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Daratumumab Plus Lenalidomide, Bortezomib, and Dexamethasone in Patients with Transplant-Eligible Newly Diagnosed Multiple Myeloma (NDMM): Updated Analysis of GRIFFIN After 12 Months of Maintenance Therapy

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INTRODUCTION AND METHODS

- Autologous stem cell transplant (ASCT) consolidation is an important standard of care for patients with transplant-eligible newly diagnosed multiple myeloma (NDMM)[1-3]
- Maintenance therapy with lenalidomide improves survival and is also standard of care[3-5]
- The phase 2 GRIFFIN study evaluates the efficacy and safety of daratumumab plus lenalidomide (R), bortezomib (V) and dexamethasone (d) (D-RVd) versus RVd for patients with transplant-eligible NDMM
  - In the primary analysis of GRIFFIN (median follow-up, 13.5 months), D-RVd significantly improved rates of stringent complete response (sCR) by the end of post-transplant consolidation therapy versus RVd (42.4% vs 32.0%; 1-sided P=0.0680), which met the pre-specified 1-sided alpha of 0.1[6]
  - With longer median follow-up (22.1 months), D-RVd versus RVd improved minimal residual disease (MRD)-negativity rates (51.0% vs 20.4%), with estimated 24-month progression-free survival (PFS) rates of 95.8% versus 89.8%[6]
  - No new safety concerns were observed with D-RVd combination therapy, and there was no clinically significant impact on stem cell mobilization or engraftment[6]
- Here, we report updated efficacy and safety from GRIFFIN following 12 months of maintenance therapy

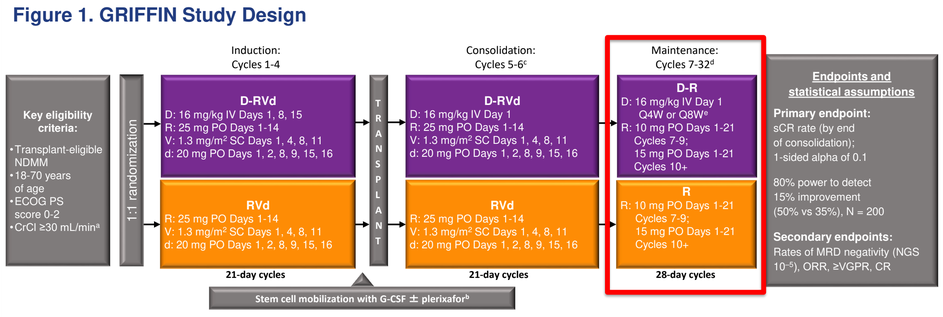
Study Design

- GRIFFIN phase 2 study enrolled patients between December 2016 and April 2018 at 35 sites across the United States
- Patients with NDMM eligible for high-dose therapy (HDT) and ASCT were randomly assigned (1:1) to receive D-RVD or RVd (**Figure 1**)

Endpoints and Assessments

- The primary endpoint was rate of sCR at the end of post-ASCT consolidation per International Myeloma Working Group (IMWG) criteria; at a 1-sided alpha of 0.1
- Key secondary endpoints included PFS and rate of MRD-negativity (10^{-5} threshold per IMWG criteria) assessed by next-generation sequencing (clonoSEQ; Adaptive Biotechnologies); all secondary analyses were evaluated using a 2-sided P value (alpha 0.05) and were not adjusted for multiplicity

Figure 1. GRIFFIN Study Design



[a]Lenalidomide dose adjustments were made for patients with CrCl ≤50 mL/min. [b]Cyclophosphamide-based mobilization was permitted if unsuccessful. [c]Consolidation was initiated 60 to 100 days post transplant. [d]Patients who complete maintenance cycles 7 to 32 may continue single-agent lenalidomide thereafter. [e]Protocol Amendment 2 allowed for the option to dose daratumumab Q4W, based on pharmacokinetic results from study SMM2001 (NCT02316106). CR, complete response; CrCl, creatinine clearance; ECOG PS, Eastern Cooperative Oncology Group performance status; G-CSF, granulocyte colony-stimulating factor; IV, intravenous; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; NGS, next-generation sequencing; ORR, overall response rate; PO, oral; Q4W, every 4 weeks; Q8W, every 8 weeks; sCR, stringent complete response; VGPR, very good partial response.

RESULTS

Demographic and Clinical Characteristics

- A total of 207 patients were randomized (D-RVd, n=104; RVd, n=103)
- Demographics and baseline clinical characteristics were well balanced between arms (**Table 1**)

Patient Disposition

- At clinical cutoff, after all patients who were still on study treatment had completed ≥12 months of maintenance therapy, median follow-up was 27.4 months
- Most patients entered the maintenance phase (D-RVd, 87%; RVd, 68%)
- Fewer patients discontinued during maintenance in the D-RVd group (12%) versus the RVd group (17%)
- Reasons for discontinuation during maintenance varied between arms (**Table 2**)

Table 2. Reasons for Discontinuation During Maintenance

Patients, n (%)	D-RVd (n = 104)	RVd (n = 103)
Patient who discontinued treatment during maintenance	12 (12)	18 (17)
Adverse event	3 (3)	7 (7)
Withdrawal by patient	1 (1)	3 (3)
Death	1 (1)	1 (1)
Progressive disease	2 (2)	5 (5)
Other	5 (5)	2 (2)

Table 1. Demographic and Clinical Characteristics (ITT)

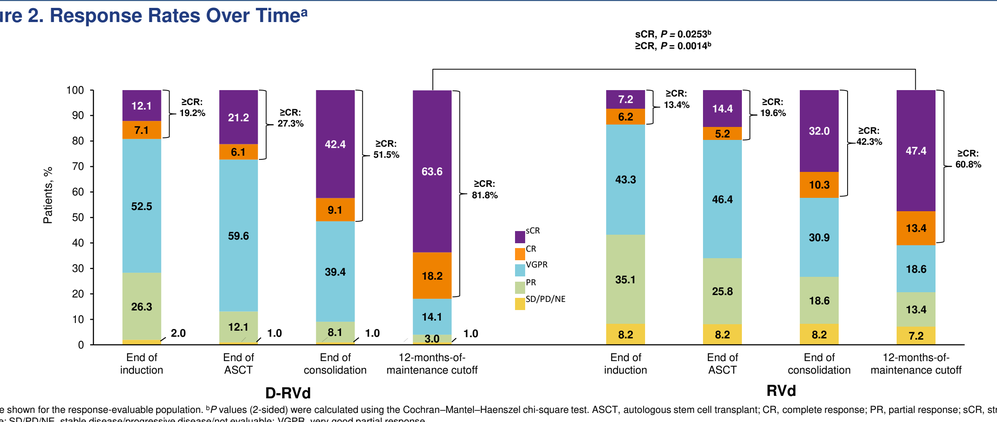
	D-RVd (n = 104)	RVd (n = 103)
Age, years		
Median (range)	59 (29-70)	61 (40-70)
≥65, n (%)	28 (27)	28 (27)
Male, n (%)	58 (56)	60 (58)
ECOG PS score,[a] n (%)	n = 101	n = 102
0	39 (39)	40 (39)
1	51 (50)	52 (51)
2	11 (11)	10 (10)
Baseline CrCl, n (%)		
30-50 mL/min	9 (9)	9 (9)
>50 mL/min	95 (91)	94 (91)
ISS disease stage,[b] n (%)		
I	49 (47)	50 (49)
II	40 (38)	37 (36)
III	14 (13)	14 (14)
Missing	1 (1)	2 (2)
Cytogenetic profile,[c] n (%)	n = 98	n = 97
Standard risk	82 (84)	83 (86)
High risk	16 (16)	14 (14)
Time since MM diagnosis, months	n = 103	n = 102
Median	0.7	0.9

[a]ECOG PS is scored on a scale from 0 to 5, with 0 indicating no symptoms and higher scores indicating increasing disability. [b]The ISS disease stage is based on the combination of serum β2-microglobulin and albumin levels. Higher stages indicate more advanced disease. [c]Cytogenetic risk was assessed by fluorescence in situ hybridization (locally tested) among patients with available cytogenetic risk data; high risk was defined as the presence of del(17p), t(4;14), or t(14;16). CrCl, creatinine clearance; ITT, intent-to-treat; ISS, International Staging System; MM, multiple myeloma.

Efficacy

- Results for end of induction, ASCT, and consolidation are based on a median follow up of 13.5 months at the primary analysis
- Median follow up at 12-months-of-maintenance therapy cutoff was 27.4 months
- sCR rate favored D-RVd versus RVd (42.4% vs 32.0%; 1-sided P=0.0680; **Figure 2**)
- Response rates and depths were greater for D-RVd at all time points

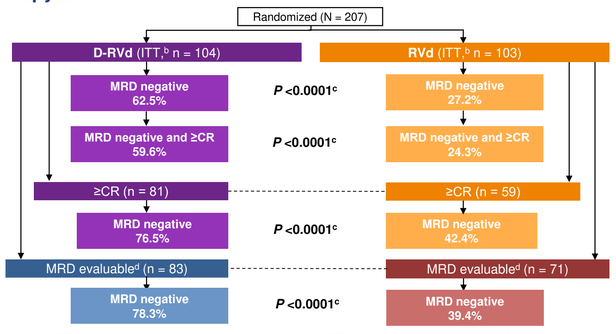
Figure 2. Response Rates Over Time[a]



[a]Data are shown for the response-evaluable population. [b]*P* values (2-sided) were calculated using the Cochran–Mantel–Haenszel chi-square test. ASCT, autologous stem cell transplant; CR, complete response; PR, partial response; sCR, stringent complete response; SD/PD/NE, stable disease/progressive disease/not evaluable; VGPR, very good partial response.

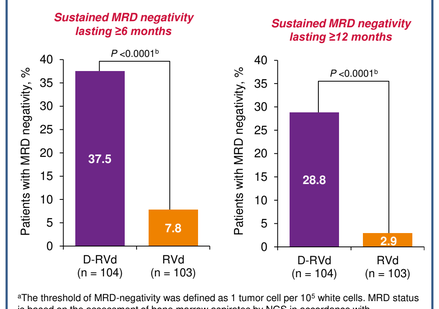
- D-RVd improved MRD-negativity rates versus RVd (**Figure 3**)
- D-RVd improved rates of sustained MRD-negativity versus RVd (**Figure 4**)
  - Among patients who achieved MRD-negative (10^{-5}) status, sustained MRD-negativity lasting ≥12 months was noted in 30/65 (46.2%) and 3/28 (10.7%) patients

Figure 3. MRD (10^{-5}) Negativity[a] at the 12-Months-of-Maintenance Therapy Cutoff



[a]The threshold of MRD negativity was defined as 1 tumor cell per 10^5 white cells. MRD status is based on the assessment of bone marrow aspirates by NGS in accordance with International Myeloma Working Group criteria. Median follow-up was 27.4 months. [b]For the ITT population, patients with a missing or inconclusive assessment were considered MRD positive. [c]*P* values were calculated using the Fisher's exact test. [d]The MRD-evaluable population includes patients who had both baseline (with clone identified/calibrated) and post-baseline MRD (with negative, positive, or indeterminate result) samples taken. CR, complete response; ITT, intent-to-treat; MRD, minimal residual disease; NGS, next-generation sequencing.

Figure 4. Durable MRD (10^{-5}) Negativity[a] Lasting ≥6 and ≥12 Months

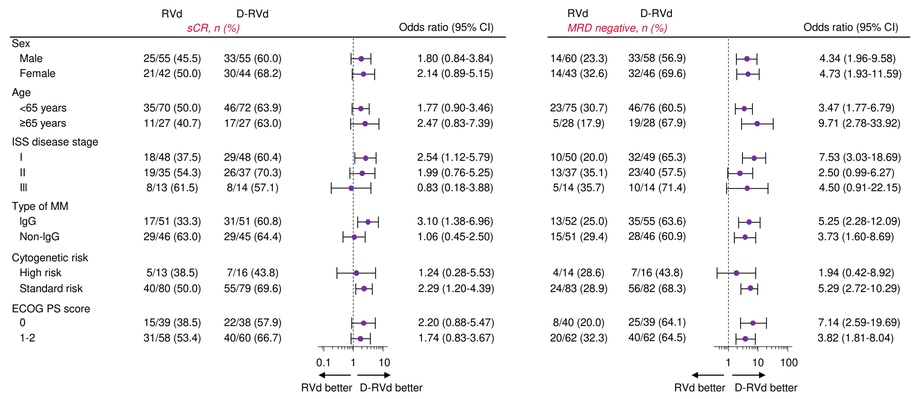


[a]The threshold of MRD-negativity was defined as 1 tumor cell per 10^5 white cells. MRD status is based on the assessment of bone marrow aspirates by NGS in accordance with International Myeloma Working Group criteria. Median follow-up was 27.4 months, and MRD-negativity rates are among the ITT population. [b]*P* values were calculated using the Fisher's exact test. ITT, intent-to-treat; MRD, minimal residual disease; NGS, next-generation sequencing.

RESULTS (CONT.)

- D-RVd improved sCR and MRD-negativity rates across most subgroups (**Figure 5**)

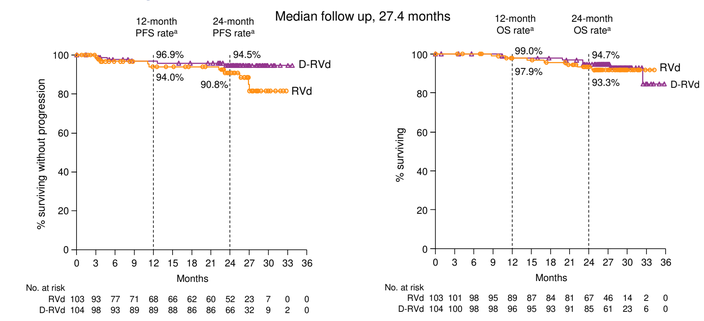
Figure 5. Subgroup Analysis of sCR and MRD-Negativity[a] by the 12-Months-of-Maintenance Therapy Cutoff



[a]The threshold of MRD-negativity was defined as 1 tumor cell per 10^5 white cells. MRD status is based on the assessment of bone marrow aspirates by NGS in accordance with International Myeloma Working Group criteria. Median follow-up was 27.4 months. CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; IgG, immunoglobulin G; ISS, International Staging System; ITT, intent-to-treat; MM, multiple myeloma; MRD, minimal residual disease; NGS, next-generation sequencing; sCR, stringent complete response.

- Median PFS and overall survival (OS) were not reached for D-RVd and RVd (**Figure 6**)

Figure 6. PFS and OS in the ITT Population



[a]Kaplan–Meier estimate. ITT, intent-to-treat; OS, overall survival; PFS, progression-free survival.

Safety

- Higher rates of neutropenia and upper respiratory infections for D-RVd versus RVd did not lead to increased rates of discontinuation

Table 3. Most Common TEAEs[a]

Most common, n (%)[a]	D-RVd (n = 99)		RVd (n = 102)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Hematologic				
Neutropenia	60 (61)	43 (43)	40 (39)	24 (24)
Thrombocytopenia	44 (44)	15 (15)	36 (35)	9 (9)
Leukopenia	38 (38)	16 (16)	30 (29)	8 (8)
Anemia	37 (37)	9 (9)	33 (32)	6 (6)
Nonhematologic				
Fatigue	70 (71)	6 (6)	63 (62)	6 (6)
Upper respiratory tract infection	67 (68)	5 (5)	51 (50)	2 (2)
Peripheral neuropathy[b]	64 (65)	7 (7)	81 (79)	8 (8)
Diarrhea	64 (65)	7 (7)	55 (54)	5 (5)
Cough	53 (54)	0	31 (30)	0
Nausea	51 (52)	2 (2)	51 (50)	1 (1)
Constipation	51 (52)	2 (2)	42 (41)	1 (1)
Pyrexia	45 (45)	3 (3)	31 (30)	3 (3)
Insomnia	44 (44)	2 (2)	31 (30)	1 (1)
Back pain	39 (39)	2 (2)	35 (34)	4 (4)
Edema peripheral	36 (36)	2 (2)	36 (35)	3 (3)
Arthralgia	36 (36)	1 (1)	35 (34)	2 (2)
Infusion-related reaction[c]	43 (43)	6 (6)	—	—

[a]Any grade TEAEs that occurred in ≥30% of patients in either group are listed. The safety analysis population included all randomized patients who received ≥1 dose of the study treatment; analysis was according to treatment received. [b]Includes patients with neuropathy peripheral and peripheral sensory neuropathy. [c]No grade 4 infusion-related reactions were reported. TEAE, treatment-emergent adverse event.

- Similar rates of any grade and grade 3/4 infections occurred for D-RVd vs RVd (**Table 4**)

Table 4. Most Common Infections with First Onset during Maintenance Therapy (Cycles 7+)[a]

Patients, n (%)	D-RVd (D-R maintenance, n=89)		RVd (R maintenance, n=71)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Most common (>5%) infections				
Upper respiratory tract infection	47 (53)	4 (4)	29 (41)	2 (3)
Pneumonia	12 (13)	5 (6)	11 (15)	9 (13)
Sinusitis	9 (10)	0	7 (10)	0
Influenza	9 (10)	0	5 (7)	0
Nasopharyngitis	9 (10)	0	1 (1)	0
Urinary tract infection	8 (9)	0	1 (1)	0
Bronchitis	7 (8)	1 (1)	5 (7)	1 (1)
Cellulitis	7 (8)	1 (1)	2 (3)	1 (1)

[a]Any grade TEAEs that occurred in >5% of patients in either group are listed. The safety analysis population included all randomized patients who received ≥1 dose of the study treatment; analysis was according to treatment received. TEAE, treatment-emergent adverse event.

CONCLUSIONS

- D-RVd followed by D-R maintenance significantly improved response rates and depth of response versus RVd followed by R maintenance
- D-R maintenance therapy improved depth of response and maintained remissions
  - sCR and MRD-negativity rates improved with maintenance therapy
- The overall safety profile of D-RVd is consistent with previous reports of daratumumab plus standard of care
- Estimated PFS and OS rates at 24 months in the D-RVd group are promising
  - Durability of PFS and OS benefits are suggested by the GRIFFIN safety run-in cohort (>40 months median follow up)
- The ongoing phase 3 PERSEUS study is evaluating daratumumab subcutaneous plus RVd in transplant-eligible patients
- These results support D-RVd as a potential new standard of care for transplant-eligible NDMM

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