine Cancer Institute/Atrium Health, Charlotte, NC, USA; [4]Vejle Hospital and University of Southern Denmark, Vejle, Denmark; [5]Department of Lymphoma and Myeloma, The University of Texas MD Anderson Cancer Center, Houston, TX, USA; [6]Hematology, University Hospital Hôtel-Dieu, Nantes, France; [7]Royal Wolverhampton Hospitals NHS Trust and University, Wolverhampton, UK; [8]Arnie Charbonneau Cancer Research Institute, University of Calgary, Calgary, AB, Canada; [9]University Clinic Heidelberg, Internal Medicine V and National Center for Tumor Diseases (NCT), Heidelberg, Germany; [10]Department of Medicine/Haematology, NUI, Galway, Republic of Ireland; [11]Cross Cancer Institute, University of Alberta, Edmonton, AB, Canada; [12]Department of Oncology, Hematology and Bone Marrow Transplantation with Section of Pneumology, University Medical Center Hamburg-Eppendorf, Hamburg, Germany; [13]Department of Hematology, Hôpital Haut Lévêque, University Hospital, Pessac, France; [14]Department of Hematology, Centre Hospitalier Lyon Sud, Hospices Civils de Lyon, Pierre-Bénite, France; [15]Carmel MC, Haifa, Israel; [16]Erasmus MC Cancer Institute, Rotterdam, The Netherlands; [17]Western Health, Sunshine Hospital, Cancer Services, St Albans, Victoria, Australia; [18]Department of Hematology, Skåne University Hospital, Lund, Sweden; [19]Janssen Research & Development, LLC, Spring House, PA, USA; [20]Janssen Research & Development, LLC, Raritan, NJ, USA; [21]Janssen Research & Development, Beerse, Belgium; [22*]Janssen Global Medical Affairs, Horsham, PA, USA; [23]Department of Hematology, Mayo Clinic Rochester, Rochester, MN, USA. (*at the time of study.)

INTRODUCTION AND METHODS

- Daratumumab (DARA) is a human IgGκ monoclonal antibody targeting CD38 with a direct on-tumor[1-4] and immunomodulatory[5-7] mechanism of action
- DARA is approved as monotherapy in relapsed/refractory multiple myeloma (RRMM) and in combination with standard of care (SOC) for RRMM and (NDMM)[8,9]
- The addition of DARA to SOC regimens in phase 3 studies has consistently improved progression-free survival (PFS) and has led to deep and durable responses, including higher rates of minimal residual disease (MRD) negativity, compared with SOC[10-14]
- In the primary analysis of the phase 3 MAIA study (median follow up, 28.0 months), a significant PFS benefit (median, not reached [NR] vs 31.9 months; hazard ratio [HR], 0.56; 95% CI, 0.43-0.73; P <0.001) and a >3-fold increase in MRD-negativity rates (10^{-5} sensitivity threshold; 24.2% vs 7.3%; P <0.001) were observed with the combination of DARA plus lenalidomide and dexamethasone (D-Rd) versus lenalidomide and dexamethasone (Rd) alone in patients with transplant-ineligible (TIE) NDMM[13]
  - With a longer follow up (median, 36.4 months), D-Rd maintained a PFS benefit and deeper and more durable responses versus Rd alone[15]
- Here, we report updated efficacy and safety findings from MAIA after approximately 4 years of follow up

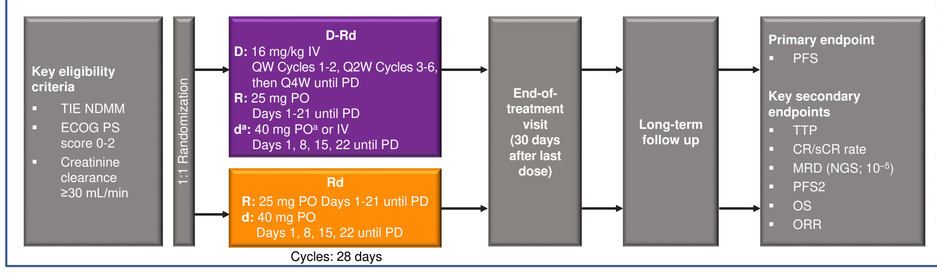
Study Design

- Patients with NDMM ineligible for high-dose chemotherapy and autologous stem cell transplant due to age ≥65 years or comorbidities were randomly assigned (1:1) to receive Rd ± DARA
  - Stratification factors were International Staging System stage (I vs II vs III), region (North America vs other), and age (<75 vs ≥75 years)
- All patients received 28-day cycles of Rd (lenalidomide, 25 mg orally once daily on Days 1-21; dexamethasone, 40 mg orally or intravenously [IV] on Days 1, 8, 15, and 22)
- In the D-Rd arm, DARA (16 mg/kg IV) was given weekly during Cycles 1 and 2, every 2 weeks during Cycles 3 through 6, and every 4 weeks thereafter (**Figure 1**)
- Patients in both treatment arms were treated until disease progression or unacceptable toxicity

Endpoints and Assessments

- The primary endpoint was PFS. Key secondary endpoints included overall response rate, MRD-negativity rate (10^{-5} sensitivity threshold, clonoSEQ® assay V2.0 [Adaptive Biotechnologies, Seattle, WA,USA]), and safety
  - MRD assessments were performed at baseline; at the time of suspected complete response (CR)/stringent CR; and at 12, 18, 24, and 30 months post Cycle 1 Day 1 (±1 month). Patients who did not achieve responses of near CR or better did not have post-baseline MRD assessments performed
  - Sustained MRD negativity is defined as having tested MRD negative with confirmation at ≥6 months and at ≥12 months apart without testing MRD positive in between
- PFS on the next subsequent line of therapy (PFS2) was defined as the time from initial randomization to disease progression on the next line of therapy or death

Figure 1. MAIA Study Design



[a]On days when DARA is administered, dexamethasone will be administered to patients in the D-Rd arm and will serve as the treatment dose of steroid for that day, as well as the required pre infusion medication. CR, complete response; DARA, daratumumab D-Rd, daratumumab plus lenalidomide/dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; NGS, next-generation sequencing; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PFS2, progression-free survival on next subsequent line of therapy; PO, oral; QW, once weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; Rd, lenalidomide/dexamethasone; sCR, stringent complete response; TIE, transplant-ineligible; TTP, time to progression;.

RESULTS

Demographic and Baseline Disease Characteristics

- Patient demographics and baseline disease characteristics are summarized in **Table 1** and have been published previously[1]
- A total of 737 patients were randomized (D-Rd, n = 368; Rd, n = 369)
- Patient baseline characteristics were well balanced between treatment arms
  - Median (range) age was 73.0 (45-90) years, with 43.6% of patients ≥75 years of age
  - Among 642 patients evaluable for fluorescence in situ hybridization/karyotyping analysis, 85.7% had standard and 14.3% had high cytogenetic risk

Patient Disposition

- Median duration of study treatment was 42.8 months for the D-Rd arm and 22.6 months for the Rd arm
- 176 (48.4%) patients receiving D-Rd and 273 (74.8%) patients receiving Rd have discontinued study treatment
  - 89 (24.5%) patients in the D-Rd group discontinued lenalidomide and continued on DARA
  - 85 (23.4%) patients with D-Rd and 113 (31.0%) patients with Rd have discontinued study treatment due to progressive disease
- 239 patients have died (107 in the D-Rd group and 132 in the Rd group)

Efficacy

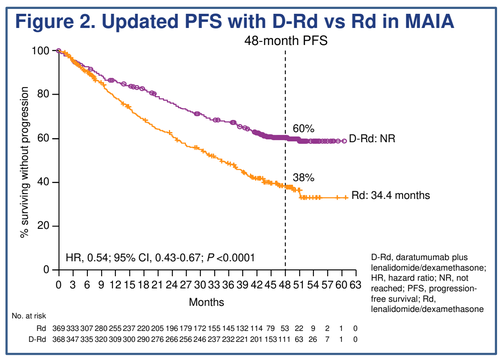
- After a median follow up of 47.9 months, median PFS was NR with D-Rd versus 34.4 months with Rd (HR, 0.54; 95% CI, 0.43-0.67; P <0.0001; **Figure 2**)
  - D-Rd demonstrated a significant benefit in PFS, with a 46% reduction in the risk of progression or death
  - PFS curves continue to separate with time; the estimated 12-, 24-, and 36-month PFS rates with D-Rd versus Rd were 86.2% versus 78.4%, 76.0% versus 61.6%, and 67.4% versus 48.4%, respectively
  - The estimated 48-month PFS rate was 60.2% with D-Rd versus 38.2% with Rd
- The PFS benefit of D-Rd versus Rd was observed in all pre-specified subgroups, except for patients with impaired hepatic function, which had a small sample size (**Figure 3**)
- A similar PFS benefit was observed in patients with high cytogenetic risk; median PFS was 45.3 months for D-Rd and 29.6 months for Rd (HR, 0.57; 95% CI, 0.33-1.00)

Table 1. Demographic and Baseline Characteristics

	D-Rd (n=368)	Rd (n=369)
Age, years		
Median (range)	73.0 (50-90)	74.0 (45-89)
Distribution, n (%)		
<65	4 (1.1)	4 (1.1)
65-<70	74 (20.1)	73 (19.8)
70-<75	130 (35.3)	131 (35.5)
≥75	160 (43.5)	161 (43.6)
ECOG PS score, n (%)		
0	127 (34.5)	123 (33.3)
1	178 (48.4)	187 (50.7)
2[a]	63 (17.1)	59 (16.0)
ISS stage, n (%)		
I	98 (26.6)	103 (27.9)
II	163 (44.3)	156 (42.3)
III	107 (29.1)	110 (29.8)
Type of measurable disease, n (%)		
IgG	225 (61.1)	231 (62.6)
IgA	65 (17.7)	66 (17.9)
Other[b]	9 (2.4)	10 (2.7)
Detected in urine only	40 (10.9)	34 (9.2)
Detected as serum-free light chain only	29 (7.9)	28 (7.6)
Cytogenetic profile, n/N (%)		
Standard risk	271/319 (85.0)	279/323 (86.4)
High risk	48/319 (15.0)	44/323 (13.6)
Median time since initial diagnosis of MM (range), months	0.95 (0.1-13.3)	0.89 (0-14.5)

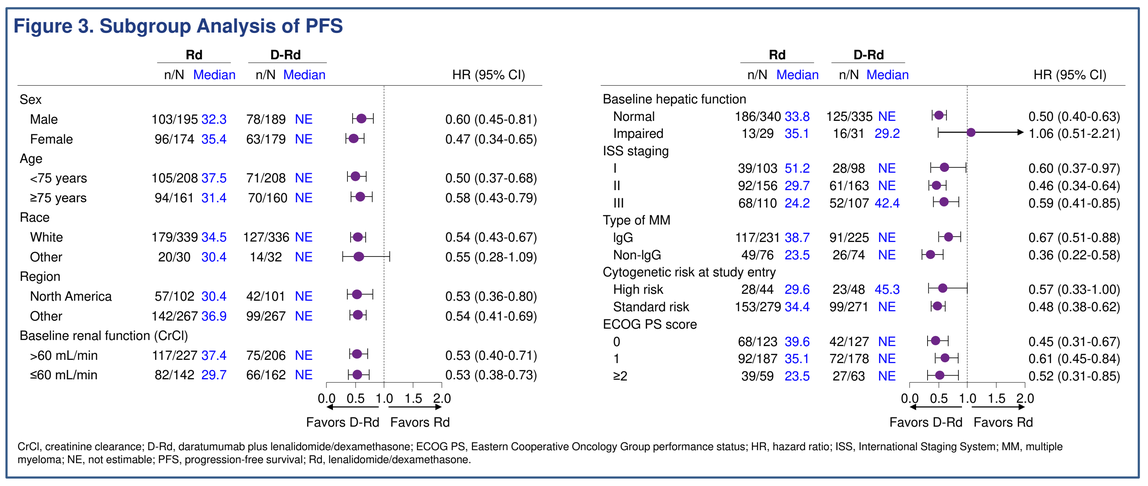
[a]2 patients had an ECOG PS score >2 (1 patient each with an ECOG PS score of 3 and 4). [b]Includes IgD, IgE, IgM, and biclonal. D-Rd, daratumumab plus lenalidomide/dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; MM, multiple myeloma; Rd, lenalidomide/dexamethasone.

Figure 2. Updated PFS with D-Rd vs Rd in MAIA



D-Rd, daratumumab plus lenalidomide/dexamethasone; HR, hazard ratio; NR, not reached; PFS, progression-free survival; Rd, lenalidomide/dexamethasone

Figure 3. Subgroup Analysis of PFS

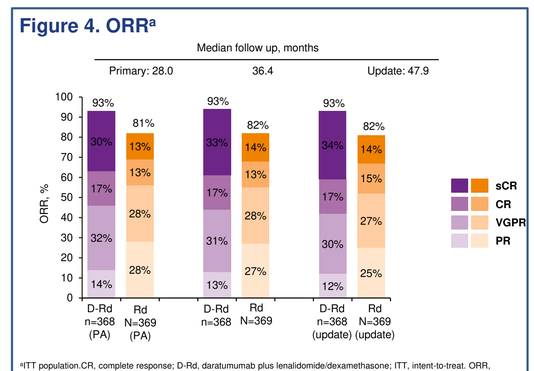


CrCl, creatinine clearance; D-Rd, daratumumab plus lenalidomide/dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; ISS, International Staging System; MM, multiple myeloma; NE, not estimable; PFS, progression-free survival; Rd, lenalidomide/dexamethasone.

RESULTS (CONT.)

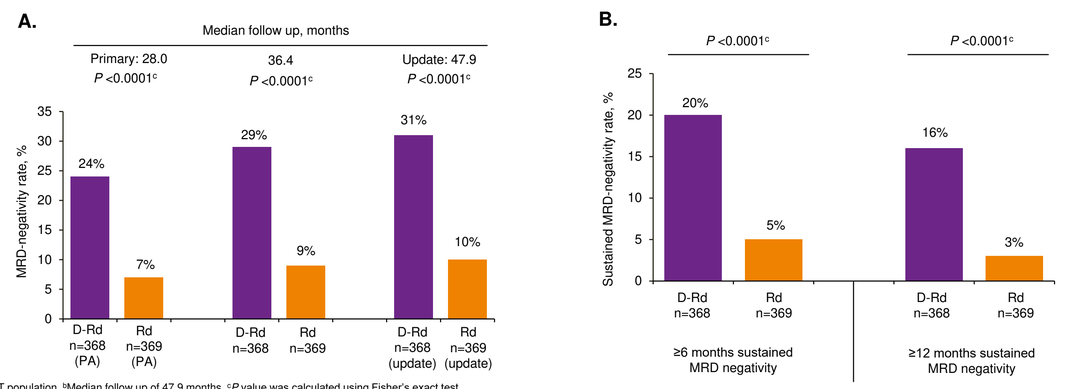
- Adding DARA to Rd resulted in deeper responses with higher rates of ≥CR and ≥VGPR, compared with Rd alone (**Figure 4**)
- Median duration of response among responders was NR with D-Rd versus 44.3 months with Rd
- The MRD-negativity rate was significantly higher with D-Rd versus Rd (31% vs 10%; P <0.0001; **Figure 5A**)
- The MRD-negativity rate was 10-fold higher in the D-Rd group (23%) compared with the Rd group (2%) in patients with high cytogenetic risk
- Patients receiving D-Rd achieved significantly higher rates of MRD durability compared with Rd, with respective sustained MRD-negativity rates of 20% versus 5% at a cutoff point of ≥6 months, and 16% versus 3% at a cutoff point of ≥12 months (**Figure 5B**)

Figure 4. ORR[a]



[a]ITT population.CR, complete response; D-Rd, daratumumab plus lenalidomide/dexamethasone; ITT, intent-to-treat. ORR, overall response rate; PA, primary analysis; PR, partial response; Rd, lenalidomide/dexamethasone; sCR, stringent complete response; VGPR, very good partial response

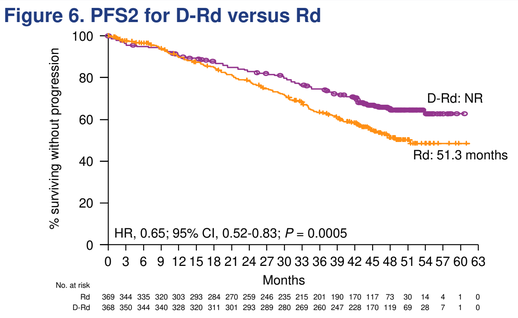
Figure 5. (A) MRD-negativity Rate[a] and (B) Sustained MRD-negativity[a] in Patients Treated with D-Rd versus Rd[b]



[a]ITT population. [b]Median follow up of 47.9 months. [c]*P* value was calculated using Fisher's exact test.
D-Rd, daratumumab plus lenalidomide/dexamethasone; ITT, intent-to-treat; MRD, minimal residual disease; PA, primary analysis; Rd, lenalidomide/dexamethasone.

- The most common first subsequent therapy regimen (both groups) was
  - Bortezomib/dexamethasone (Vd): D-Rd, n = 17; Rd, n = 28
  - Bortezomib/cyclophosphamide/dexamethasone (VCd): D-Rd, n = 14; Rd, n = 29
  - Bortezomib/melphalan/prednisone (VMP): D-Rd, n = 13; Rd, n = 27
- After a median follow up of 47.9 months, median PFS2 was NR for D-Rd versus 51.3 months for Rd (HR, 0.65; 95% CI, 0.52-0.83; P = 0.0005**; Figure 6**); follow up is ongoing
- Longer follow up demonstrated a significant benefit in PFS2 favoring D-Rd versus Rd alones

Figure 6. PFS2 for D-Rd versus Rd



D-Rd, daratumumab plus lenalidomide/dexamethasone; HR, hazard ratio; NR, not reached; PFS2, progression-free survival on the next subsequent line of therapy; Rd, lenalidomide/dexamethasone.

Safety

- With ≈4 years of follow up, safety profiles were similar to those reported for the primary and updated analyses, with no new safety concerns observed
- Grade 3/4 treatment-emergent adverse events (TEAEs; **Table 2**) occurring in ≥10% of patients were neutropenia (53% for D-Rd vs 37% for Rd), pneumonia (18% vs 11%), anemia (16% vs 21%), lymphopenia (16% vs 11%), hypokalemia (12% vs 10%), leukopenia (11% vs 6%), and cataract (11% vs 10%)
- Grade 3/4 infection rates were 40% for D-Rd versus 29% for Rd
- The most common serious TEAE was pneumonia (17% for D-Rd vs 11% for Rd)
- 11% of patients in the D-Rd arm and 22% in the Rd arm discontinued treatment due to TEAEs

Table 2. TEAEs for D-Rd versus Rd[a]

	D-Rd (n=364)		Rd (n=365)	
	Any grade[b]	Grade 3 or 4[c]	Any grade[b]	Grade 3 or 4[c]
Hematologic, n (%)				
Neutropenia	221 (61)	194 (53)	162 (44)	135 (37)
Anemia	150 (41)	59 (16)	148 (41)	78 (21)
Leukopenia	72 (20)	40 (11)	40 (11)	23 (6)
Lymphopenia	71 (20)	59 (16)	47 (13)	41 (11)
Nonhematologic, n (%)				
Diarrhea	235 (65)	30 (8)	183 (50)	21 (6)
Fatigue	159 (44)	31 (9)	111 (30)	16 (4)
Constipation	156 (43)	6 (2)	134 (37)	1 (<1)
Peripheral edema	149 (41)	9 (3)	114 (31)	3 (1)
Back pain	141 (39)	13 (4)	105 (29)	13 (4)
Asthenia	131 (36)	19 (5)	97 (27)	14 (4)
Nausea	125 (34)	7 (2)	87 (24)	2 (1)
Bronchitis	124 (34)	12 (3)	85 (23)	6 (2)
Cough	119 (33)	2 (1)	63 (17)	0
Dyspnea	116 (32)	12 (3)	61 (17)	4 (1)
Insomnia	114 (31)	11 (3)	114 (31)	13 (4)
Weight decreased	110 (30)	10 (3)	69 (19)	11 (3)
Muscle spasms	110 (30)	2 (1)	85 (23)	4 (1)
Pneumonia	107 (29)	67 (18)	66 (18)	39 (11)
Hypokalemia	91 (25)	43 (12)	68 (19)	36 (10)
Cataract	87 (24)	39 (11)	80 (22)	38 (10)

[a]Safety analysis set. [b]Any-grade TEAEs occurring in ≥30% of patients. [c]Grade 3 or 4 TEAEs occurring in ≥10% of patients. D-Rd, daratumumab plus lenalidomide/dexamethasone; Rd, lenalidomide/dexamethasone; TEAE, treatment-emergent adverse event.

CONCLUSIONS

- After a median follow up of 47.9 months, the addition of DARA to Rd continues to demonstrate a superior PFS benefit and more patients continue to have deeper and more durable responses, including a tripling of the MRD-negativity rate, versus Rd alone in patients with TIE NDMM
  - The estimated 48-month PFS rate was substantially higher for D-Rd than Rd
  - D-Rd showed a PFS benefit and improvement in MRD-negativity rate in patients with high cytogenetic risk
- The longer follow up also demonstrated a significant benefit in PFS2 favoring D-Rd versus Rd alone
- No new safety concerns were observed with longer follow up

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LK: Janssen: Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel support, personal fees; Takeda: Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel support, personal fees; GlaxoSmithKline: Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel support; Abbvie: Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel support; Amgen: Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Travel support, personal fees; Celgene: Other: Personal fees. MP: Janssen: Other: for factor XI inhibitor. AB: Janssen, Celgene, Takeda, Amgen, BMS: Consultancy, Honoraria, Other: Travel expenses. Hansson: Amgen, Celgene, Takeda, Janssen Cilag: Consultancy. WR: N/A. MH: N/A. MK: Janssen: Current Employment. JW: Janssen: Current Employment. RVR: Janssen: Current Employment. JU: Janssen: Current Employment, Current equity holder in publicly-traded company. CMU: Janssen: Current Employment, Current equity holder in publicly-traded company. RK: Janssen: Current Employment, Current equity holder in publicly-traded company. SKK: Sanofi: Research Funding; Carsgen: Other, Research Funding; Cellectar: Other; Celgene/BMS: Other: Research funding for clinical trials to the institution, Consulting/Advisory Board participation with no personal payments; Genentech/Roche: Other: Research funding for clinical trials to the institution, Consulting/Advisory Board participation with no personal payments; Takeda: Other: Research funding for clinical trials to the institution, Consulting/Advisory Board participation with no personal payments; Janssen Oncology: Other: Research funding for clinical trials to the institution, Consulting/Advisory Board participation with no personal payments; Novartis: Research Funding; Oncopeptides: Consultancy, Other: Independent Review Committee; IRC member; Karyopharm: Consultancy; Merck: Consultancy, Research Funding; Kite Pharma: Consultancy, Research Funding; AbbVie: Other: Research funding for clinical trials to the institution, Consulting/Advisory Board participation with no personal payments; Tenebio: Other, Research Funding; BMS: Consultancy, Research Funding; MedImmune: Research Funding; Genecentrix: Consultancy; Dr. Reddy's Laboratories: Honoraria; Amgen: Consultancy, Other: Research funding for clinical trials to the institution, Consulting/Advisory Board participation with no personal payments, Research Funding; Adaptive Biotechnologies: Consultancy.The authors thank the patients participating in this study and their families, as well as the staff members at the study sites, the data and safety monitoring committee, and staff members involved in data collection and analyses. 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