Subcutaneous Daratumumab Plus Lenalidomide Versus Lenalidomide Alone as Maintenance Therapy in Newly Diagnosed Multiple Myeloma After Transplant: Primary Results From the Phase 3 AURIGA Study

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AURIGA: Introduction

- Induction / consolidation therapy with ASCT followed by R maintenance is SoC for TE patients with NDMM[1]
- In GRIFFIN and PERSEUS, D-VRd induction/consolidation followed by D-R maintenance improved PFS[2-4]
  - D-R maintenance improved MRD-negative conversion rates compared to R alone[3,5]
  - In patients with NDMM, achievement of MRD negativity is associated with superior PFS and OS[6,7]
- To date, no randomized trial has directly compared DARA-based maintenance therapy versus SoC R maintenance therapy in TE patients with NDMM

- **Here, we report the primary results of the phase 3 AURIGA study that evaluated the addition of DARA to R maintenance in TE patients with NDMM who were anti-CD38 naïve and MRD positive[a] following ASCT after SoC induction/consolidation**
  - ClinicalTrials.gov Identifier: NCT03901963

ASCT, autologous stem cell transplant; R, lenalidomide; SoC, standard of care; TE, transplant-eligible; NDMM, newly diagnosed multiple myeloma; D-VRd, daratumumab plus bortezomib/lenalidomide/dexamethasone; D-R, daratumumab/lenalidomide; PFS, progression-free survival; MRD, minimal residual disease; OS, overall survival; DARA, daratumumab; NGS, next-generation sequencing. [a]MRD based on NGS (clonoSEQ®; Adaptive Biotechnologies).

1. Dimopoulos MA, et al. *Hemasphere*. 2021;5(2):e528. 2. Voorhees PM, et al. *Blood*. 2020;136(8):936-945. 3. Voorhees PM, et al. *Lancet Haematol*. 2023;10(10):e825-837. 4. Sonneveld P, et al. *N Engl J Med*. 2024;390(4):301-313. 5. Sonneveld P, et al. *Blood*. 2023;142(suppl 2):LBA-1. 6. Munshi NC, et al. *Blood Adv*. 2020;4(23):5988-5999. 7. Perrot A, et al. *Blood*. 2018;132(23):2456-2464.

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AURIGA: Study Design

- Objective: To determine the impact of adding DARA to R maintenance on MRD-negative conversion

Key eligibility criteria

- 18-79 years of age
- NDMM with ≥4 cycles of induction therapy and underwent ASCT within 12 months of the start of induction
- ≥VGPR at screening[a]
- MRD[b] positive (10^{-5}) post-ASCT
- No prior anti-CD38
- Randomization within 6 months of ASCT date

Stratification factor

- Cytogenetic risk[c] (standard risk/unknown vs high risk)

1:1 RANDOMIZATION (N = 200)

Maintenance: up to 36 cycles[d] (28-day cycles)

D-R

D: 1,800 mg SC[e] QW Cycles 1-2, Q2W Cycles 3-6, Q4W Cycles 7+

R: 10 mg PO daily Days 1-28 (after Cycle 3, 15 mg PO daily if tolerated)

R

R: 10 mg PO daily Days 1-28 (after Cycle 3, 15 mg PO daily if tolerated)

MRD[b] obtained after 12, 18, 24, and 36 cycles

Primary endpoint

- MRD-negative (10^{-5}) conversion rate from baseline to 12 months after maintenance treatment
  - N = 214 planned to achieve ≥85% power to detect 20% improvement

Secondary endpoints

- PFS, overall MRD-negative conversion rate, sustained MRD-negative rate, response rates, duration of ≥CR, OS, safety

VGPR, very good partial response; D, daratumumab; SC, subcutaneous; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; PO, orally; CR, complete response. [a]As assessed by International Myeloma Working Group 2016 criteria. [b]MRD based upon NGS (clonoSEQ®; Adaptive Biotechnologies). [c]For stratification, cytogenetic risk was evaluated per investigator assessment, in which high risk was defined as the presence of ≥1 of the following cytogenetic abnormalities: del[17p], t[4;14], or t[14;16]. [d]Study treatment continued for a planned maximum duration of 36 cycles or until progressive disease, unacceptable toxicity, or withdrawal of consent. After the end of the study treatment period of 36 months and after the end of the study, patients benefiting from treatment with DARA and/or R could continue receiving treatment per the investigator's discretion. [e]DARA SC (DARA 1,800 mg co-formulated with recombinant human hyaluronidase PH20 [rHuPH20; 2,000 U/mL; ENHANZE® drug delivery technology; Halozyme, Inc., San Diego, CA, USA]).

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AURIGA: Demographic and Disease Characteristics (ITT) Were Generally Well Balanced

Characteristic	D-R (n = 99)	R (n = 101)
Age, years, n (%)		
Median (range)	63 (35-77)	62 (35-78)
<65	61 (61.6)	61 (60.4)
65-70	23 (23.2)	21 (20.8)
≥70	15 (15.2)	19 (18.8)
Sex, n (%)		
Male	61 (61.6)	58 (57.4)
Race, n (%)		
White	67 (67.7)	68 (67.3)
Black	20 (20.2)	24 (23.8)
Asian	5 (5.1)	1 (1.0)
American Indian or Alaska Native	0	1 (1.0)
Other[a]	5 (5.1)	5 (5.0)
Not reported	2 (2.0)	2 (2.0)
ECOG PS score, n (%)		
0	45 (45.5)	55 (54.5)
1	52 (52.5)	44 (43.6)
2	2 (2.0)	2 (2.0)
ISS disease stage at diagnosis, n (%)		
n	91	98
I	40 (44.0)	38 (38.8)
II	28 (30.8)	37 (37.8)
III	23 (25.3)	23 (23.5)

Characteristic	D-R (n = 99)	R (n = 101)
Cytogenetic risk at diagnosis,[b] n (%)		
n	92	89
Standard risk	63 (68.5)	66 (74.2)
High risk[c]	22 (23.9)	15 (16.9)
del[17p]	13 (14.1)	3 (3.4)
t[4;14]	10 (10.9)	12 (13.5)
t[14;16]	6 (6.5)	7 (7.9)
Unknown	7 (7.6)	8 (9.0)
Revised cytogenetic risk at diagnosis,[b] n (%)		
n	93	89
Standard risk	52 (55.9)	53 (59.6)
High risk[d]	32 (34.4)	30 (33.7)
Unknown	9 (9.7)	6 (6.7)
Induction cycles		
Median (range)[e]	5.0 (4.0-8.0)	5.0 (4.0-8.0)
≥2 induction cycles with V and R included, n (%)	78 (78.8)	84 (83.2)
Patient response category at baseline,[f] n (%)		
sCR	14 (14.1)	13 (12.9)
CR	14 (14.1)	17 (16.8)
VGPR	71 (71.7)	71 (70.3)

ITT, intent-to-treat; ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; V, bortezomib; sCR, stringent complete response. [a]Patients reporting multiple races are included under other. [b]Assessed by local fluorescence in situ hybridization/karyotype test at diagnosis. [c]High-risk cytogenetics are defined as ≥1 abnormality including del[17p], t[4;14], or t[14;16]. [d]Revised high-risk cytogenetics are defined as ≥1 abnormality including del[17p], t[4;14], t[14;16], t[14;20], or gain/amp[1q21]. [e]Evaluable patients for the median number of induction cycles included those with ≥1 induction therapy (D-R, n = 98; R, n = 99). [f]Response was assessed by computerized algorithm, based on International Uniform Response Criteria Consensus Recommendations.

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AURIGA: Patient Disposition

- Median follow-up: **32.3** months
- Median (range) duration of study treatment:
  - D-R: **30.7** (0.7-37.5) months
  - R: **20.6** (0-37.7) months
- At the time of the primary analysis, all patients completed ≥12 months of maintenance, had disease progression, died, or discontinued/withdrew

Patients, n (%)	D-R (n = 99)	R (n = 101)
Patients who received treatment	96 (97.0)	98 (97.0)
Patients who completed all study treatments[a]	33 (34.4)	20 (20.4)
Patients who discontinued all study treatments[a]	27 (28.1)	47 (48.0)

Patients, n (%)	D-R (n = 99)	R (n = 101)
Patients who discontinued R[a]		
Patients who discontinued	32 (33.3)	47 (48.0)
Primary reason for discontinuation		
Progressive disease	11 (11.5)	23 (23.5)
Adverse event	12 (12.5)	8 (8.2)
Patient withdrawal	3 (3.1)	4 (4.1)
Death	2 (2.1)	1 (1.0)
Physician decision	2 (2.1)	4 (4.1)
Patient refused further study treatment	1 (1.0)	5 (5.1)
Protocol deviation	0	1 (1.0)
Other	1 (1.0)	1 (1.0)
Patients who discontinued DARA[a]		
Patients who discontinued	27 (28.1)	–
Primary reason for discontinuation		
Progressive disease	13 (13.5)	–
Adverse event	6 (6.3)	–
Patient withdrawal	3 (3.1)	–
Death	2 (2.1)	–
Physician decision	2 (2.1)	–
Patient refused further study treatment	1 (1.0)	–

[a]Percentages are based upon the number of patients treated in each group.

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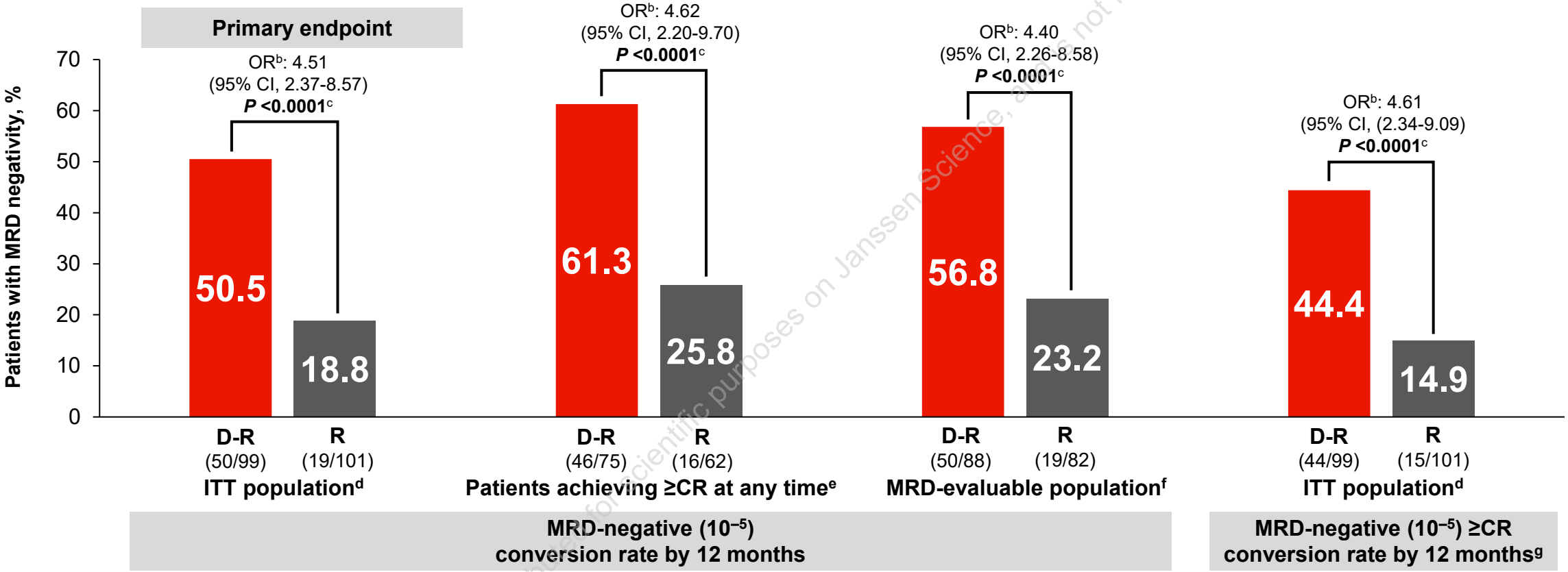
AURIGA: MRD-negative (10^{-5}) Conversion Rate From Baseline to 12 Months of Maintenance Treatment[a]



- **The addition of DARA to R more than doubled the MRD-negative conversion rate by 12 months**
- **Similar benefits were seen in supplemental MRD analyses**

OR, odds ratio; CI, confidence interval. [a]Defined as the proportion of patients who achieved MRD-negative status (at 10^{-5}) by NGS by 12 months after maintenance treatment and prior to progressive disease or subsequent antimyeloma therapy. [b]Mantel–Haenszel estimate of the common OR for stratified tables was used. The stratification factor was baseline cytogenetic risk per investigator assessment (high vs standard/unknown), as used for randomization. An OR >1 indicates an advantage for D-R. [c]*P* <0.0001 from Fisher's exact test. [d]ITT analysis set is defined as all patients who were randomized to treatment. [e]Patients who achieved ≥CR at any time during the study per International Myeloma Working Group computerized algorithm. [f]MRD-evaluable analysis set included all randomized patients who had an MRD assessment at baseline and had ≥1 post-baseline MRD evaluation. [g]Defined as the proportion of patients who achieved ≥CR response and had MRD negative status (at 10^{-5}) by NGS by 12 months after maintenance and prior to progressive disease and subsequent anti-myeloma therapy.

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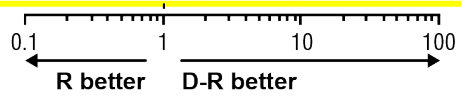
AURIGA: MRD-negative (10^{-5}) Conversion Rate From Baseline to 12 Months of Maintenance Treatment in Subgroups

- MRD-negative (10^{-5}) conversion rates by 12 months were consistently higher with D-R versus R across all clinically relevant subgroups

	D-R MRD-negative rate, n/N (%)	R MRD-negative rate, n/N (%)	OR (95% CI)
ITT (overall)	50/99 (50.5)	19/101 (18.8)	4.51 (2.37-8.57)
Sex			
Male	32/61 (52.5)	11/58 (19.0)	4.71 (2.06-10.78)
Female	18/38 (47.4)	8/43 (18.6)	3.94 (1.45-10.68)
Age			
<65 years	30/61 (49.2)	12/61 (19.7)	3.95 (1.76-8.85)
≥65 years	20/38 (52.6)	7/40 (17.5)	5.24 (1.86-14.74)
Race			
White	31/67 (46.3)	14/68 (20.6)	3.32 (1.55-7.10)
Black	12/20 (60.0)	4/24 (16.7)	7.50 (1.85-30.34)
Other	7/12 (58.3)	1/9 (11.1)	11.20 (1.04-120.36)
Weight			
≤70 kg	12/23 (52.2)	4/18 (22.2)	3.82 (0.96-15.18)
>70 kg	38/76 (50.0)	15/81 (18.5)	4.40 (2.14-9.03)
Baseline ECOG PS score			
0	20/45 (44.4)	9/55 (16.4)	4.09 (1.62-10.31)
≥1	30/54 (55.6)	10/46 (21.7)	4.50 (1.86-10.88)
ISS at diagnosis			
I	19/40 (47.5)	8/38 (21.1)	3.39 (1.25-9.19)
II	13/28 (46.4)	7/37 (18.9)	3.71 (1.23-11.25)
III	15/23 (65.2)	3/23 (13.0)	12.50 (2.83-55.25)
Cytogenetlc risk at diagnosis			
High risk[a]	7/22 (31.8)	1/15 (6.7)	6.53 (0.71-60.05)
Standard risk	35/63 (55.6)	14/66 (21.2)	4.64 (2.15-10.04)
Revised cytogenetic risk at diagnosis			
High risk[b]	14/32 (43.8)	4/30 (13.3)	5.06 (1.43-17.88)
Standard risk	28/52 (53.8)	12/53 (22.6)	3.99 (1.72-9.26)



Benefit favoring D-R in MRD-negative conversion rate was observed in patients with high-risk and standard-risk disease

[a]High-risk cytogenetics are defined as ≥1 abnormality including del[17p], t[4;14], or t[14;16]. [b]Revised high-risk cytogenetics are defined as ≥1 abnormality including del[17p], t[4;14], t[14;16], t[14;20], or gain/amp[1q21].

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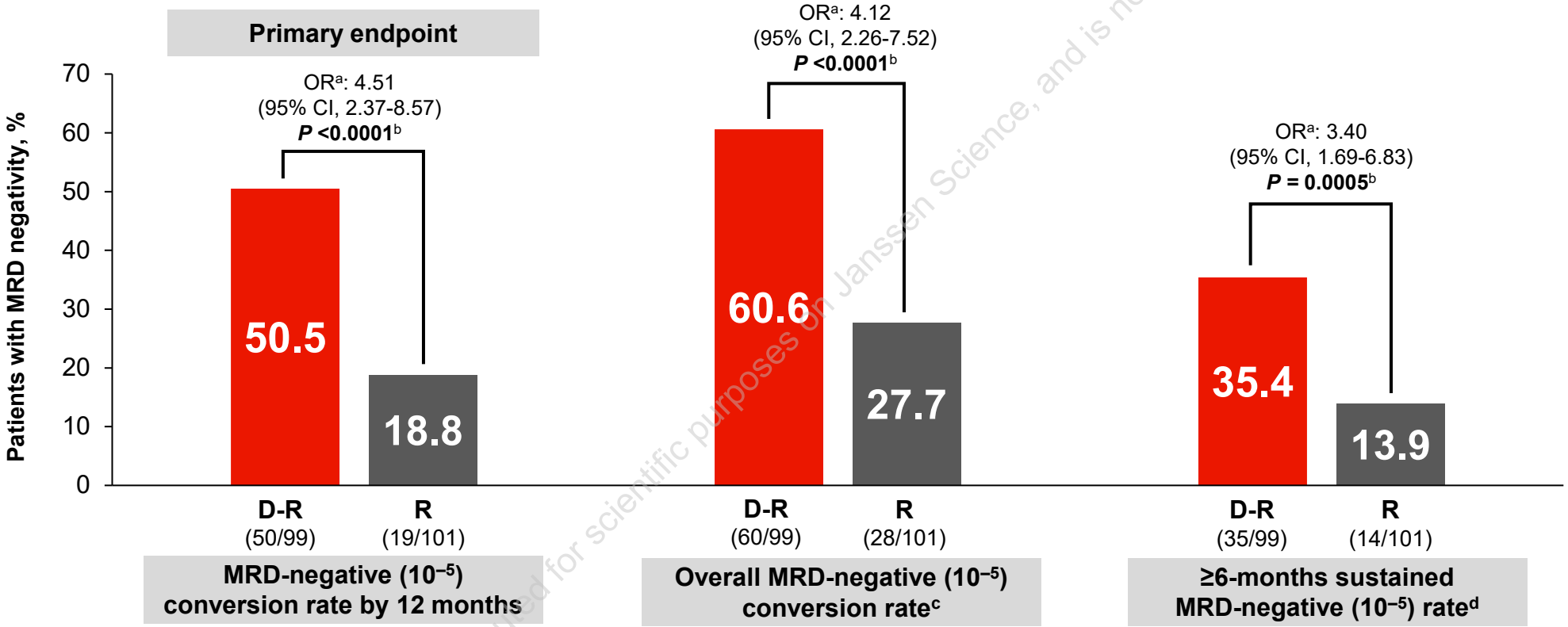
AURIGA: Increased MRD-negative Conversion Over Time and Sustained MRD Negativity at the 10^{-5} Threshold



DARA more than doubled overall MRD-negative conversion rate and sustained MRD-negative rate

[a]Mantel–Haenszel estimate of the common OR for stratified tables was used. The stratification factor was baseline cytogenetic risk per investigator assessment (high vs standard/unknown), as used for randomization. An OR >1 indicates an advantage for D-R. [b]*P* value from Fisher's exact test. [c]Defined as the proportion of patients who achieved MRD-negative status any time after the date of randomization. [d]Defined as those who achieved MRD-negative status (at 10^{-5}) in 2 bone marrow aspirate assessments with a minimum of 6 months apart, without any assessment showing MRD-positive status in between assessments.

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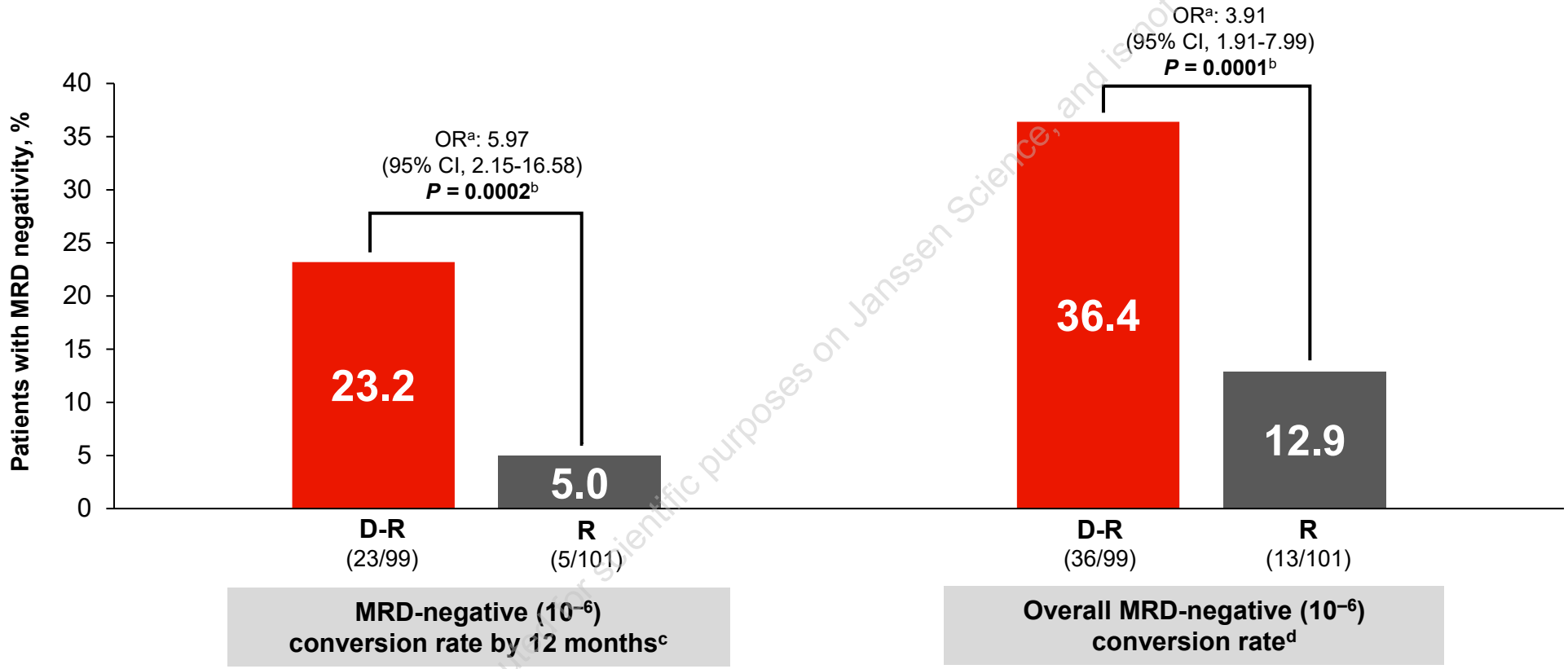
AURIGA: MRD Analyses at the 10^{-6} Threshold



- D-R maintenance quadrupled the rate of MRD-negative (10^{-6}) conversion by 12 months
- D-R nearly tripled the rate of overall MRD-negative (10^{-6}) conversion

[a]Mantel–Haenszel estimate of the common OR for stratified tables was used. The stratification factor was baseline cytogenetic risk per investigator assessment (high vs standard/unknown), as used for randomization. An OR >1 indicates an advantage for D-R. [b]*P* value from Fisher's exact test. [c]Defined as the proportion of patients who achieved MRD-negative status (at 10^{-6}) by NGS by 12 months after maintenance treatment and prior to PD or subsequent antimyeloma therapy. [d]Defined as the proportion of patients who achieved MRD-negative status (at 10^{-6}) at any time after the date of randomization.

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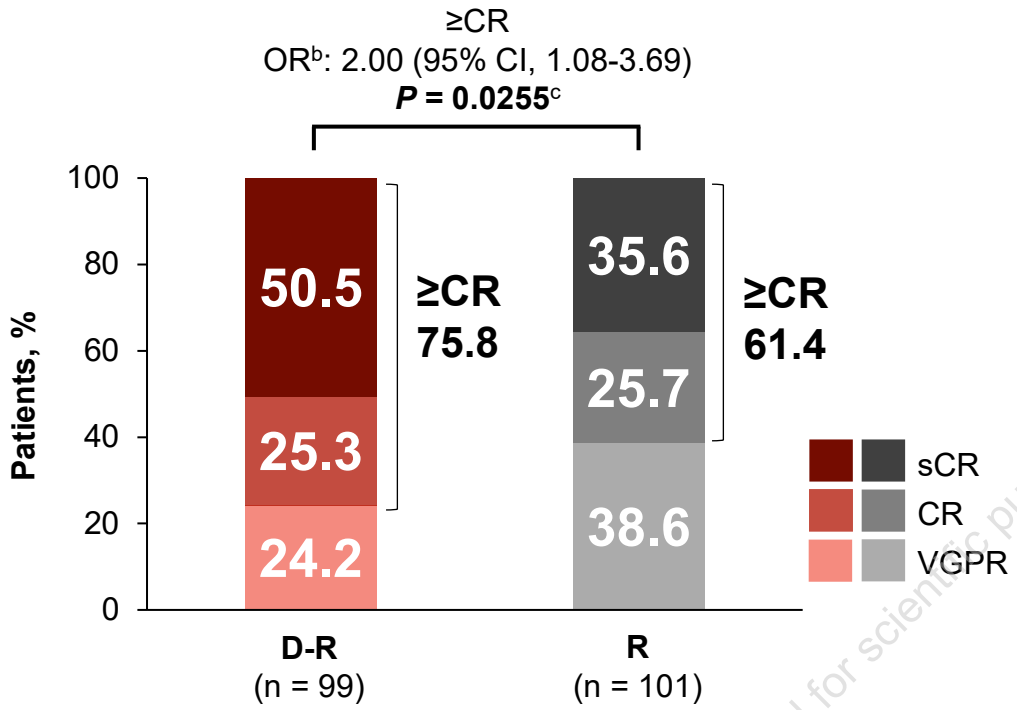
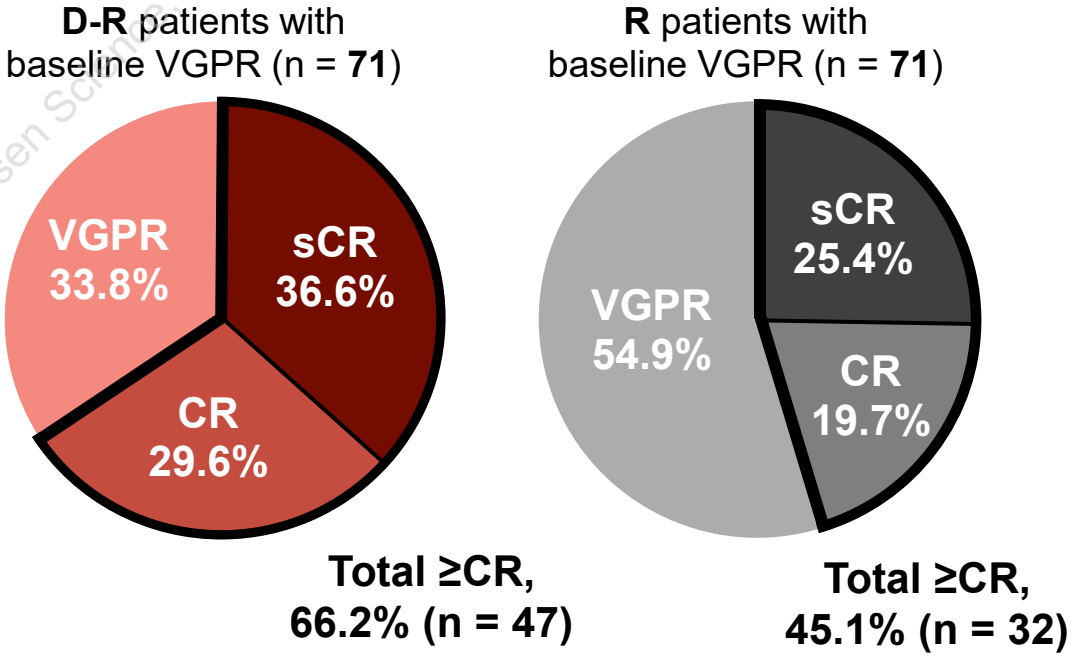
AURIGA: Overall Best Response[a]



Improved response in patients with VGPR at baseline



- **≥CR rate was higher with D-R versus R maintenance**
- **Among patients with VGPR, D-R deepened more responses to CR or sCR than R alone**

[a]As per eligibility criteria, all patients had achieved a ≥VGPR at the time of screening. [b]Mantel–Haenszel estimate of the common OR for stratified tables was used. The stratification factor was baseline cytogenetic risk per investigator assessment (high vs standard/unknown), as used for randomization. An OR >1 indicates an advantage for D-R. [c]*P* value from Cochran–Mantel–Haenszel chi-squared test.

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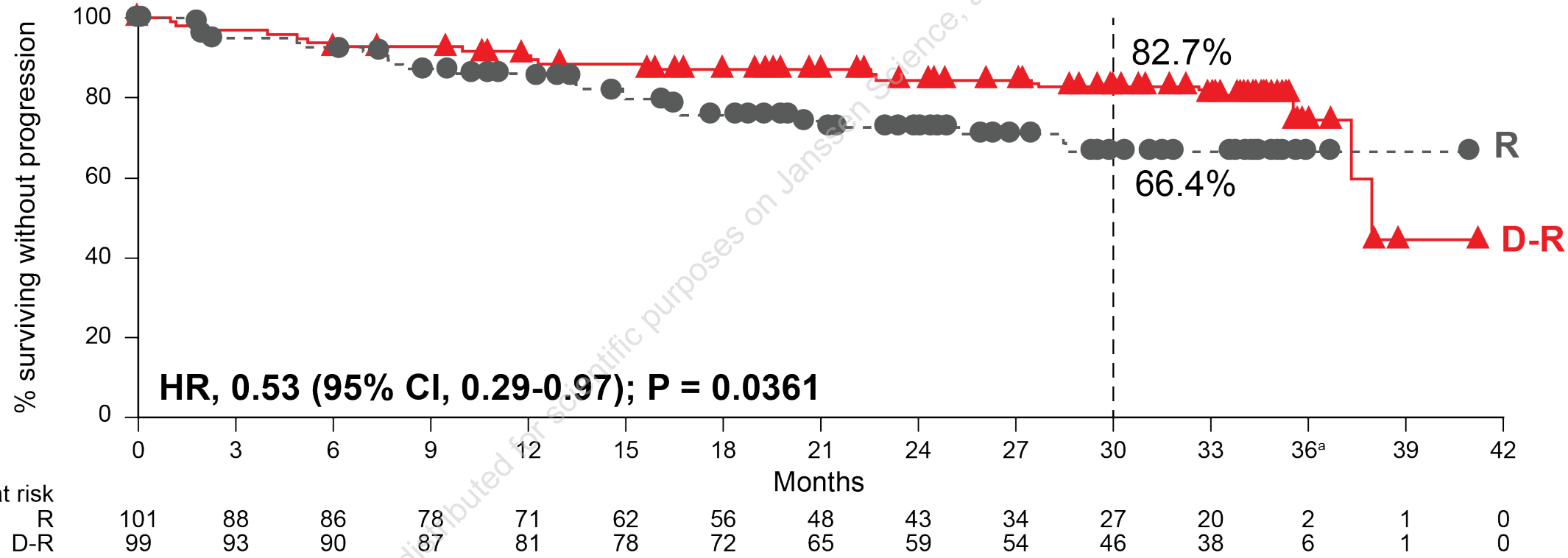
AURIGA: PFS in the ITT Population

- Median follow-up: **32.3** months



PFS favored D-R versus R, with a 47% reduction in the risk of disease progression or death

HR, hazard ratio. [a]Per study protocol, disease assessments stopped at the end of study treatment (Cycle 36), after which patients were only followed for survival. At the time of this analysis, the number of patients who reached end of study treatment was low, thus resulting in a low number of patients at risk.

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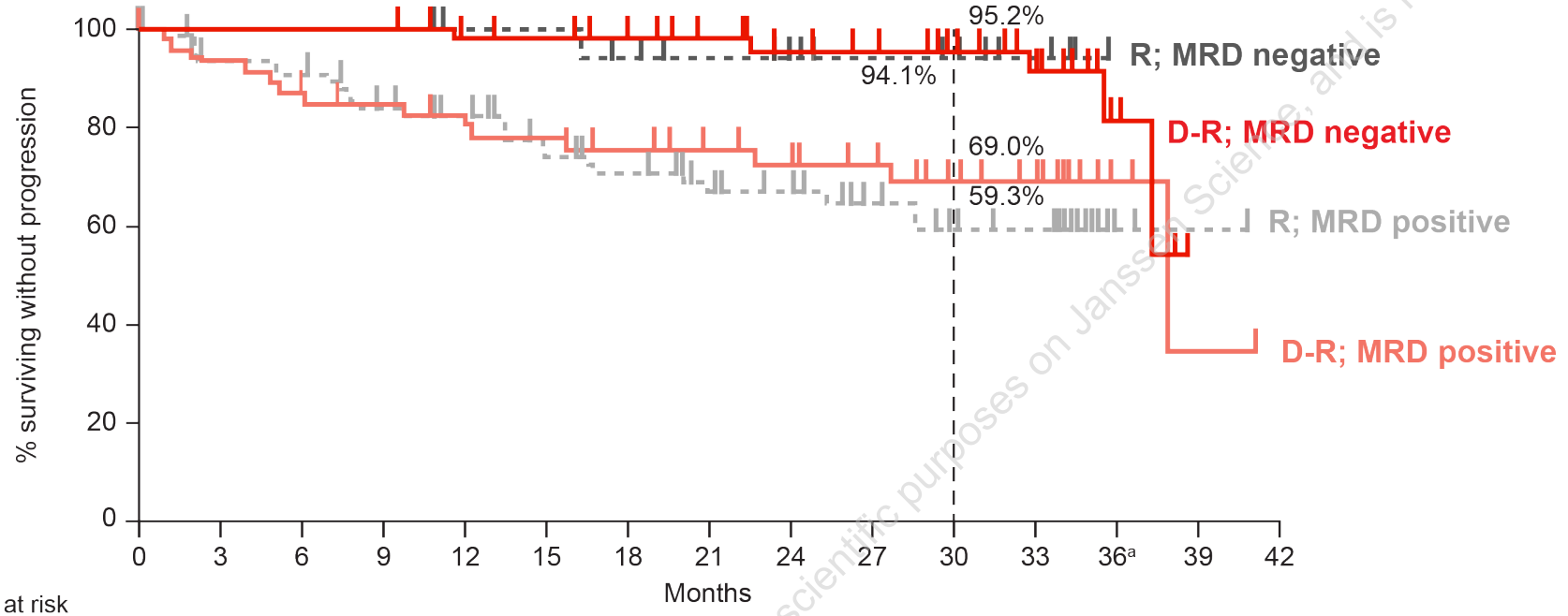
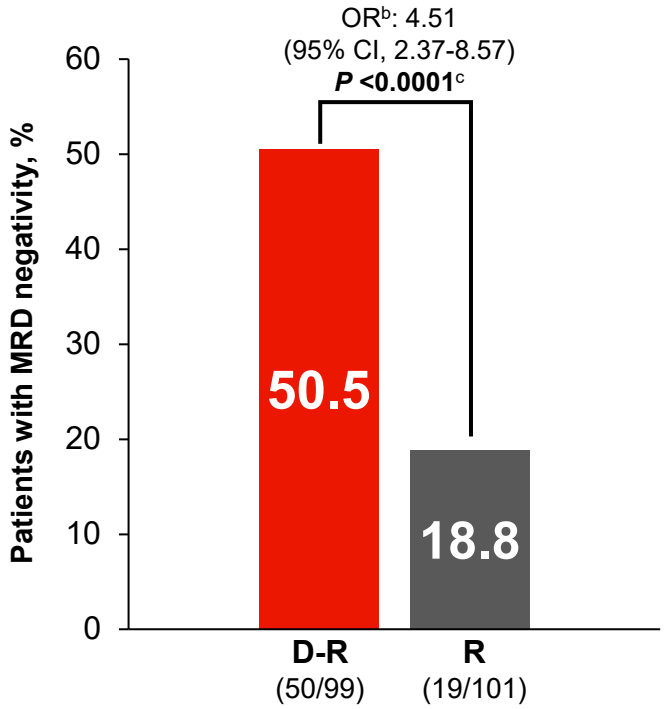
AURIGA: PFS by MRD-negative (10^{-5}) Conversion Status by 12 Months in the ITT Population



No. at risk															
R; MRD negative	19	19	19	19	17	17	15	13	11	9	8	4	0	0	0
R; MRD positive	82	69	67	59	54	45	41	35	32	25	19	16	2	1	0
D-R; MRD negative	50	50	50	50	46	45	42	38	34	32	28	23	3	0	0
D-R; MRD positive	49	43	40	37	35	33	30	27	25	22	18	15	3	1	0

Primary endpoint:
MRD-negative (10^{-5}) conversion rate by 12 months in ITT



- **MRD-negative conversion was associated with improved PFS**
- **D-R more than doubled 12-month MRD-negative conversion rate, with improved long-term outcomes**

[a]Per study protocol, disease assessments stopped at the end of study treatment (Cycle 36), after which patients were only followed for survival. At the time of this analysis, the number of patients who reached end of study treatment was low, thus resulting in a low number of patients at risk. [b]Mantel–Haenszel estimate of the common OR for stratified tables was used. The stratification factor was baseline cytogenetic risk per investigator assessment (high vs standard/unknown), as used for randomization. An OR >1 indicates an advantage for D-R. [c]*P* value from Fisher's exact test.

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AURIGA: Most Common TEAEs[a,b]

TEAE, n (%)	D-R (n = 96)		R (n = 98)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Hematologic				
Neutropenia	62 (64.6)	45 (46.9)	60 (61.2)	41 (41.8)
Leukopenia	25 (26.0)	9 (9.4)	29 (29.6)	6 (6.1)
Thrombocytopenia	23 (24.0)	3 (3.1)	28 (28.6)	2 (2.0)
Lymphopenia	23 (24.0)	10 (10.4)	13 (13.3)	5 (5.1)
Anemia	22 (22.9)	4 (4.2)	17 (17.3)	3 (3.1)
Nonhematologic				
Diarrhea	59 (61.5)	3 (3.1)	54 (55.1)	5 (5.1)
Fatigue	44 (45.8)	2 (2.1)	46 (46.9)	3 (3.1)
URTI	40 (41.7)	0	26 (26.5)	0
Cough	37 (38.5)	0	36 (36.7)	0
Hypokalemia	33 (34.4)	7 (7.3)	36 (36.7)	6 (6.1)
Arthralgia	32 (33.3)	1 (1.0)	36 (36.7)	1 (1.0)

TEAE, n (%)	D-R (n = 96)		R (n = 98)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Nonhematologic (cont)				
Back pain	31 (32.3)	0	20 (20.4)	1 (1.0)
COVID-19	28 (29.2)	1 (1.0)	29 (29.6)	3 (3.1)
Nausea	26 (27.1)	0	26 (26.5)	0
Nasal congestion	25 (26.0)	0	19 (19.4)	0
Headache	24 (25.0)	1 (1.0)	17 (17.3)	0
Constipation	22 (22.9)	0	26 (26.5)	0
Muscle spasms	22 (22.9)	0	21 (21.4)	0
Pain in extremity	22 (22.9)	1 (1.0)	17 (17.3)	0
Rash maculo-papular	21 (21.9)	1 (1.0)	17 (17.3)	2 (2.0)
Hypertension	14 (14.6)	7 (7.3)	10 (10.2)	4 (4.1)
Pneumonia	10 (10.4)	5 (5.2)	14 (14.3)	4 (4.1)
Infusion-related reactions	13 (13.5)	0	–	–

There were no new safety concerns with D-R or R maintenance

TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection. [a]TEAEs of any grade that occurred in ≥20% of patients and grade 3/4 TEAEs that occurred in ≥5% of patients in either treatment group.
[b]One death in the D-R group was considered related to study treatment. The cause of death was COVID-19 pneumonia and was considered related to treatment.

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AURIGA: Conclusions

- In TE patients with NDMM who were anti-CD38 naïve and MRD positive post-ASCT, D-R maintenance versus R alone resulted in:
  - More than doubling of the MRD-negative conversion rate by 12 months and overall at 10^{-5}
  - Improved MRD-negative conversion rates by 12 months across subgroups and disease risk status at 10^{-5}
  - More than doubling of ≥6-month sustained MRD-negative rate at 10^{-5}
  - Quadrupling of MRD-negative conversion rate by 12 months at 10^{-6}
  - Further deepening of response rates
  - 47% reduction in the risk of disease progression or death, with a 30-month PFS rate of 83%
  - No new safety concerns

AURIGA data demonstrate the benefit of D-R maintenance therapy versus R alone in patients who were MRD positive after ASCT

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1st First Edition

Daratumumab with lenalidomide as maintenance after transplant in newly diagnosed multiple myeloma: the AURIGA study

Ashraf Badros, Laahn Foster, Larry D. Anderson Jr, Chakra P. Chaulagain, Erin Pettijohn, Andrew J. Cowan, Caitlin Costello, Sarah Larson, Douglas W. Sborov, Kenneth H. Shain, Rebecca Silbermann, Nina Shah, Alfred Chung, Maria Krevvata, Huiling Pei, Sharmila Patel, Vipin Khare, Annelore Cortoos, Robin Carson, Thomas S. Lin, and Peter Voorhees

https://doi.org/10.1182/blood.2024025746

AURIGA: Study Population and Screening

- Patients were enrolled from 52 sites across the United States and Canada between June 4, 2019, and May 4, 2023
- Among the 452 patients screened:
  - 200 were randomized on the study
  - 252 had screen failures
    - MRD negative, n = 115
    - Failure to achieve ≥VGPR, n = 25
    - Lack of index clone, n = 49
    - Other, n = 63

MRD, minimal residual disease; VGPR, very good partial response.

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AURIGA: Breakdown of Revised Cytogenetic Risk at Diagnosis

Characteristic	D-R (n = 99)	R (n = 101)
Revised cytogenetic risk at diagnosis,[a,b] n (%)		
n	93	89
Standard risk	52 (55.9)	53 (59.6)
High risk	32 (34.4)	30 (33.7)
del[17p]	13 (14.0)	3 (3.4)
t[4;14]	10 (10.8)	12 (13.5)
t[14;16]	6 (6.5)	7 (7.9)
t[14;20]	1 (1.1)	2 (2.2)
gain/amp[1q21]	16 (17.2)	22 (24.7)
Unknown	9 (9.7)	6 (6.7)

D-R, daratumumab/lenalidomide; R, lenalidomide.
[a]Assessed by local fluorescence in situ hybridization/karyotype test at diagnosis. [b]Revised high-risk cytogenetics are defined as ≥1 abnormality including del[17p], t[4;14], t[14;16], t[14;20], or gain/amp[1q21].

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AURIGA: Treatment Duration and Dose Modifications[a]

- Median (range) duration of study treatment was 30.7 (0.7-37.5) months in the D-R group and 20.6 (0-37.7) months in the R group
- Median (range) number of cycles was 33.0 (1-36) in the D-R group and 21.5 (1-36) in the R group
  - 88.5% (85/96) and 78.6% (77/98) of patients in the D-R and R groups, respectively, completed ≥12 maintenance cycles
- Median relative dose intensities were similar across both D-R and R groups

Patients, n (%)	D-R (n = 96)	R (n = 98)	Total (n = 194)
Patients with cycle delays	77 (80.2)	75 (76.5)	152 (78.4)
Reason for cycle delay			
Adverse event	64 (66.7)	60 (61.2)	124 (63.9)
Other	38 (39.6)	40 (40.8)	78 (40.2)
Patients with dose delays			
DARA	60 (62.5)	0	60 (30.9)
R	73 (76.0)	69 (70.4)	142 (73.2)
Patients with doses skipped			
DARA	27 (28.1)	0	27 (13.9)
Reason for dose skipped			
Adverse event	27 (28.1)	0	27 (13.9)
Other	2 (2.1)	0	2 (1.0)
R	74 (77.1)	64 (65.3)	138 (71.1)
Reason for dose skipped			
Adverse event	57 (59.4)	44 (44.9)	101 (52.1)
Other	59 (61.5)	48 (49.0)	107 (55.2)
Patients with dose adjusted			
R	69 (71.9)	57 (58.2)	126 (64.9)
Reason for dose adjusting			
Adverse event	49 (51.0)	43 (43.9)	92 (47.4)
Other	38 (39.6)	33 (33.7)	71 (36.6)

D-R, daratumumab/lenalidomide; R, lenalidomide; DARA, daratumumab.
[a]A given patient may have had multiple reasons and multiple occurrences for dose modifications. Each patient is only counted once for each row.

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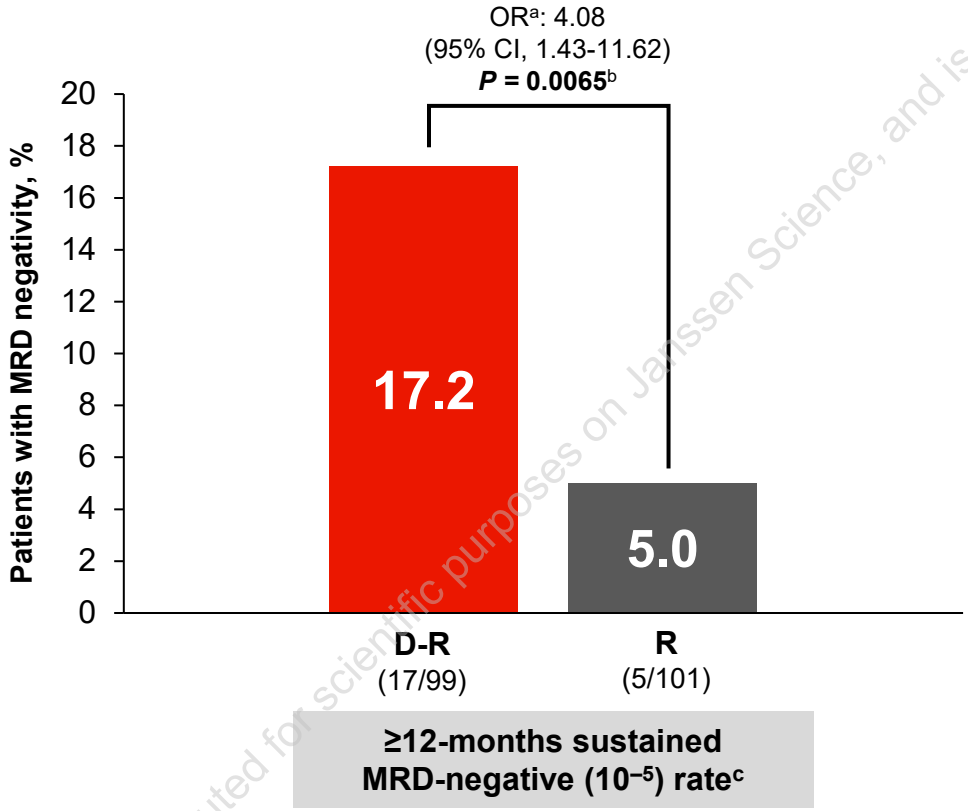
AURIGA: Sustained MRD Negativity Lasting ≥12 months at the 10^{-5} Threshold



The addition of DARA to R maintenance improved sustained MRD-negative (10^{-5}) rate lasting ≥12 months

MRD, minimal residual disease; OR, odds ratio; CI, confidence interval; D-R, daratumumab/lenalidomide; R, lenalidomide; DARA, daratumumab. [a]Mantel–Haenszel estimate of the common OR for stratified tables was used. The stratification factor was baseline cytogenetic risk per investigator assessment (high vs standard/unknown), as used for randomization. An OR >1 indicates an advantage for D-R. [b]*P* value from Fisher's exact test. [c]Defined as those who achieved MRD-negative status (at 10^{-5}) in 2 bone marrow aspirate assessments with a minimum of 12 months apart, without any assessment showing MRD-positive status in between assessments.

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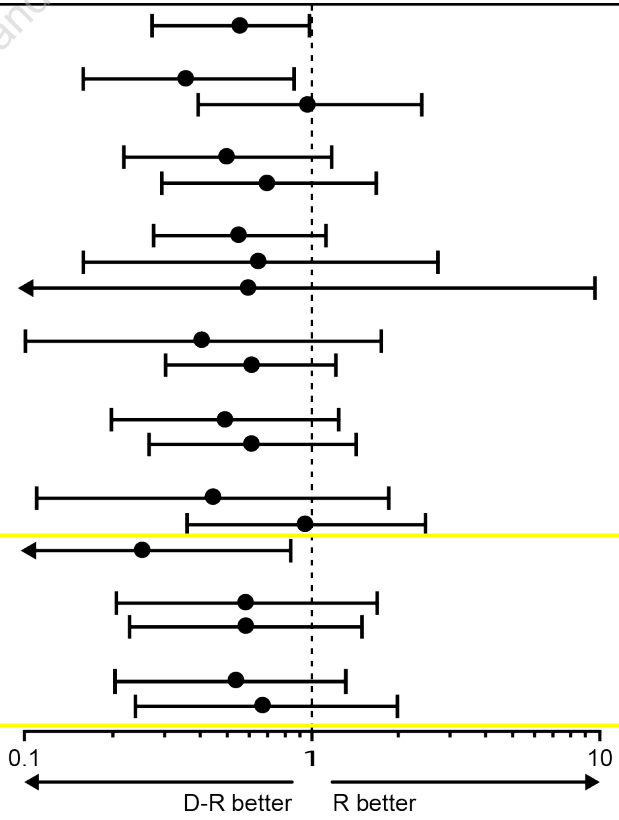
AURIGA: PFS in Subgroups

	D-R		R		
	n/N	Median PFS (months)	n/N	Median PFS (months)	Hazard ratio (95% CI)
ITT (overall)	19/99	37.9	26/101	NR	0.53 (0.29-0.97)
Sex					
Male	9/61	NR	17/58	NR	0.37 (0.16-0.87)
Female	10/38	37.9	9/43	NR	0.98 (0.40-2.41)
Age					
<65 years	9/61	37.9	14/61	NR	0.51 (0.22-1.18)
≥65 years	10/38	NR	12/40	NR	0.71 (0.30-1.67)
Race					
White	14/67	NR	20/68	NR	0.56 (0.28-1.12)
Black	3/20	NR	5/24	NR	0.66 (0.16-2.75)
Other	2/12	37.9	1/9	NR	0.60 (0.04-9.67)
Weight					
≤70 kg	4/23	37.9	5/18	NR	0.42 (0.10-1.76)
>70 kg	15/76	NR	20/81	NR	0.62 (0.31-1.22)
Baseline ECOG PS score					
0	8/45	NR	14/55	NR	0.50 (0.20-1.24)
≥1	11/54	37.3	12/46	NR	0.62 (0.27-1.43)
ISS at diagnosis					
I	3/40	NR	6/38	NR	0.46 (0.11-1.84)
II	8/28	37.9	9/37	NR	0.95 (0.37-2.49)
III	5/23	NR	10/23	28.5	0.26 (0.08-0.85)
Cytogenetlc risk at diagnosis					
High risk[a]	9/22	NR	6/15	16.7	0.60 (0.21-1.70)
Standard risk	8/63	37.9	11/66	NR	0.59 (0.23-1.49)
Revised cytogenetic risk at diagnosis					
High risk[b]	9/32	NR	10/30	NR	0.53 (0.21-1.31)
Standard risk	7/52	37.9	8/53	NR	0.69 (0.24-1.95)



PFS benefits were observed for D-R versus R across all clinically relevant subgroups

PFS, progression-free survival; D-R, daratumumab/lenalidomide; R, lenalidomide; CI, confidence interval; ITT, intent-to-treat; ECOG PS, Eastern Cooperative Oncology Group performance status; ISS, International Staging System; NR, not reached. [a]High-risk cytogenetics are defined as ≥1 abnormality including del[17p], t[4;14], or t[14;16]. [b]Revised high-risk cytogenetics are defined as ≥1 abnormality including del[17p], t[4;14], t[14;16], t[14;20], or gain/amp[1q21].

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