Long-Term Outcomes With Daratumumab, Bortezomib, Lenalidomide, and Dexamethasone (DVRd) Versus VRd in Transplant-Eligible Newly Diagnosed Multiple Myeloma (TE-NDMM) in the Phase 3 PERSEUS Study

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Presented by P Sonneveld at the 23rd International Myeloma Society (IMS) Annual Meeting & Exposition; September 23–26, 2026; Glasgow, Scotland

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Disclosures

COI statement of the presenting author

- **Research funding:** Amgen, BMS, Celgene, Johnson & Johnson, Karyopharm Therapeutics
- **Consulting/advisory role:** Amgen, BMS, Celgene, Johnson & Johnson, Karyopharm Therapeutics, Pfizer

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PERSEUS: Introduction

- PERSEUS established DVRd induction/consolidation followed by DR maintenance as a standard of care in TE-NDMM, improving depth of response and PFS versus VRd followed by R maintenance[1]

- A projected PFS of 17.1 years (range, 13.2–21.2) with DVRd-DR suggests some patients may remain progression-free for prolonged periods; projections used NICE survival extrapolation guidance, capped by general population mortality data

- This long-term analysis provides almost 7 years of median follow-up and evaluates whether deeper and more sustained MRD-negativity rates translate into durable PFS and PFS2 benefit after protocol-defined MRD-guided daratumumab discontinuation

DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; NICE, National Institute for Health and Care Excellence; PFS, progression-free survival; PFS2, progression-free survival on next line of therapy; R, lenalidomide; VRd, bortezomib, lenalidomide, and dexamethasone; TE-NDMM, transplant-eligible newly diagnosed multiple myeloma.

1. Sonneveld P, et al. *N Engl J Med.* 2024;390(4):301-313.

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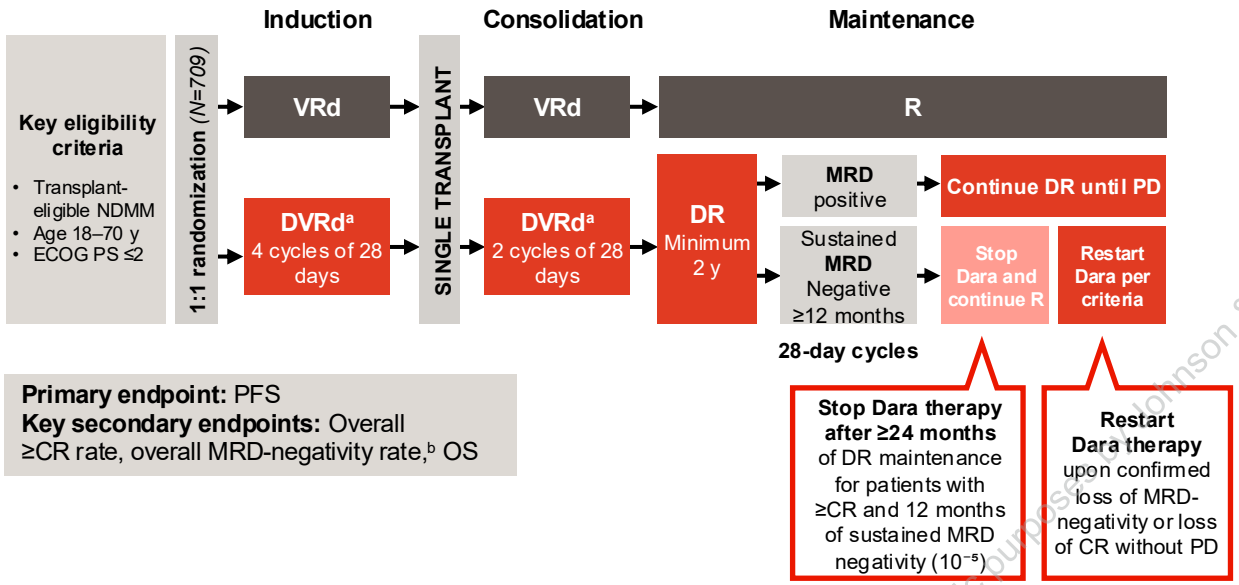
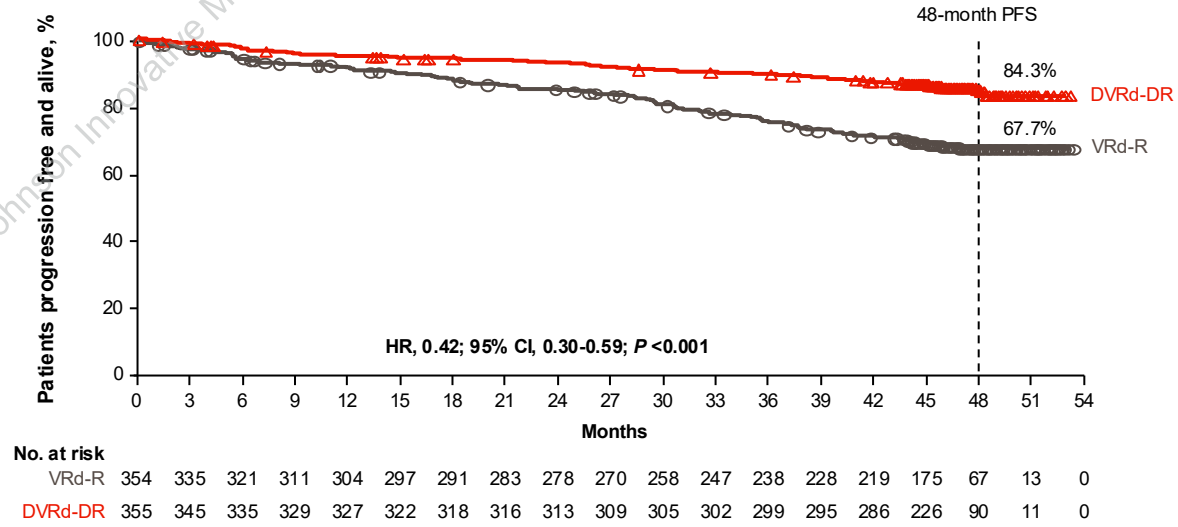
PERSEUS: DVRd-ASCT-DR as Standard of Care



Primary endpoint: PFS
Key secondary endpoints: Overall ≥CR rate, overall MRD-negativity rate,[b] OS

Median follow-up (primary analysis[c]): 47.5 months



58% reduction in the risk of progression or death in patients receiving DVRd

This long-term PFS analysis reports outcomes with ~3 years (34 months) of additional follow-up

[a]Dara 1,800 mg co-formulated with rHuPH20 (2,000 U/mL; ENHANZE® drug delivery technology, Halozyme, Inc., San Diego, CA, USA). [b]MRD was assessed using the clonoSEQ assay (v.2.0; Adaptive Biotechnologies, Seattle, WA, USA) in patients with ≥VGPR post-consolidation and at the time of suspected ≥CR. Overall MRD-negativity rate: proportion of patients who achieved both MRD negativity (10^{-5} threshold) and ≥CR at any time. [c]Primary analysis clinical cutoff was August 1, 2023.
≥CR, complete response or better; Dara, daratumumab; DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; IMS/IMWG, International Myeloma Society/International Myeloma Working Group; ISS, International Staging System; IV, intravenous; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma;
NGS, next-generation sequencing; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PO, oral; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; ≥VGPR, very good partial response or better; VRd, bortezomib, lenalidomide, and dexamethasone; y, years. Sonneveld P, et al. *N Engl J Med*. 2024;390(4):301-313.

PERSEUS: Disposition and Treatment Exposure

Disposition

n (%)	DVRd-DR (n=355)	VRd-R (n=354)
End of study		
Discontinued study	71 (20.0)	106 (29.9)
Reason for discontinuation (≥5%)		
Death	51 (14.4)	84 (23.7)
End of treatment[a]		
Still on treatment[a]	216 (61.5)	88 (25.4)
Discontinued treatment[a]	135 (38.5)	259 (74.6)
Reason for discontinuation (≥5%)		
Adverse event	47 (13.4)	109 (31.4)
Progressive disease	43 (12.3)	94 (27.1)
Subject refused further study treatment	19 (5.4)	23 (6.6)

Treatment exposure

	DVRd-DR (n=355)	VRd-R (n=354)
Treatment duration, months, median (range)		
Total	68.7 (0.49–88.25)	42.2 (0.07–87.72)
Maintenance	63.8 (0.03–78.98)	39.8 (0.16–78.26)
Treatment cycles, n, median (range)		
Total	67.0 (1–92)	39.0 (1–91)
Maintenance	61.5 (1–86)	42.0 (1–85)

After almost 7 years of median follow-up, median duration of exposure was over 2 years longer in the DVRd-DR arm

[a]Percentages are calculated based on the number of subjects treated: DVRd-DR, n=351; VRd-R, n=347.
Median follow-up: 81.3 (0.03–88.3) months.
DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; R, lenalidomide; VRd, bortezomib, lenalidomide, and dexamethasone.

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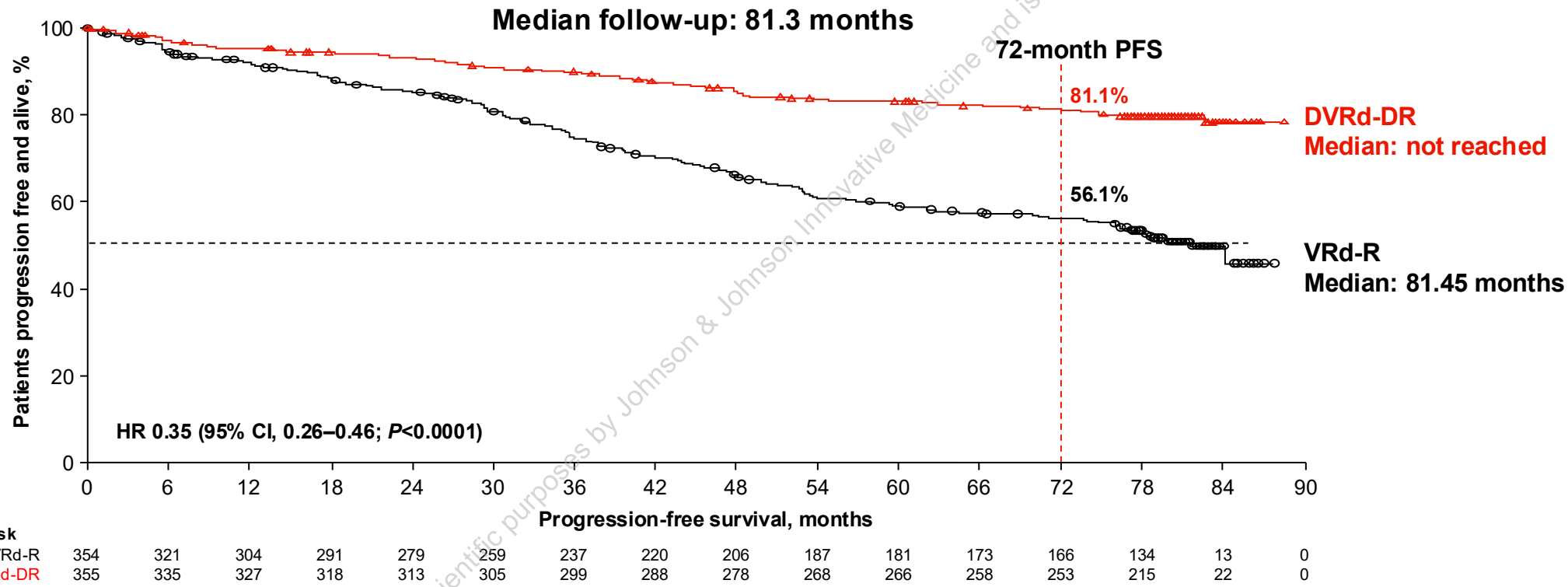
PERSEUS: Long-Term Progression-Free Survival



PFS benefit continued to favor DVRd-DR versus VRd-R; 72-month PFS rates were higher with DVRd-DR vs VRd-R (81.1% vs 56.1%)

Nominal 2-sided *P*-values reported are not adjusted for multiplicity. DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; PFS, progression-free survival; R, lenalidomide; VRd, bortezomib, lenalidomide, and dexamethasone.

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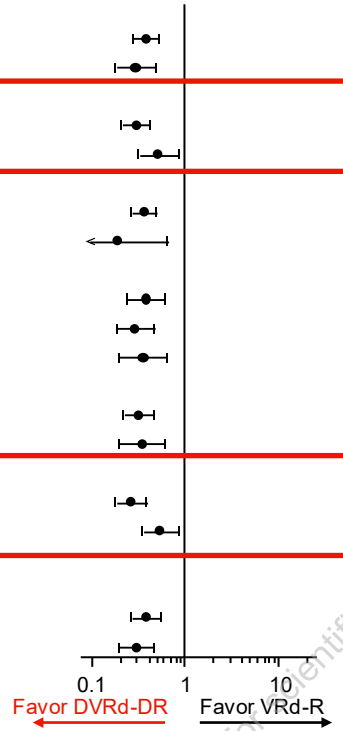
PERSEUS: Progression-Free Survival in Clinically Relevant Subgroups

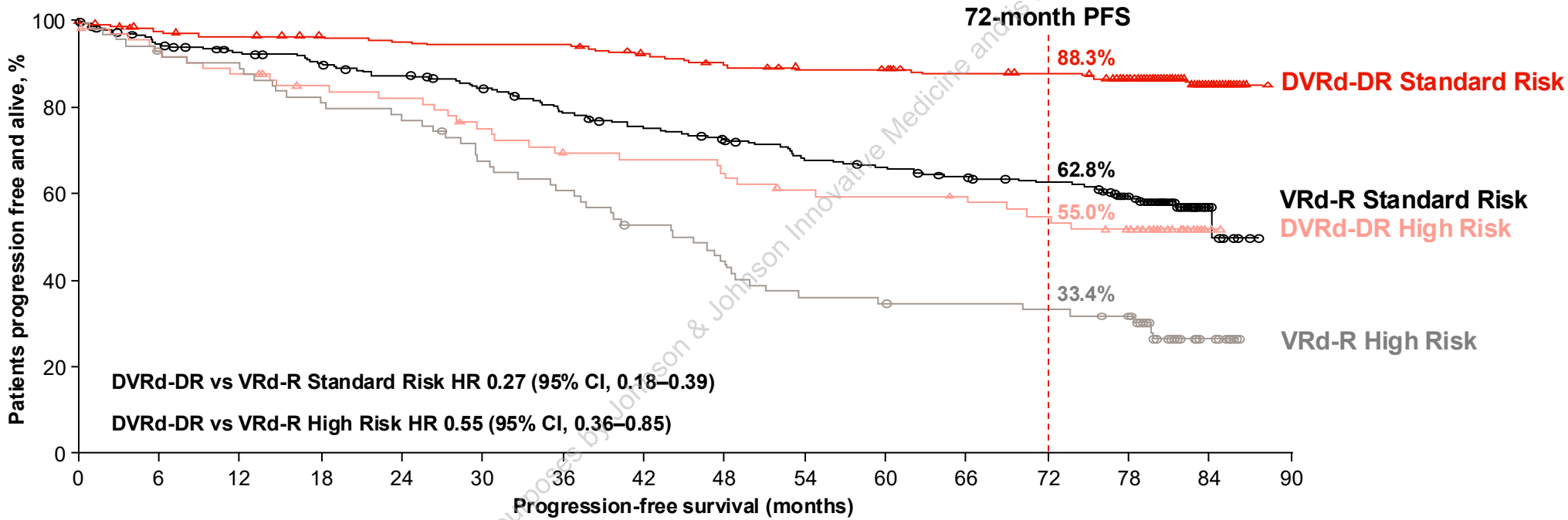
	Hazard ratio and 95% CI	VRd-R Events/N	VRd-R Median	DVRd-DR Events/N	DVRd-DR Median	HR (95% CI)
Sex						
Male		97/205	79.6	47/211	NE	0.38 (0.27–0.54)
Female		60/149	NE	22/144	NE	0.30 (0.18, 0.49)
Age						
<65 years		114/267	84.1	43/261	NE	0.30 (0.21–0.42)
≥65 years		43/87	76.1	26/94	NE	0.52 (0.32–0.85)
Race						
White		142/323	84.1	66/330	NE	0.37 (0.27–0.49)
Other		15/31	76.8	3/25	NE	0.19 (0.06–0.66)
ISS staging						
I		57/178	NE	26/186	NE	0.38 (0.24–0.61)
II		65/125	56.0	26/114	NE	0.30 (0.19–0.47)
III		35/50	40.7	17/55	NE	0.36 (0.20–0.64)
Type of MM						
IgG		87/185	75.6	40/204	NE	0.32 (0.22–0.46)
Non-IgG		48/96	73.8	17/78	NE	0.35 (0.20–0.61)
Cytogenetic risk[a]						
Standard risk		100/266	84.1	33/264	NE	0.27 (0.18–0.39)
High risk		53/78	45.6	34/76	NE	0.55 (0.36–0.85)
Baseline ECOG PS						
0		88/230	NE	40/221	NE	0.39 (0.27–0.56)
≥1		69/124	60.0	29/134	NE	0.30 (0.20–0.47)



With a PFS hazard ratio of 0.27 in the standard-risk subpopulation, PFS benefit continued to favor DVRd-DR versus VRd-R across clinically relevant subgroups

[a]Cytogenetic risk was assessed by means of fluorescence in situ hybridization; high risk was defined as the presence of del(17p), t(4;14), or t(14;16). Indeterminate cytogenetic risk was 2/15 in DVRd-DR and 4/10 in VRd-R, with no effect in either group. DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; MM, multiple myeloma; PFS, progression-free survival; R, lenalidomide; VRd, bortezomib, lenalidomide, and dexamethasone.

PERSEUS: Progression-Free Survival in Standard and High-Risk[a] Subgroups



No. at risk																
VRd-R Standard Risk	266	242	230	222	213	203	187	177	169	156	151	144	138	109	9	0
DVRd-DR Standard Risk	264	250	246	242	239	237	237	228	221	215	214	208	206	175	19	0
VRd-R High Risk	78	70	67	62	59	50	45	38	32	26	25	24	23	21	3	0
DVRd-DR High Risk	76	70	66	61	59	53	48	47	45	41	40	39	36	30	3	0

PFS benefit continued to favor DVRd-DR versus VRd-R; 72-month PFS rates were higher with DVRd-DR vs VRd-R in standard (88.3% vs 62.8%) and high-risk subgroups (55.0% vs 33.4%)

[a]High-risk as the presence of ≥1 of the following: del17p, t[4;14], or t[14;16] by fluorescence in situ hybridization [FISH]).
DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; PFS, progression-free survival; R, lenalidomide; VRd, bortezomib, lenalidomide, and dexamethasone.

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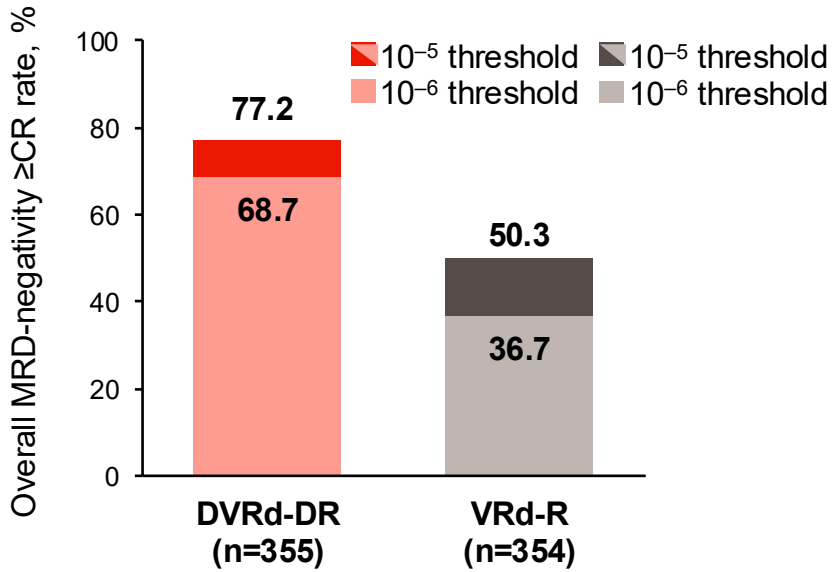
PERSEUS: Overall MRD-Negativity ≥CR Rates

Overall MRD-negativity ≥CR rate[a]



At 10^{-5}: OR 3.41; 95% CI 2.46–4.73; *P*<0.0001
At 10^{-6}: OR 3.88; 95% CI 2.83–5.31; *P*<0.0001

Rates of MRD conversion from end of consolidation to negative during maintenance

	DVRd-DR	VRd-R	DVRd-DR	VRd-R
Sensitivity threshold	**10^{-5}**		**10^{-6}**	
Subjects without MRD negativity and ≥CR at the end of consolidation[b]				
Achieved MRD negativity and ≥CR during maintenance, n (%)	85/134 (63.4)	72/149 (48.3)	136/212 (64.2)	81/206 (39.3)
Odds ratio (95% CI); *P*-value	1.86 (1.15–2.99); *P*=0.0108		2.76 (1.86–4.10); *P*<0.0001	

Overall MRD-negativity ≥CR rates favored DVRd-DR versus VRd-R, and there were higher rates of MRD conversion during maintenance at both 10^{-5} and 10^{-6}

[a]Proportion of patients who achieved MRD-negativity and ≥CR. Nominal 2-sided *P*-values reported are not adjusted for multiplicity [b]Includes patients who tested MRD positive, patients with indeterminate results, patients without NGS index clone, patients with <CR, and patients who did not provide samples. ≥CR, complete response or better; DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; NGS, next-generation sequencing; PFS, progression-free survival; OR, odds ratio; R, lenalidomide; VRd, bortezomib, lenalidomide, and dexamethasone.

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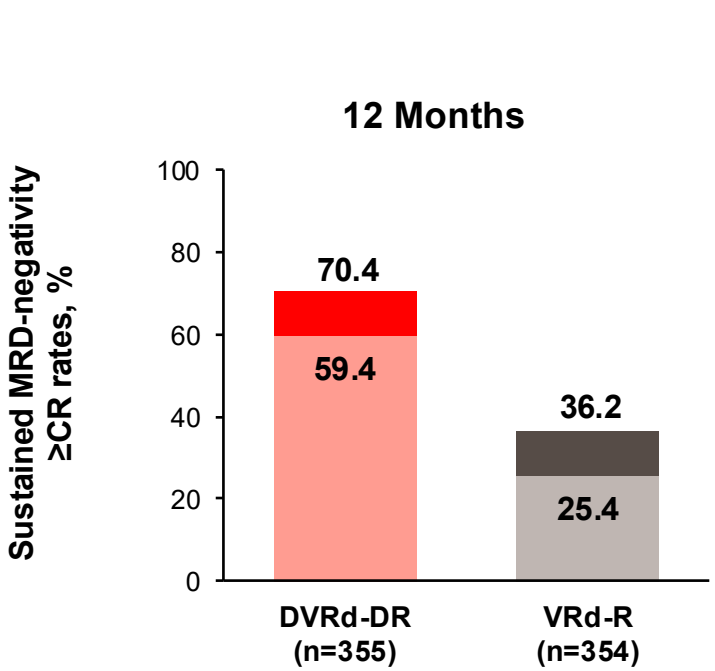
PERSEUS: Sustained MRD-Negativity ≥CR Rates



10^{-5}: OR 4.29; 95% CI 3.12–5.89; *P*<0.0001

10^{-6}: OR 4.40; 95% CI 3.19–6.08; *P*<0.0001

Sustained MRD-negativity ≥CR rates for ≥12, 24, or 36 months were consistently higher with DVRd-DR versus VRd-R at both 10^{-5} and 10^{-6}

Sustained MRD-negativity ≥CR was defined as 2 consecutive MRD negative reads ≥12 months (±1) or ≥24 or ≥36 months (±3) apart with no MRD-positive result in between and ≥CR. Nominal 2-sided *P*-values reported are not adjusted for multiplicity. ≥CR, complete response or better; DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; OR, odds ratio; VRd, bortezomib, lenalidomide, and dexamethasone.

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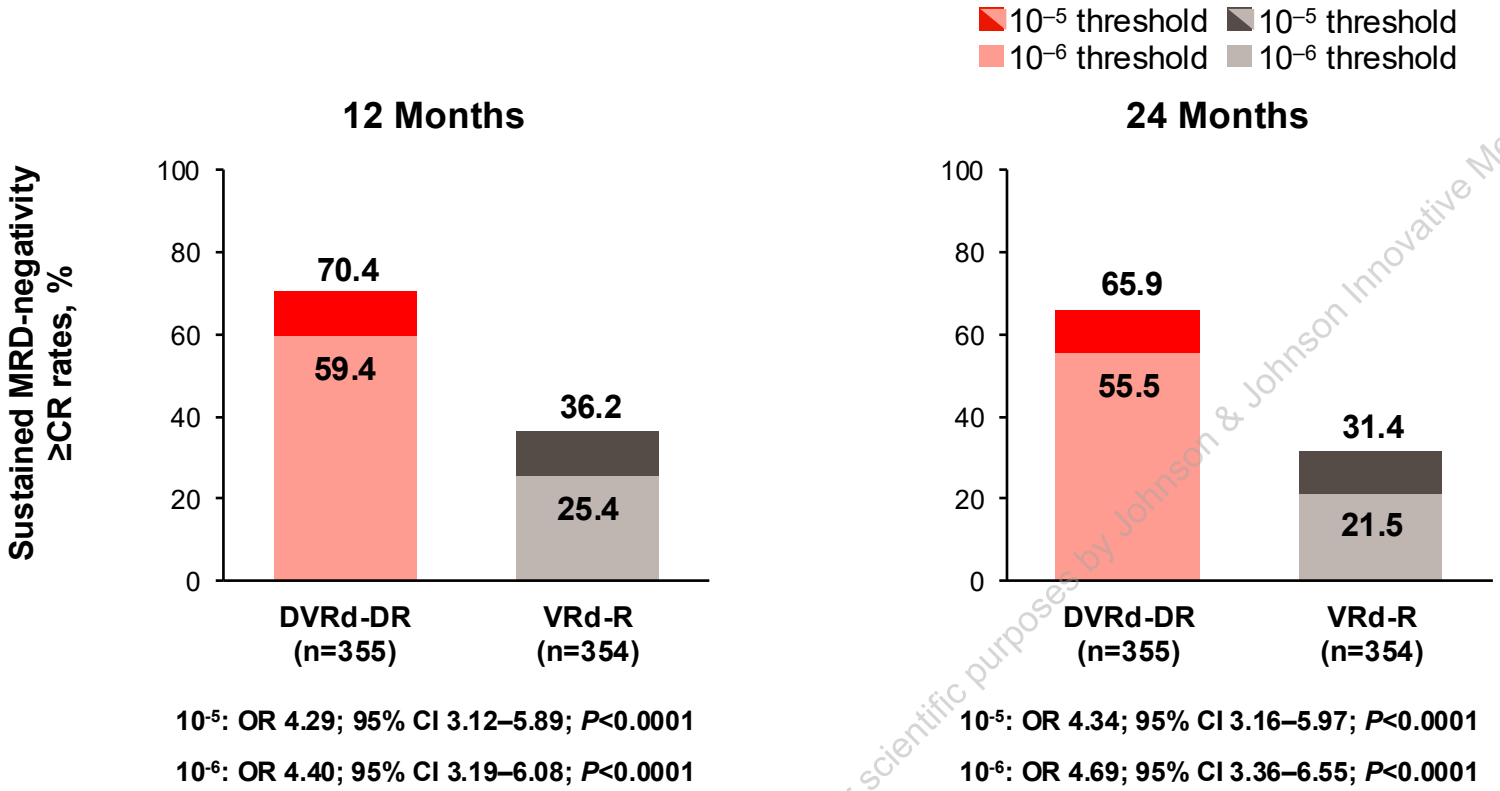
PERSEUS: Sustained MRD-Negativity ≥CR Rates



10^{-5}: OR 4.29; 95% CI 3.12–5.89; *P*<0.0001

10^{-6}: OR 4.40; 95% CI 3.19–6.08; *P*<0.0001

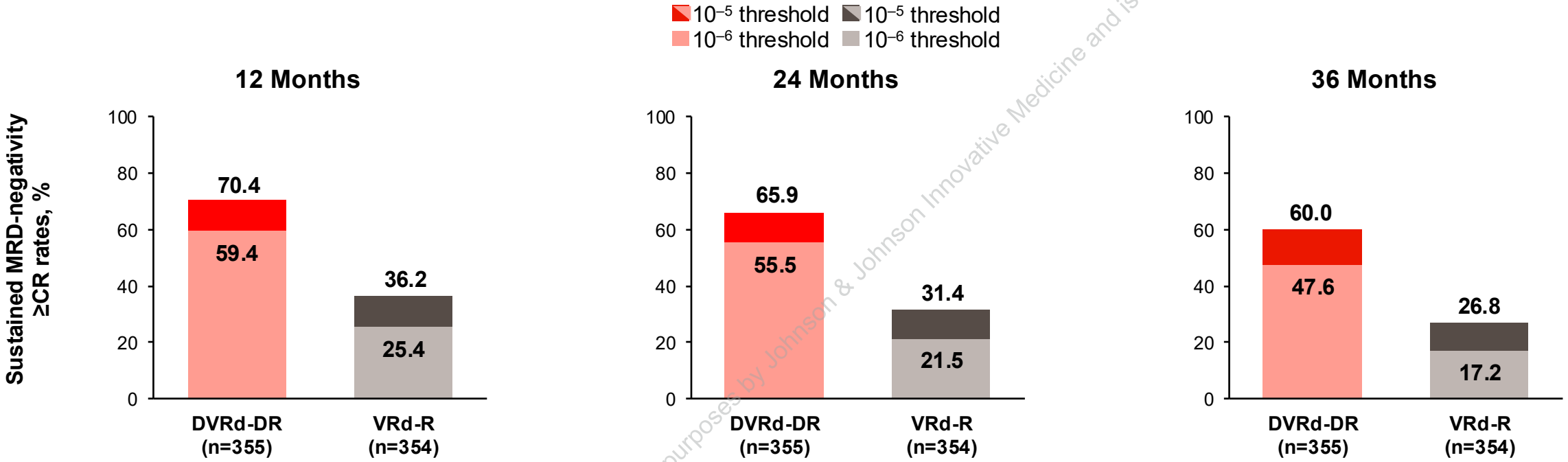
10^{-5}: OR 4.34; 95% CI 3.16–5.97; *P*<0.0001

10^{-6}: OR 4.69; 95% CI 3.36–6.55; *P*<0.0001

Sustained MRD-negativity ≥CR rates for ≥12, 24, or 36 months were consistently higher with DVRd-DR versus VRd-R at both 10^{-5} and 10^{-6}

Sustained MRD-negativity ≥CR was defined as 2 consecutive MRD negative reads ≥12 months (±1) or ≥24 or ≥36 months (±3) apart with no MRD-positive result in between and ≥CR. Nominal 2-sided *P*-values reported are not adjusted for multiplicity. ≥CR, complete response or better; DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; OR, odds ratio; VRd, bortezomib, lenalidomide, and dexamethasone.

PERSEUS: Sustained MRD-Negativity ≥CR Rates



12 Months

10^{-5}: OR 4.29; 95% CI 3.12–5.89; *P*<0.0001

10^{-6}: OR 4.40; 95% CI 3.19–6.08; *P*<0.0001

24 Months

10^{-5}: OR 4.34; 95% CI 3.16–5.97; *P*<0.0001

10^{-6}: OR 4.69; 95% CI 3.36–6.55; *P*<0.0001

36 Months

10^{-5}: OR 4.25; 95% CI 3.08–5.88; *P*<0.0001

10^{-6}: OR 4.47; 95% CI 3.15–6.34; *P*<0.0001

Sustained MRD-negativity ≥CR rates for ≥12, 24, or 36 months were consistently higher with DVRd-DR versus VRd-R at both 10^{-5} and 10^{-6}

Sustained MRD-negativity ≥CR was defined as 2 consecutive MRD negative reads ≥12 months (±1) or ≥24 or ≥36 months (±3) apart with no MRD-positive result in between and ≥CR. Nominal 2-sided *P*-values reported are not adjusted for multiplicity. ≥CR, complete response or better; DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; OR, odds ratio; VRd, bortezomib, lenalidomide, and dexamethasone.

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PERSEUS: MRD-Guided Daratumumab Discontinuation During Maintenance

n (%)	DVRd-DR (n=351)
Subjects received maintenance treatment	322 (91.7)
Subjects who have stopped daratumumab[a,b]	236 (73.3)
Subjects who have not restarted daratumumab[c,d]	175 (74.2)
Median duration of maintenance prior to stop[e], months (range)	26.83 (24.5–68.5)
Median duration from daratumumab stop to CCO[f], months (range)	44.06 (1.3–52.9)

These data reinforce the feasibility of sustained MRD-guided daratumumab discontinuation during maintenance

[a]Sustained 12 months MRD negativity and ≥CR and at least 24 months maintenance treatment, percentages are calculated with the number of subjects in DVRd arm as denominator. [b]Percentages are calculated with the number of subjects who receive maintenance as denominator. [c]Percentages are calculated with the number of subjects who stopped daratumumab and continued maintenance therapy as denominator.
[d] "still on treatment", e.g., without end of treatment. [e]Duration of daratumumab exposure during maintenance prior to daratumumab stop. [f]CCO for analysis is 1 June 2026.
CCO, clinical cutoff; DVRd-DR, daratumumab, bortezomib, lenalidomide, and dexamethasone induction/consolidation plus DR maintenance; MRD, minimal residual disease.

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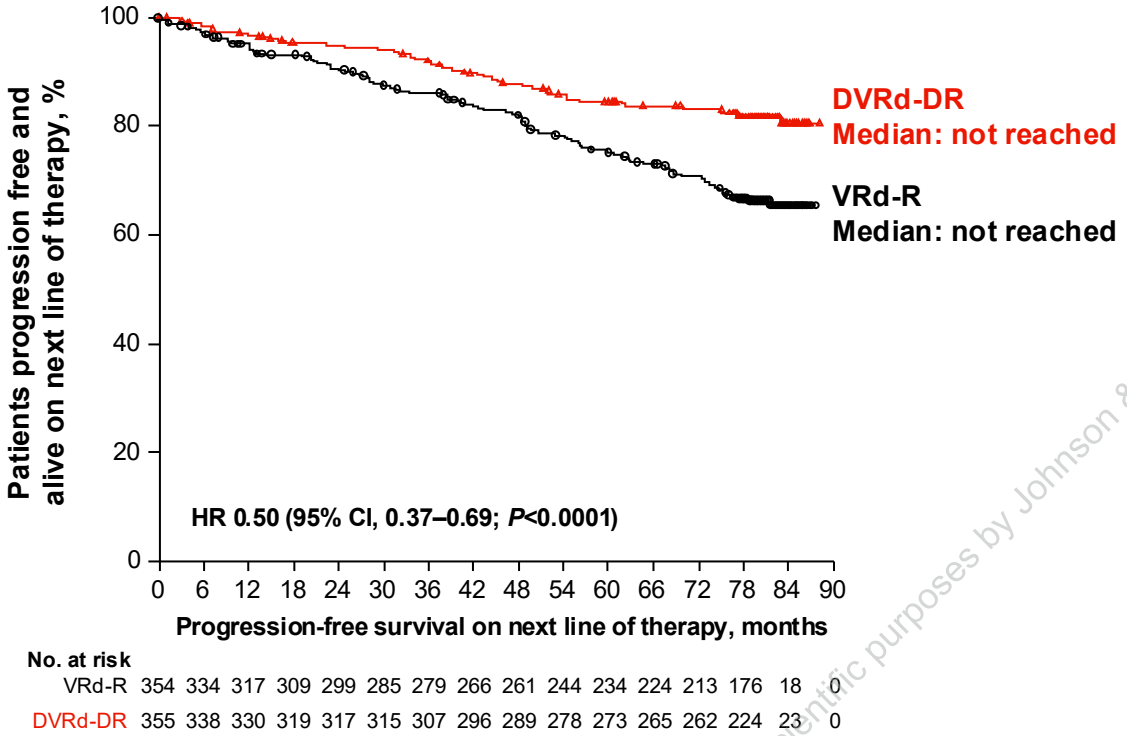
PERSEUS: Progression-Free Survival on Next Line of Therapy (PFS2)



n (%)	DVRd-DR (n=355)	VRd-R (n=354)
Patients receiving 2L therapy	50 (14.2)	136 (39.2)
Anti-CD38[a]	8 (16.0)	99 (72.8)

PFS2 favored DVRd-DR versus VRd-R despite most VRd-R patients receiving an anti-CD38 as second-line treatment (99/136 [72.8%])

[a]Percentages are calculated with the number of subjects who received 2L therapy as denominator.
Nominal 2-sided *P*-values reported are not adjusted for multiplicity. DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; R, lenalidomide; VRd, bortezomib, lenalidomide, and dexamethasone.

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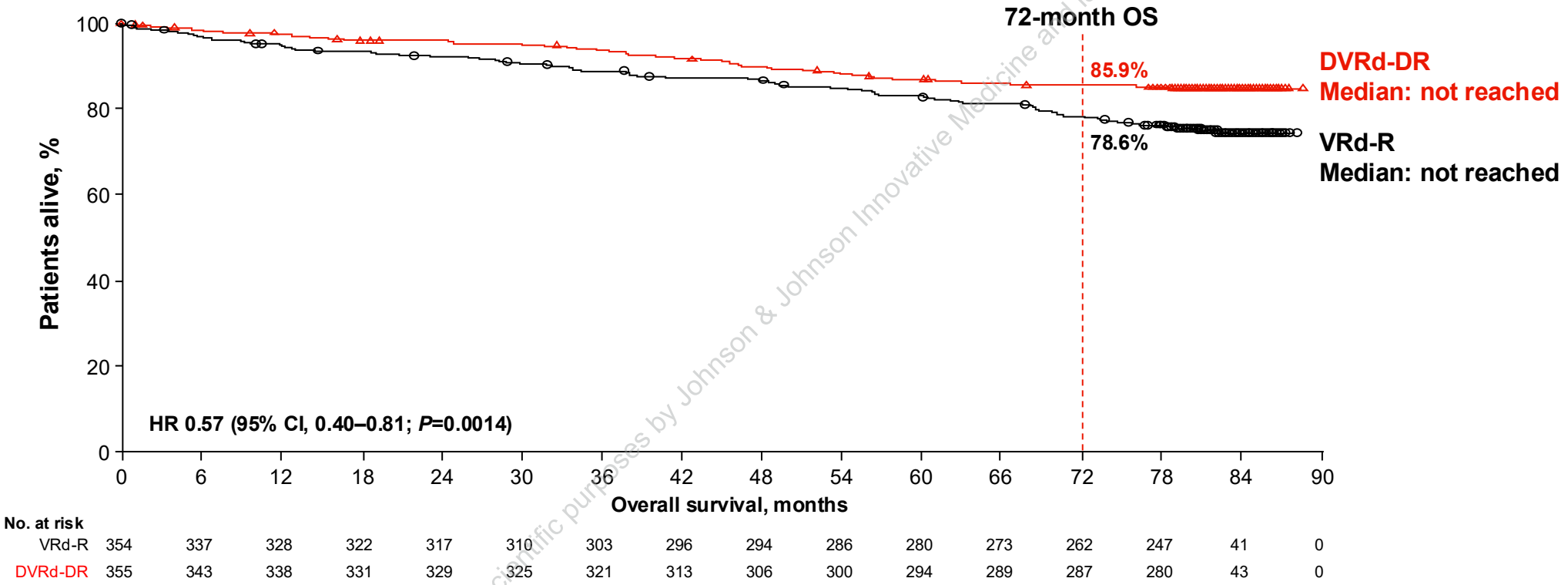
PERSEUS: Overall Survival



OS remains immature; median OS was not reached in either arm, with 51 (DVRd-DR) and 84 (VRd-R) deaths observed

Overall survival in the ITT population.
DR, daratumumab and lenalidomide; DVRd, daratumumab, bortezomib, lenalidomide, and dexamethasone; R, lenalidomide; VRd, bortezomib, lenalidomide, and dexamethasone.

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PERSEUS: Conclusions

After ~7 years (81.3 months) median follow-up, the PERSEUS regimen confirmed deep and durable benefit of daratumumab-based treatment across induction/consolidation and maintenance settings

- DVRd-DR improved long-term PFS versus VRd-R, with 72-month PFS rates of 81.1% vs 56.1% (HR 0.35), respectively
- Deeper and more durable responses were seen with DVRd-DR vs VRd-R
  - Sustained MRD-negativity ≥CR rates for ≥36 months were consistently higher at both 10^{-5} and 10^{-6} sensitivity thresholds
  - Nearly 3 out of 4 (73%) DVRd-DR patients receiving maintenance achieved 12-month sustained MRD negativity, enabling them to discontinue daratumumab per protocol[a]
  - A higher percentage of patients achieved MRD negativity ≥CR (10^{-5} and 10^{-6}) with DR vs R maintenance
- No new safety signals were observed with an additional ~3 years (34 months) of follow-up

DVRd-DR demonstrated among the deepest and most durable responses in NDMM, even after per-protocol MRD-guided discontinuation of daratumumab maintenance

[a]29 patients restarted daratumumab, and 19 remain on daratumumab.
DR, daratumumab and lenalidomide; DVRd, daratumumab plus bortezomib, lenalidomide, and dexamethasone; MRD, minimal residual disease; NDMM, newly diagnosed multiple myeloma; R, lenalidomide; TE, transplant eligible.

Presented by P Sonneveld at the 23rd International Myeloma Society (IMS) Annual Meeting & Exposition; September 23–26, 2026; Glasgow, Scotland

PERSEUS: Acknowledgments

- Patients who participated in this study and their families and caregivers
- Staff members at the study sites
- Data and safety monitoring committee
- Staff members involved in data collection and analyses
- The European Myeloma Network (EMN) and Johnson & Johnson
- The EMN acknowledges the valuable contributions and participation of the National Myeloma Study Groups of all participating countries in Europe and Australia

- This study was sponsored by the European Myeloma Network in collaboration with Johnson & Johnson

Medical writing support was provided by Carlee M. Cunningham, PhD, of Envision Medical Communications, and funded by Johnson & Johnson.

Presented by P Sonneveld at the 23rd International Myeloma Society (IMS) Annual Meeting & Exposition; September 23–26, 2026; Glasgow, Scotland

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