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August 26, 2021

Kristina Gregory, MSN;RN
3025 Chemical Road
Plymouth Meeting, PA 19462
USA

Dear Ms. Gregory,

Please consider the following information.

Response(s):

- DARZALEX - Compendia Communication - NCCN - Use of DARZALEX in Combination with Lenalidomide and Dexamethasone Overall Survival- August 2021
- Overall survival results with daratumumab, lenalidomide, and dexamethasone versus lenalidomide and dexamethasone in transplant-ineligible newly diagnosed multiple myeloma: phase 3 MAIA study

I look forward to working with you as you consider the enclosed information. The information provided is not intended as an endorsement of any usage not contained in the Prescribing Information. For complete information, please refer to the full Prescribing Information, including the following sections: INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and ADVERSE REACTIONS.

If you require further information, please feel free to contact me via the Janssen Medical Information Center at 1-800-JANSSEN (1-800-526-7736).

Sincerely,

Rachael Lai, PharmD
Medical Information Fellow

Inquiry #:02483897

Enclosure(s)/Electronic Link(s):

- DARZALEX® (daratumumab) Prescribing Information at https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-dc33e1e3-dde0-4c18-b1e3-a3a79c07d600
- DARZALEX Prescribing Information

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DARZALEX® (daratumumab)
Compendia Communication – NCCN – Use of DARZALEX in Combination with Lenalidomide and Dexamethasone Overall Survival – August 2021

Name: Lori Hopkins, PharmD
Company/Organization: Janssen Biotech, Inc.
Address: 850 Ridgeview Drive Horsham, PA 19044
Phone: 215-325-2280
E-mail: LHopkin1@its.jnj.com
Date of request: August 26, 2021
NCCN Guidelines® Panel: Multiple Myeloma

Dear NCCN,

On behalf of Janssen Biotech, Inc., I respectfully request that the NCCN Guidelines® - Multiple Myeloma Panel review the enclosed data regarding the overall survival (OS) results with the use of DARZALEX® (daratumumab) in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma (NDMM) who are transplant ineligible.

Specific Change Requested: We request a change to the Guidelines and compendium monograph to remove the footnote "j: This is the only regimen shown to have overall survival benefit" (MYEL-G 2 of 4, Version 1.2022).

FDA Clearance: The FDA has approved DARZALEX® (daratumumab) for the treatment of adult patients with multiple myeloma (1) in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for autologous stem cell transplant and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy, (2) in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for autologous stem cell transplant, (3) in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant, (4) in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy, (5) in combination with carfilzomib and dexamethasone in patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy, (6) in combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor (PI), and (7) as monotherapy, in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.[1]

Rationale: Updated efficacy and safety results from a prespecified interim OS analysis of MAIA after a median follow-up of 56.2 months demonstrated an OS benefit for DARZALEX (daratumumab) in combination with lenalidomide and dexamethasone (D-Rd), with estimated 5-year OS rates of 66.3% in the D-Rd arm and 53.1% in the lenalidomide and dexamethasone (Rd) arm (HR, 0.68; 95% CI, 0.53-0.86; P=0.0013).

MAIA (54767414MMY3008) Study

MAIA[2] is an ongoing, international, phase 3, randomized, open-label, active-controlled, multicenter study evaluating the efficacy and safety of D-Rd compared to Rd in transplant-ineligible NDMM patients. Efficacy and safety results from the MAIA study were previously published in *The New England Journal of Medicine* and included in our previous submission.

Facon et al[3] presented an approximately 5-year update of efficacy and safety of the MAIA study at the 2021 European Hematology Association (EHA) Congress. The estimated 5-year

OS rate was 66.3% in the D-Rd arm and 53.1% in the Rd arm (HR, 0.68; 95% CI, 0.53-0.86; *P*=0.0013). The estimated 5-year progression-free survival (PFS) rate was 52.5% in the D-Rd arm and 28.7% in the Rd arm. No new safety concerns were identified with continuous therapy and longer follow-up. Among the most common grade 3/4 (>5%) treatment-emergent adverse events (TEAEs) were: neutropenia (D-Rd: 54%, Rd: 37%) and pneumonia (D-Rd: 19%, Rd: 11%). Complete efficacy and safety results from the MAIA OS study have been accepted to *Lancet Oncology* and the manuscript is pending publication.

The following oral presentation is submitted with the Full Prescribing Information.

- Facon T, Kumar SK, Plesner T, et al. Overall survival results with daratumumab, lenalidomide, and dexamethasone versus lenalidomide and dexamethasone in transplant-ineligible newly diagnosed multiple myeloma: phase 3 MAIA study. Oral Presentation presented at: European Hematology Association (EHA) Congress; June 9-17, 2021; Virtual.
- DARZALEX (daratumumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-dc33e1e3-dde0-4c18-b1e3-a3a79c07d600.

If you require further information, please feel free to contact me via the Janssen Medical Information Center at 1-800-JANSSEN (1-800-526-7736).

Sincerely,
Lori Hopkins, PharmD
Associate Director, Medical Information and Knowledge Integration
Janssen Scientific Affairs, LLC

REFERENCES

1. DARZALEX (daratumumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc.; https://imedicalknowledge.veevavault.com/ui/approved_viewer?token=7994-dc33e1e3-dde0-4c18-b1e3-a3a79c07d600.
2. Facon T, Kumar S, Plesner T, et al. Daratumumab plus lenalidomide and dexamethasone for untreated myeloma. N Engl J Med. 2019;380(22):2104-2115.
3. Facon T, Kumar SK, Plesner T, et al. Overall survival results with daratumumab, lenalidomide, and dexamethasone versus lenalidomide and dexamethasone in transplant-ineligible newly diagnosed multiple myeloma: phase 3 MAIA study. Oral Presentation presented at: European Hematology Association (EHA) Congress; June 9-17, 2021; Virtual.

Connecting Hematology - For Clinical and Research Excellence

OVERALL SURVIVAL RESULTS WITH DARATUMUMAB, LENALIDOMIDE, AND DEXAMETHASONE VERSUS LENALIDOMIDE AND DEXAMETHASONE IN TRANSPLANT-INELIGIBLE NEWLY DIAGNOSED MULTIPLE MYELOMA: PHASE 3 MAIA STUDY

Thierry Facon,[1,*] Shaji K. Kumar,[2] Torben Plesner,[3] Robert Z. Orlowski,[4] Philippe Moreau,[5] Nizar Bahlis,[6] Supratik Basu,[7] Hareth Nahi,[8] Cyrille Hulin,[9] Hang Quach,[10] Hartmut Goldschmidt,[11] Michael O'Dwyer,[12] Aurore Perrot,[13] Christopher P. Venner,[14] Katja Weisel,[15] Joseph R. Mace,[16] Noopur Raje,[17] Mourad Tiab,[18] Margaret Macro,[19] Laurent Frenzel,[20] Xavier Leleu,[21] Tahamtan Ahmadi,[22] Jianping Wang,[23] Rian Van Rampelbergh,[24] Clarissa M. Uhlar,[25] Brenda Tromp,[26] Maria Delioukina,[25] Jessica Vermeulen,[26] Saad Z. Usmani[27]

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*Presenting author.

Disclosures

Thierry Facon, University of Lille, CHU Lille, Service des Maladies du Sang, Lille, France

- Any compensation received was provided directly to CHU Lille
  - Speakers bureaus: Janssen, Bristol Myers Squibb, Takeda
  - Advisory boards: Janssen, Bristol Myers Squibb, Takeda, Sanofi, Roche, Karyopharm, Oncopeptides, Amgen

Introduction

- The phase 3 ALCYONE, MAIA, and CASSIOPEIA studies established the PFS benefit of daratumumab (DARA) in combination with standard of care versus standard of care alone for patients with NDMM[1-3]; ALCYONE also established, for the first time, an OS benefit of a DARA-based regimen in NDMM[4]
- The phase 3 SWOG S0777 study in patients with NDMM without intent for immediate transplant (69% of whom were intended for eventual transplant) established VRd as a standard-of-care regimen for elderly patients[5]
  - At a median follow-up of 84 months, median PFS was 41 months for VRd and 29 months for Rd (HR, 0.742); median OS was not reached versus 69 months (HR, 0.709)[6]
  - 43% of patients in SWOG S0777 were ≥65 years (vs 99% in MAIA); however, a significant OS benefit in this subgroup was not observed for VRd versus Rd (median, 65 months vs 56 months; HR, 0.769; *P* = 0.168)[6]
- Real-world data indicate that >50% of nontransplant elderly patients with NDMM do not receive any subsequent therapy, suggesting that the most effective therapy should be used upfront and not saved for relapse,[7] at which time additional genetic mutations conferring resistance may have been acquired[8]
- In the last MAIA update (Kumar SK, et al. ASH 2020), D-Rd prolonged PFS and PFS2 versus Rd alone; OS data were not yet mature[9]

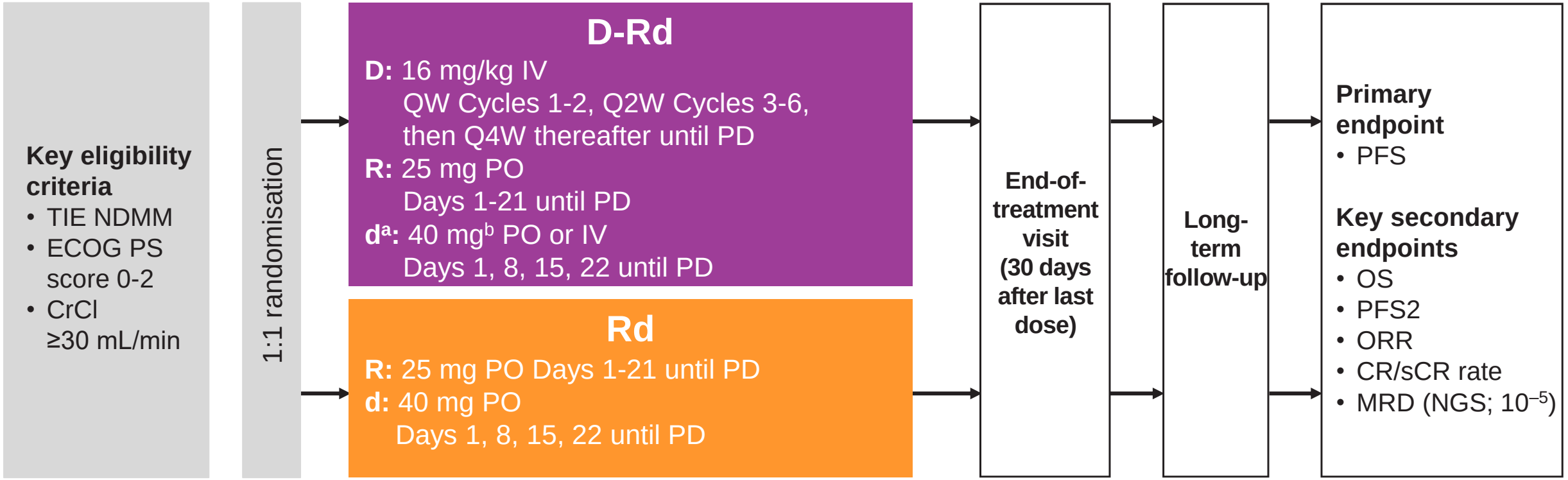
Here, we report updated efficacy and safety results from a prespecified interim OS analysis of MAIA after a median follow-up of approximately 56 months

PFS, progression-free survival; NDMM, newly diagnosed multiple myeloma; OS, overall survival; VRd, bortezomib/lenalidomide/dexamethasone; Rd, lenalidomide/dexamethasone; HR, hazard ratio; D-Rd, daratumumab plus lenalidomide/dexamethasone; PFS2, progression-free survival on the next subsequent line of therapy.

1. Mateos MV, et al. *N Engl J Med*. 2018;378(6):518-528. 2. Facon T, et al. *N Engl J Med*. 2019;380(22):2104-2115. 3. Moreau P, et al. *Lancet*. 2019;394(10192):29-38. 4. Mateos MV, et al. *Lancet Oncol*. 2020;21(4):565-578. 5. Durie BGM, et al. *Lancet*. 2017;389(10068):519-527. 6. Durie BGM, et al. *Blood Cancer J*. 2020;10(5):53. 7. Fonseca R, et al. *BMC Cancer*. 2020;20(1):1087. 8. Suzuki K, et al. *Cancers (Basel)*. 2021;13(2):215. 9. Kumar SK, et al. *Blood*. 2020;136(suppl 1):24-26.

Study Design

– Patients were enrolled in MAIA from March 2015 through January 2017



Cycles: 28 days

MAIA is a multicentre, randomised, open-label, active-controlled, phase 3 study of D-Rd versus Rd alone in patients with NDMM who are transplant ineligible

TIE, transplant-ineligible; ECOG PS, Eastern Cooperative Oncology Group performance status; CrCl, creatinine clearance; IV, intravenous; QW, once weekly; Q2W, once every 2 weeks; Q4W, once every 4 weeks; PD, progressive disease; PO, oral; ORR, overall response rate; CR, complete response; sCR, stringent complete response; MRD, minimal residual disease; NGS, next-generation sequencing; BMI, body mass index.

[a]On days that D-Rd 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. [b]For patients >75 years of age or with BMI <18.5 kg/m^2, dexamethasone was administered at a dose of 20 mg QW.

Demographics 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)	4 (1)
65-<70	74 (20)	73 (20)
70-<75	130 (35)	131 (36)
≥75	160 (43)	161 (44)
ECOG PS score, n (%)		
0	127 (35)	123 (33)
1	178 (48)	187 (51)
2[a]	63 (17)	59 (16)
ISS stage, n (%)		
I	98 (27)	103 (28)
II	163 (44)	156 (42)
III	107 (29)	110 (30)

	D-Rd (n = 368)	Rd (n = 369)
Type of measurable disease, n (%)		
IgG	225 (61)	231 (63)
IgA	65 (18)	66 (18)
Other[b]	9 (2)	10 (3)
Detected in urine only	40 (11)	34 (9)
Detected as serum-free light chain only	29 (8)	28 (8)
Cytogenetic profile, n/total n (%)		
Standard risk	271/319 (85)	279/323 (86)
High risk	48/319 (15)	44/323 (14)
Median time since initial diagnosis of MM (range), months	0.95 (0.1-13.3)	0.89 (0-14.5)

Demographics and baseline characteristics were well balanced between arms

ISS, International Staging System; MM, multiple myeloma.
[a]2 patients had an ECOG PS score of 3 at baseline (1 patient in each arm with an ECOG PS score of 3 and 4). [b]Includes IgD, IgE, IgM, and biclonal.
Note: percentages may not add up to 100% due to rounding.

Treatment Exposure and Patient Disposition

Median duration of follow-up, 56.2 months

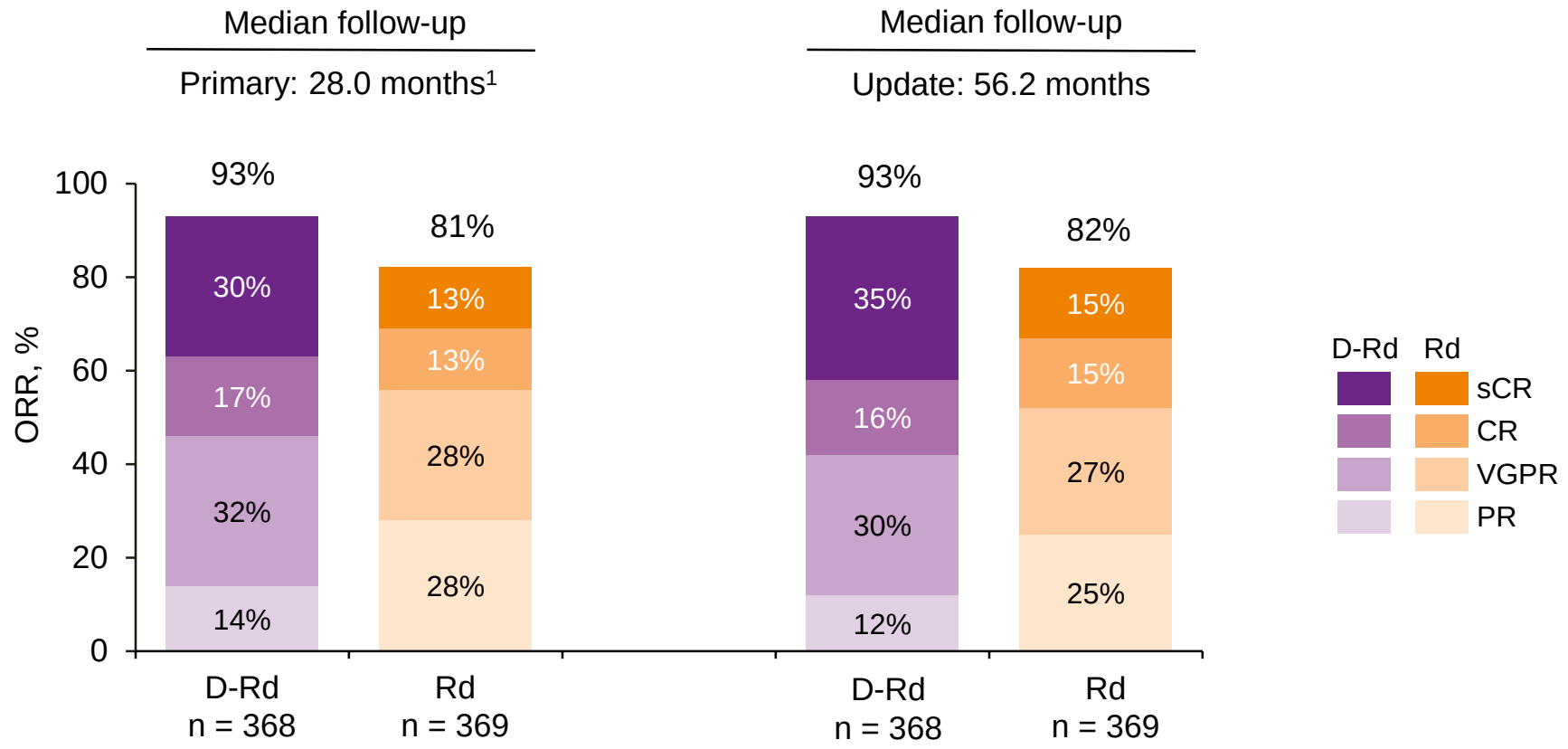
Safety population (received ≥1 dose of study treatment)	D-Rd (n = 364)	Rd (n = 365)
Median duration of study treatment, months (range)	47.5 (0.10-69.26)	22.6 (0.03-69.22)
Lenalidomide median RDI, % (range)	66 (8-206)	86 (5-239)
Discontinued lenalidomide only while continuing other study treatment, n (%)	33 (9)	14 (4)
Intravenous daratumumab median RDI, % (range)	98 (3-107)	–
Discontinued daratumumab only while continuing other study treatment, n (%)	5 (1)	–

ITT population	D-Rd (n = 368)	Rd (n = 369)
Remaining on study treatment, %	42	18
Discontinued study treatment, %	57	81
Progressive disease	27	34
Adverse event	13	23
Death	7	7
Noncompliance with study drug	5	8
Physician decision	4	6
Other	1	1
Lost to follow-up	<1	1
Patient withdrawal	0	2

42% of patients in the D-Rd arm and 18% of patients in the Rd arm remained on treatment; more patients discontinued Rd for AEs

RDI, relative dose intensity; ITT, intent-to-treat.
Note: percentages may not add up to 100% due to rounding.

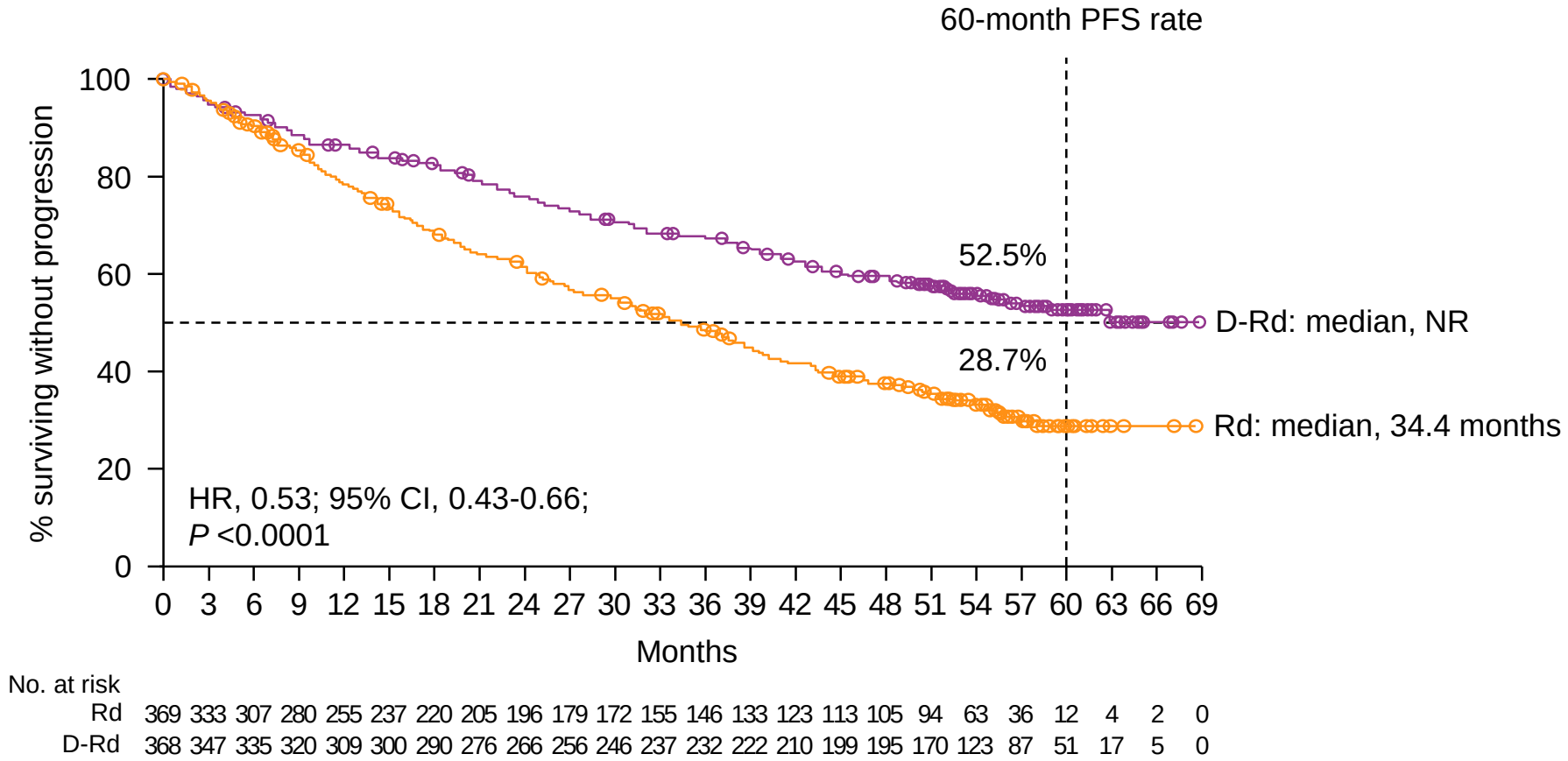
ORR[a]



- **D-Rd induced deeper responses with significantly higher rates of ≥CR and ≥VGPR, compared with Rd**
  - **With >28 months of additional follow-up, responses deepened with continued DARA therapy**

VGPR, very good partial response; PR, partial response.
[a]ITT population.
1. Facon T, et al. *N Engl J Med*. 2019;380(22):2104-2115.
Note: percentages may not add up to the total due to rounding.

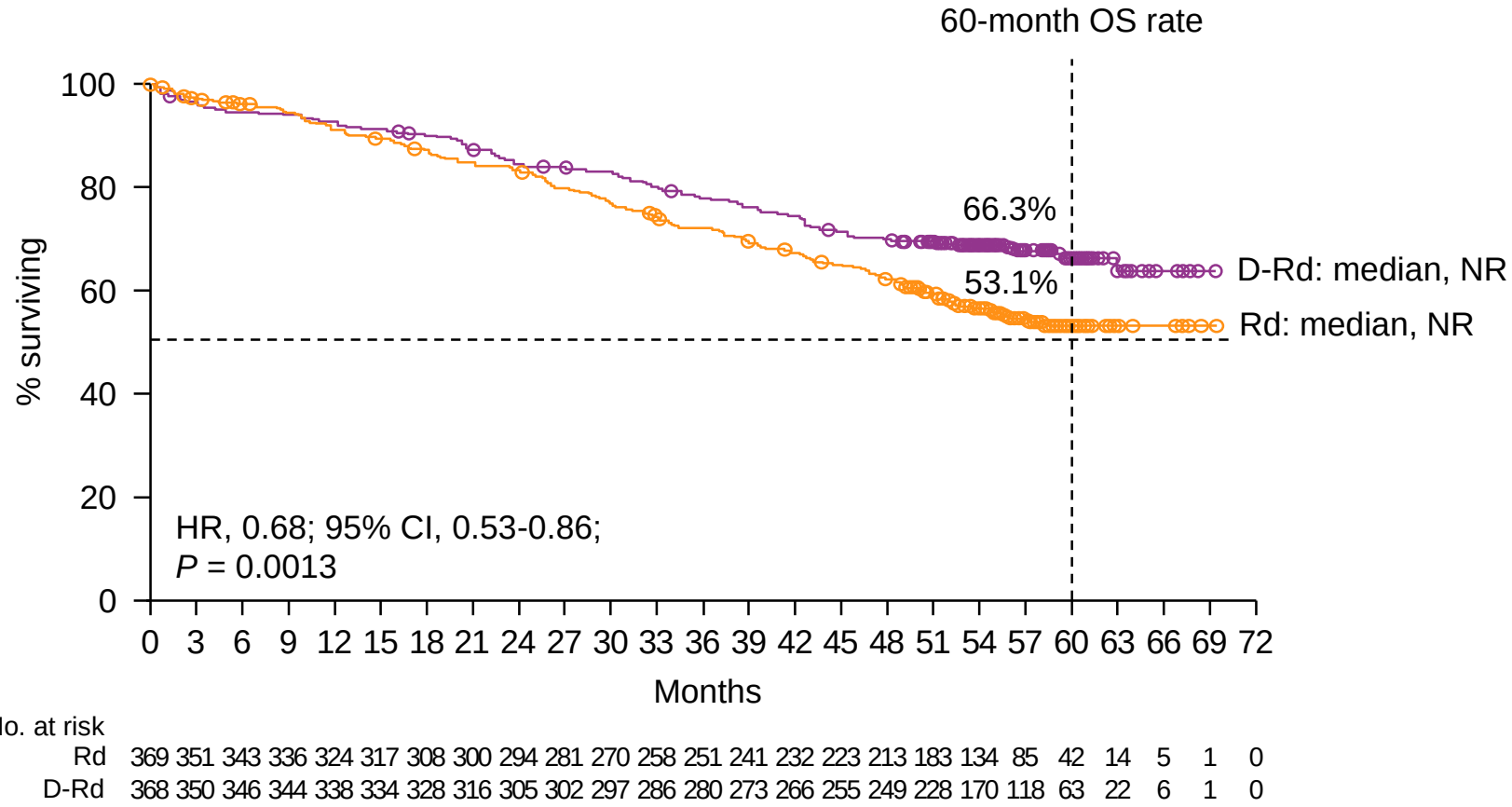
Updated PFS



- D-Rd continued to demonstrate a significant PFS benefit, with median PFS not reached with D-Rd
- These data provide a new PFS benchmark in patients with NDMM who are transplant ineligible

NR, not reached; CI, confidence interval.

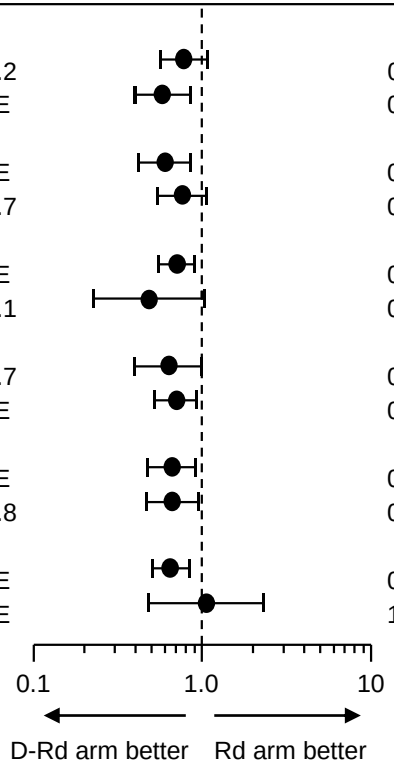
OS

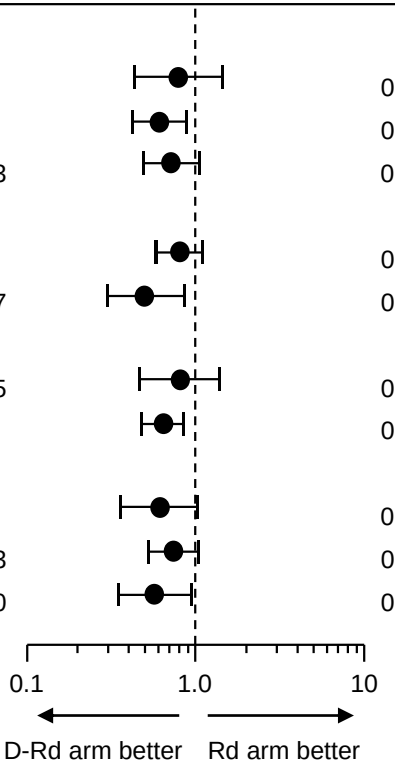


D-Rd demonstrated a significant benefit in OS, with a 32% reduction in the risk of death, in patients with NDMM who are transplant ineligible

Subgroup Analysis of OS

	D-Rd No. of deaths/ total no.	Rd No. of deaths/ total no.	D-Rd Median OS (months)	Rd Median OS (months)	HR (95% CI)
Sex					
Male	71/189	88/195	NE	57.2	0.78 (0.57-1.06)
Female	46/179	68/174	NE	NE	0.58 (0.40-0.84)
Age					
<75 years	52/208	80/208	NE	NE	0.60 (0.42-0.85)
≥75 years	65/160	76/161	NE	55.7	0.76 (0.55-1.06)
Race					
White	106/336	138/339	NE	NE	0.71 (0.55-0.91)
Other	11/32	18/30	NE	49.1	0.48 (0.23-1.03)
Region					
North America	33/101	46/102	NE	55.7	0.63 (0.40-0.98)
Other	84/267	110/267	NE	NE	0.70 (0.53-0.93)
Baseline renal function (CrCl)					
>60 mL/min	59/206	89/227	NE	NE	0.66 (0.48-0.92)
≤60 mL/min	58/162	67/142	NE	54.8	0.67 (0.47-0.96)
Baseline hepatic function					
Normal	104/335	144/340	NE	NE	0.65 (0.51-0.84)
Impaired	13/31	12/29	NE	NE	1.05 (0.48-2.30)
ISS disease stage					
I	19/98	24/103	NE	NE	0.79 (0.43-1.44)
II	50/163	69/156	NE	NE	0.61 (0.42-0.88)
III	48/107	63/110	62.8	47.3	0.72 (0.49-1.04)
Type of MM					
IgG	74/225	90/231	NE	NE	0.80 (0.59-1.09)
Non-IgG	22/74	37/76	NE	53.7	0.50 (0.30-0.86)
Cytogenetic risk at study entry					
High risk	25/48	26/44	55.6	42.5	0.80 (0.46-1.39)
Standard risk	80/271	116/279	NE	NE	0.64 (0.48-0.85)
ECOG PS score					
0	24/127	36/123	NE	NE	0.61 (0.36-1.02)
1	64/178	82/187	NE	58.3	0.74 (0.53-1.03)
≥2	29/63	38/59	62.8	39.0	0.57 (0.35-0.94)





OS benefit with D-Rd was generally consistent across patient subgroups

NE, not estimable; CrCl, creatinine clearance.

Subsequent Therapy

- Median time to next treatment was not reached with D-Rd versus 42.4 months with Rd (HR, 0.47; 95% CI, 0.37-0.59; *P* <0.0001)
- 114 patients in the D-Rd arm and 186 patients in the Rd arm received subsequent therapy; of these:
  - A PI-containing regimen without an IMiD was the most common first subsequent therapy (53% vs 54% with D-Rd and Rd, respectively)
  - 15% of patients in the D-Rd arm and 46% of patients in the Rd arm received daratumumab as any subsequent therapy

PI, proteasome inhibitor; IMiD, immunomodulatory drug.

Most Common Grade 3/4 (>5%) TEAEs[a]

	D-Rd (n = 364)	Rd (n = 365)
Haematologic, n (%)		
Neutropenia	197 (54)	135 (37)
Anaemia	61 (17)	79 (22)
Lymphopenia	60 (16)	41 (11)
Leukopenia	42 (12)	23 (6)
Thrombocytopenia	32 (9)	34 (9)
Nonhaematologic, n (%)		
Pneumonia	70 (19)	39 (11)
Hypokalaemia	46 (13)	36 (10)
Cataract	40 (11)	39 (11)
Diarrhoea	32 (9)	22 (6)
Fatigue	32 (9)	17 (5)
Hypertension	31 (9)	16 (4)
Hyperglycaemia	28 (8)	14 (4)
Pulmonary embolism	26 (7)	19 (5)
Asthenia	19 (5)	17 (5)
Acute kidney injury	19 (5)	12 (3)
Chronic kidney disease	19 (5)	10 (3)

- A lower percentage of grade 3/4 and serious TEAEs occurred after 24 months versus during the first 24 months of treatment in both arms

No new safety concerns were identified with longer follow-up

TEAE, treatment-emergent adverse event
[a]Median duration of study treatment was 47.5 months in the D-Rd arm and 22.6 months in the Rd arm. Data are not exposure adjusted.

Conclusions

- After almost 5 years of follow-up, a significant OS benefit of D-Rd versus Rd given to progression was demonstrated in patients with transplant-ineligible NDMM, representing a 32% reduction in the risk of death
  - The estimated 5-year OS rate was 66.3% with D-Rd and 53.1% with Rd, which will likely lead to a substantial improvement of median OS in this patient population
- The significant PFS benefit of D-Rd versus Rd was maintained, with a 47% reduction in risk of disease progression or death (median PFS for D-Rd, not reached)
  - The estimated 5-year PFS rate was 52.5% with D-Rd and 28.7% with Rd
  - These data provide a new PFS benchmark in patients with NDMM who are transplant ineligible
- These PFS and OS results have been achieved in a study population with 44% of patients aged 75 to 90 years
- No new safety concerns were identified with continuous therapy and longer follow-up

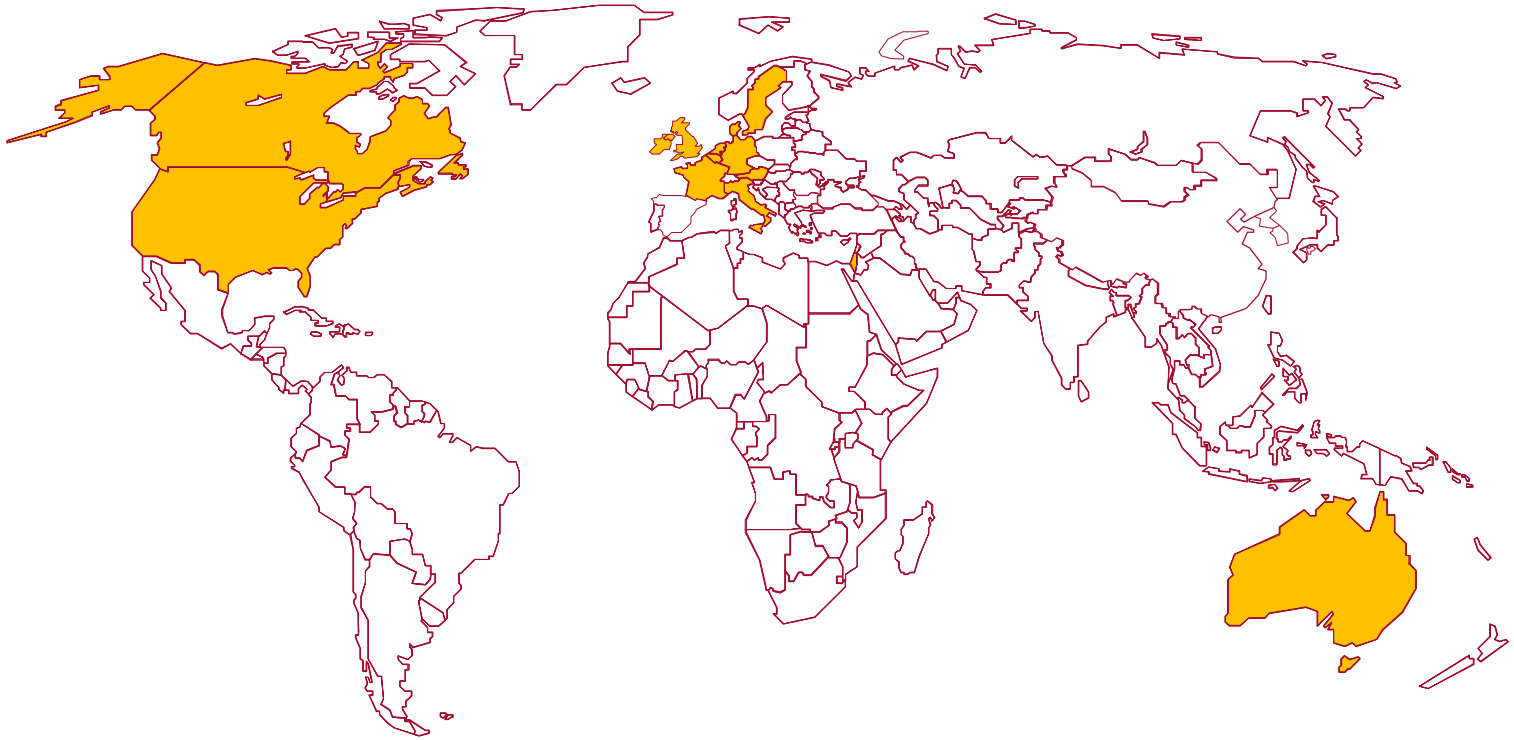
These results strongly support upfront D-Rd as a new standard of care for patients with transplant-ineligible NDMM

Acknowledgements

- Patients who participated in this study
- All investigators who contributed to the study
  - Intergroupe Francophone du Myélome
- Staff members at the study sites
- Data and safety monitoring committee
- Staff members involved in data collection and analyses

MAIA

14 countries



- Other ongoing frontline registration daratumumab studies include:
  - Transplant ineligible: CEPHEUS (D-VRd)
  - Transplant eligible: PERSEUS (D-VRd)

D-VRd, daratumumab plus bortezomib/lenalidomide/dexamethasone.
This study (ClinicalTrials.gov Identifier: NCT02252172) was sponsored by Janssen Research & Development, LLC.
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