Daratumumab Plus Lenalidomide (D-R) Versus Lenalidomide (R) Alone as Maintenance Therapy in Newly Diagnosed Multiple Myeloma (NDMM) After Transplant: Analysis of the Phase 3 AURIGA Study Among Clinically Relevant Subgroups

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AURIGA: Introduction

- The phase 3 AURIGA study (NCT03901963) evaluated the addition of DARA SC to R maintenance in transplant-eligible patients with NDMM who were anti-CD38 naïve and MRD-positive post-ASCT, which was the first randomized study to directly compare D-R versus R maintenance therapy[1]
  - In the primary analysis (median follow-up, 32.3 months), D-R maintenance versus R alone resulted in:
    - A statistically significant increase (D-R, 50.5% vs R, 18.8%) in the MRD-negative (10^{-5}) conversion rate by 12 months of maintenance treatment (OR, 4.51; 95% CI, 2.37-8.57; *P* <0.0001)
    - A 47% reduction in the risk of disease progression or death (HR, 0.53; 95% CI, 0.29-0.97; *P* = 0.0361)

Here, we present a post hoc analysis of clinically relevant subgroups from the AURIGA study including:

- **Elderly and Black patients**
- **Patients with high-risk disease per ISS disease staging**
- **Patients with high cytogenetic risk per the standard, revised, and IMS 2024 high-risk criteria[2,a]**

DARA, daratumumab; SC, subcutaneous; R, lenalidomide; NDMM, newly diagnosed multiple myeloma; MRD, minimal residual disease; ASCT, autologous stem cell transplant; D-R, daratumumab/lenalidomide; OR, odds ratio; CI, confidence interval; HR, hazard ratio; ISS, International Staging System; IMS, International Myeloma Society. [a]Per the available AURIGA data. 1. Badros AZ, et al. *Blood*. Published online September 27, 2024. doi:10.1182/blood.2024025746. 2. Moreau P. Presented at: 21st International Myeloma Society (IMS) Annual Meeting; September 25-28, 2024; Rio de Janeiro, Brazil.

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AURIGA: Study Design

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-negativity status was assessed regardless of response and obtained after 12, 18, 24, and 36 cycles[b]

Primary endpoint

- MRD-negative (10^{-5}) conversion rate (NGS) 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; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; PO, orally; PFS, progression-free survival; CR, complete response; OS, overall survival; IMWG, International Myeloma Working Group; NGS, next-generation sequencing. [a]As assessed by IMWG 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: Subgroup Definitions

- The following clinically relevant subgroups were explored in this post hoc analysis:

Demographic and disease characteristics

Race
Black
White

Age
<65 years
≥65 years

ISS disease stage at diagnosis
I
II
III

Baseline response status upon entering the study[a]
<CR
≥CR

Cytogenetic risk[b]

Standard and revised definitions

Standard high risk (≥1 HRCA)
del(17p)
t(4;14)
t(14;16)
t(14;20)
Gain/amp(1q21)
Revised high risk (≥1 HRCA)

Standard definition (per protocol)
Standard risk
High risk

Revised definition
Revised standard risk (0 HRCAs)
Revised high risk (≥1 HRCA)
1 HRCA
≥2 HRCAs
Gain/amp(1q21)[c,d]
Isolated gain/amp(1q21)[c]

IMS 2024 high-risk multiple myeloma[1]

Modified IMS 2024 high-risk criteria in AURIGA[b,e]

~~High ß2M (>5.5 mg/dL) + creatinine <1.2 mg/dL~~
≥20% del(17p)[f]
~~TP53 mutation~~
~~Biallelic del(1p32)~~
Association of ≥2
t(4;14) *or* t(14;16) *or* t(14;20)
Gain/amp(1q21)
~~Monoallelic~~ del(1p32)

Modified IMS 2024 definition
Modified IMS 2024 standard risk[g]
Modified IMS 2024 high risk
≥20% del(17p)
t(4;14)/(14;16)/(14;20) + gain/amp(1q21)[c] and/or del(1p32)
Del(1p32) + gain/amp(1q21)[c]

HRCA, high-risk cytogenetic abnormality; FISH, fluorescence in-situ hybridization; ß2M, ß-2-microglobulin. [a]Per IMWG 2016 criteria. [b]Cytogenetic risk was assessed at diagnosis using available local FISH/karyotype testing. [c]Gain (3 copies) or amplification (≥4 copies) of 1q21. [d]Irrespective of occurrence of other HRCAs. [e]In this analysis, high risk per the IMS 2024 criteria was determined using criteria shown based on data available; in the AURIGA study, data were not collected on TP53 mutation, differentiation between monoallelic versus biallelic del(1p32), baseline ß2M levels (ISS disease stage was gathered at diagnosis, but no associated creatinine levels collected at baseline), and creatinine levels. [f]Cancer clone fraction, by analyses conducted on CD138-positive/purified cells. [g]A patient was considered standard risk per modified IMS 2024 criteria if it was concluded with certainty that their cytogenetic results were not in any of the 3 modified IMS 2024 high-risk subcategories listed. 1. Moreau P. Presented at: 21st International Myeloma Society (IMS) Annual Meeting; September 25-28, 2024; Rio de Janeiro, Brazil.

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AURIGA: Demographic and Disease Characteristics (ITT)

- This post hoc analysis occurred at the time of primary analysis (median follow-up, 32.3 months)

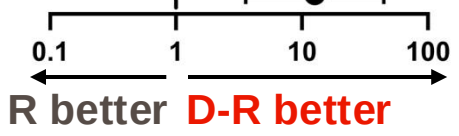
Characteristic, n (%)	D-R (n = 99)	R (n = 101)
Age, years		
<65	61 (61.6)	61 (60.4)
≥65	38 (38.4)	40 (39.6)
Race		
White	67 (67.7)	68 (67.3)
Black	20 (20.2)	24 (23.8)
ISS disease stage		
n	91	98
I	40 (44.0)	38 (38.8)
II	28 (30.8)	37 (37.8)
III	23 (25.3)	23 (23.5)
Patient response category at baseline[a]		
<CR (VGPR)	71 (71.7)	71 (70.3)
≥CR	28 (28.3)	30 (29.7)

Characteristic, n (%)	D-R (n = 99)	R (n = 101)
Cytogenetic risk at diagnosis per standard definition[b,c]		
n	92	89
Standard risk	63 (68.5)	66 (74.2)
High risk	22 (23.9)	15 (16.9)
Unknown	7 (7.6)	8 (9.0)
Cytogenetic risk at diagnosis per revised definition[d]		
n	93	89
Revised standard risk (0 HRCAs)	52 (55.9)	53 (59.6)
Revised high risk (≥1 HRCA)	32 (34.4)	30 (33.7)
1 HRCA	21 (22.6)	20 (22.5)
≥2 HRCAs	11 (11.8)	10 (11.2)
Gain/amp(1q21)	16 (17.2)	22 (24.7)
Isolated gain/amp(1q21)	10 (10.8)	15 (16.9)
Unknown	9 (9.7)	6 (6.7)
Cytogenetic risk per modified IMS 2024 criteria[1,e]		
n	93	90
Modified IMS 2024 standard risk	67 (72.0)	68 (75.6)
Modified IMS 2024 high risk	17 (18.3)	8 (8.9)
≥20% del(17p)	10 (10.8)	2 (2.2)
t(4;14)/(14;16)/(14;20) + gain/amp(1q21) and/or del(1p32)	5 (5.4)	6 (6.7)
Del(1p32) + gain/amp(1q21)	4 (4.3)	0
Unknown	9 (9.7)	14 (15.6)

ITT, intent-to-treat. [a]Per IMWG 2016 criteria. [b]High-risk cytogenetics per the standard definition are defined as ≥1 abnormality including del(17p), t(4;14), or t(14;16). [c]The imbalance in cytogenetic risk between arms, especially a higher number of patients with del(17p) for patients randomized to the D-R arm, was due to the fact that some assessments were made on cytogenetic data at screening and some on cytogenetic data at the time of diagnosis. [d]Revised high-risk cytogenetics per the revised definition are defined as ≥1 abnormality including del(17p), t(4;14), t(14;16), t(14;20), or gain/amp(1q21). [e]High risk per the modified IMS 2024 criteria is defined as the presence of ≥20% del(17p); or the association of ≥2 of the following: t(4;14) or t(14;16) or t(14;20); gain/amp(1q21); or del(1p32) [in the AURIGA study, data were not available on TP53 mutations, baseline ß2M, and creatinine levels and differentiation between monoallelic versus biallelic del(1p32)]. 1. Moreau P. Presented at: 21st International Myeloma Society (IMS) Annual Meeting; September 25-28, 2024; Rio de Janeiro, Brazil.

AURIGA: MRD-negative (10^{-5}) Conversion Rate by 12 Months of Maintenance[a] by Subgroups

	MRD-negative (10^{-5}) conversion rate,[a] n/N (%)		OR[b] (95% CI)
	D-R	R	
ITT[c]	50/99 (50.5)	19/101 (18.8)	4.51 (2.37-8.57)
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)
ISS disease stage			
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)
Baseline response status[d]			
<CR	27/71 (38.0)	11/71 (15.5)	3.35 (1.50-7.46)
≥CR	23/28 (82.1)	8/30 (26.7)	12.65 (3.58-44.64)



D-R improved MRD-negative conversion rate by 12 months versus R regardless of age, race, ISS disease stage, or response upon study entry

[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 is used for ITT; Mantel-Haenszel estimate of the common OR for unstratified tables is used for subgroups. An OR >1 indicates an advantage for D-R. [c]ITT analysis set is defined as all patients who were randomized to treatment. [d]Response status upon entering the study as assessed by IMWG 2016 criteria.

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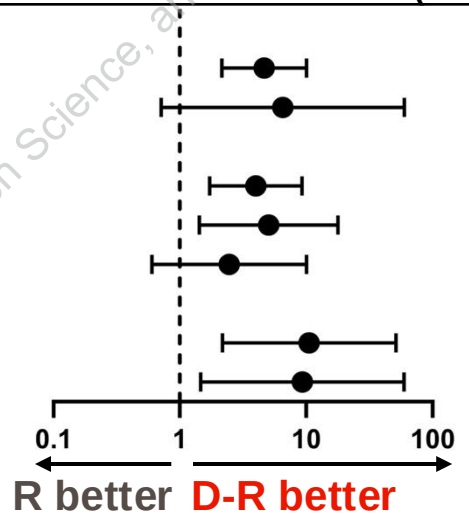
AURIGA: MRD-negative (10^{-5}) Conversion Rate by 12 Months of Maintenance[a] by Risk Status

	MRD-negative (10^{-5}) conversion rate,[a] n/N (%)		OR[b] (95% CI)
	D-R	R	
Cytogenetic risk at diagnosis			
Standard risk	35/63 (55.6)	14/66 (21.2)	4.64 (2.15-10.04)
High risk[c]	7/22 (31.8)	1/15 (6.7)	6.53 (0.71-60.05)
Revised cytogenetic risk at diagnosis			
Revised standard risk (0 HRCAs)	28/52 (53.8)	12/53 (22.6)	3.99 (1.72-9.26)
Revised high risk[d] (≥1 HRCA)	14/32 (43.8)	4/30 (13.3)	5.06 (1.43-17.88)
1 HRCA	8/21 (38.1)	4/20 (20.0)	2.46 (0.60-10.04)
≥2 HRCAs	6/11 (54.5)	0/10 (0)	NE (NE-NE)[e]
Gain/amp(1q21)	10/16 (62.5)	3/22 (13.6)	10.56 (2.17-51.42)
Isolated gain/amp(1q21)	7/10 (70.0)	3/15 (20.0)	9.33 (1.46-59.48)



D-R improved MRD-negative conversion rate by 12 months versus R even among patients with ultra-high–risk disease, as well as standard-risk disease

NE, not estimable. [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 unstratified tables is used. An OR >1 indicates an advantage for D-R. [c]High-risk cytogenetics per the standard definition are defined as ≥1 abnormality including del(17p), t(4;14), or t(14;16). [d]Revised high-risk cytogenetics per the revised definition are defined as ≥1 abnormality including del(17p), t(4;14), t(14;16), t(14;20), or gain/amp(1q21). [e]Not evaluable because no patient in the R arm had MRD-negative conversion.

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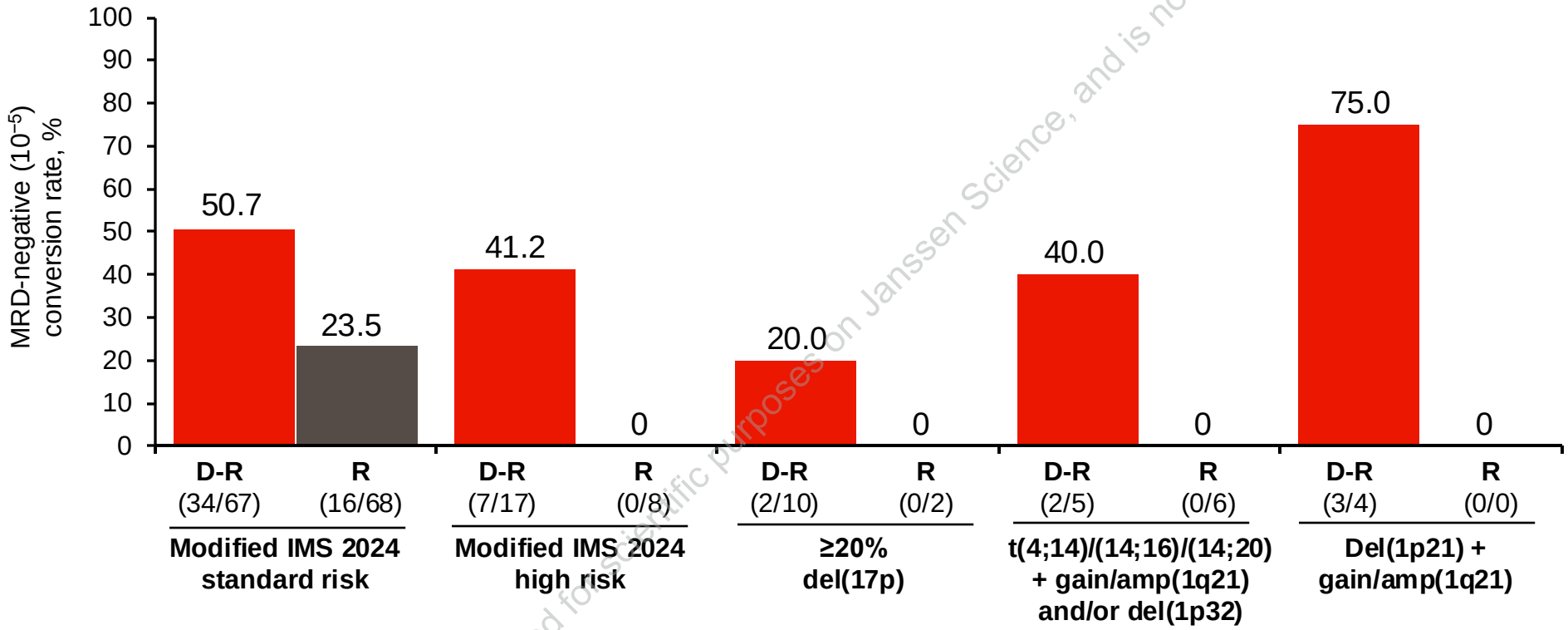
AURIGA: MRD-negative (10^{-5}) Conversion Rate by 12 Months With Modified IMS 2024 Criteria[1,a,b]

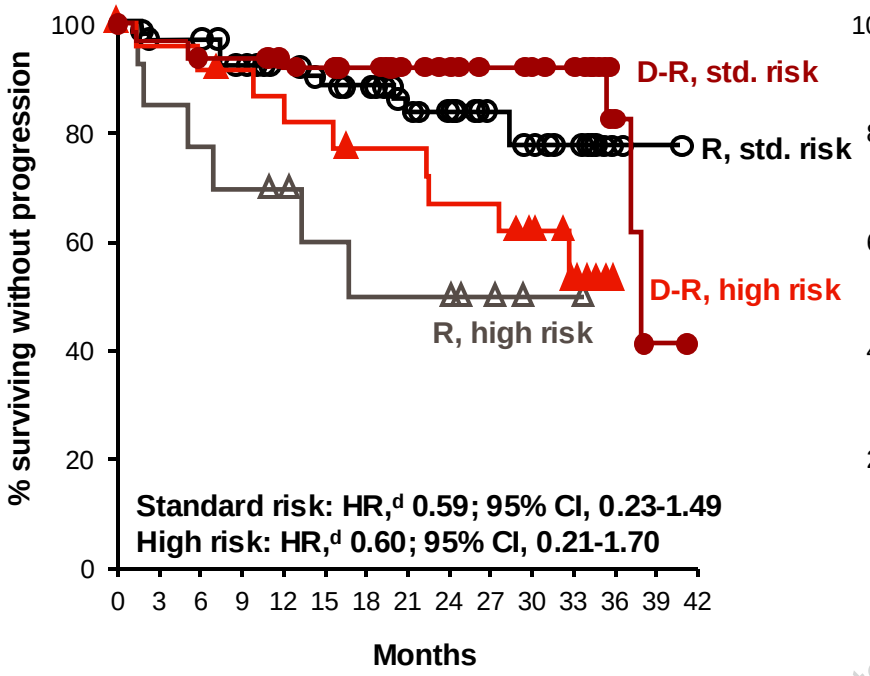


D-R improved MRD-negative conversion rate by 12 months of maintenance versus R among patients with modified IMS 2024 high-risk disease

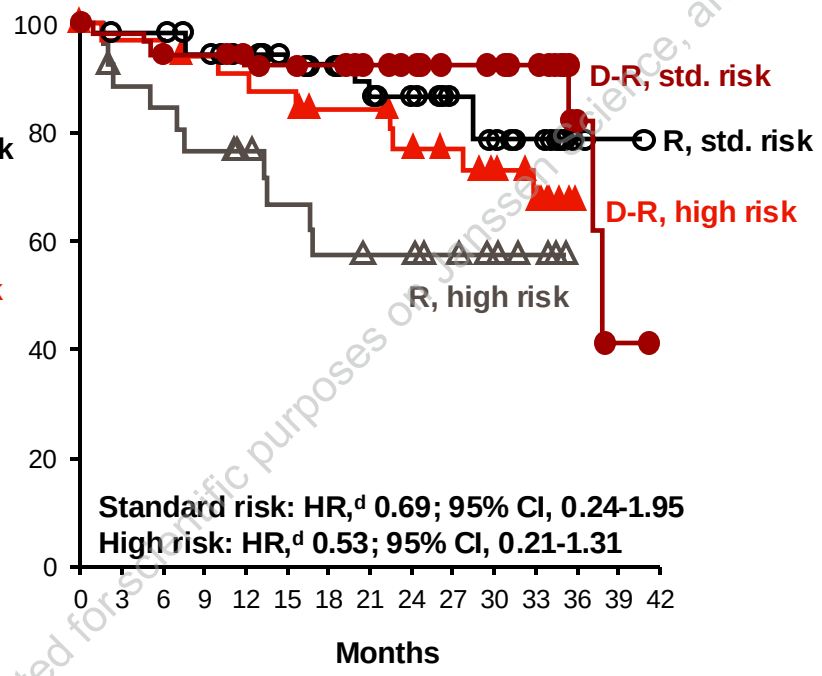
[a]High risk per the modified IMS 2024 criteria is defined as the presence of ≥20% del(17p), or the association of ≥2 of the following: t(4;14) or t(14;16) or t(14;20); gain/amp(1q21); or del(1p32) [in the AURIGA study, data were not available on TP53 mutations, baseline ß2M, and creatinine levels and differentiation between monoallelic versus biallelic del(1p32)]. [b]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. 1. Moreau P. Presented at: 21st International Myeloma Society (IMS) Annual Meeting; September 25-28, 2024; Rio de Janeiro, Brazil.

AURIGA: PFS by Cytogenetic Risk per Standard, Revised, and Modified IMS 2024 Definitions

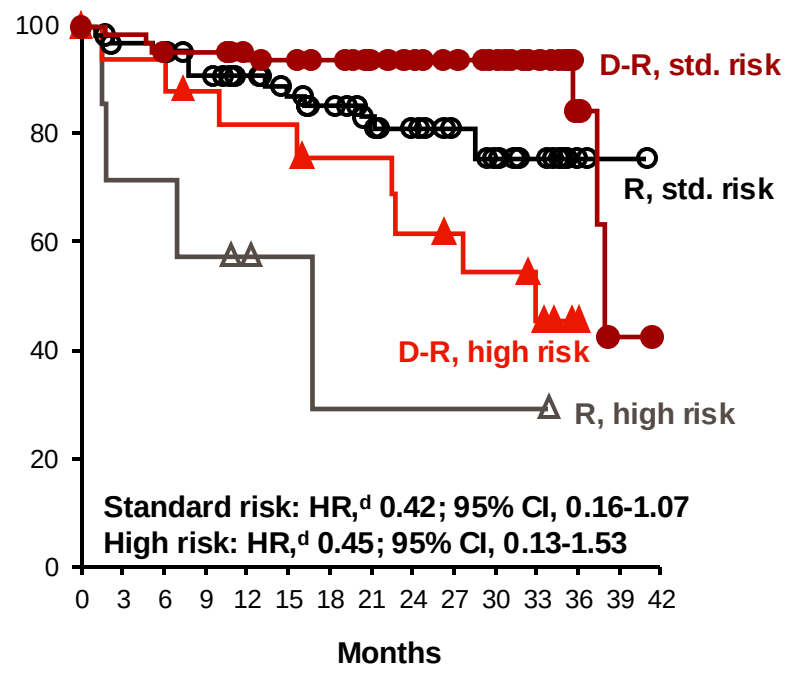
Standard criteria[a]



Revised criteria[b]



Modified IMS 2024 criteria[c]



D-R maintenance demonstrated a PFS benefit versus R across various definitions of high cytogenetic risk, in addition to patients with standard-risk disease

[a]High-risk cytogenetics per the standard definition are defined as ≥1 abnormality including del(17p), t(4;14), or t(14;16).[b]Revised high-risk cytogenetics per the revised definition are defined as ≥1 abnormality including del(17p), t(4;14), t(14;16), t(14;20), or gain/amp(1q21). [c]High risk per the modified IMS 2024 criteria is defined as the presence of ≥20% del(17p); or the association of ≥2 of the following: t(4;14) or t(14;16) or t(14;20); gain/amp(1q21); or del(1p32) [in the AURIGA study, data were not available on TP53 mutations, baseline ß2M, and creatinine levels and differentiation between monoallelic versus biallelic del(1p32)]. [d]HR and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable. A HR <1 indicates an advantage for D-R.

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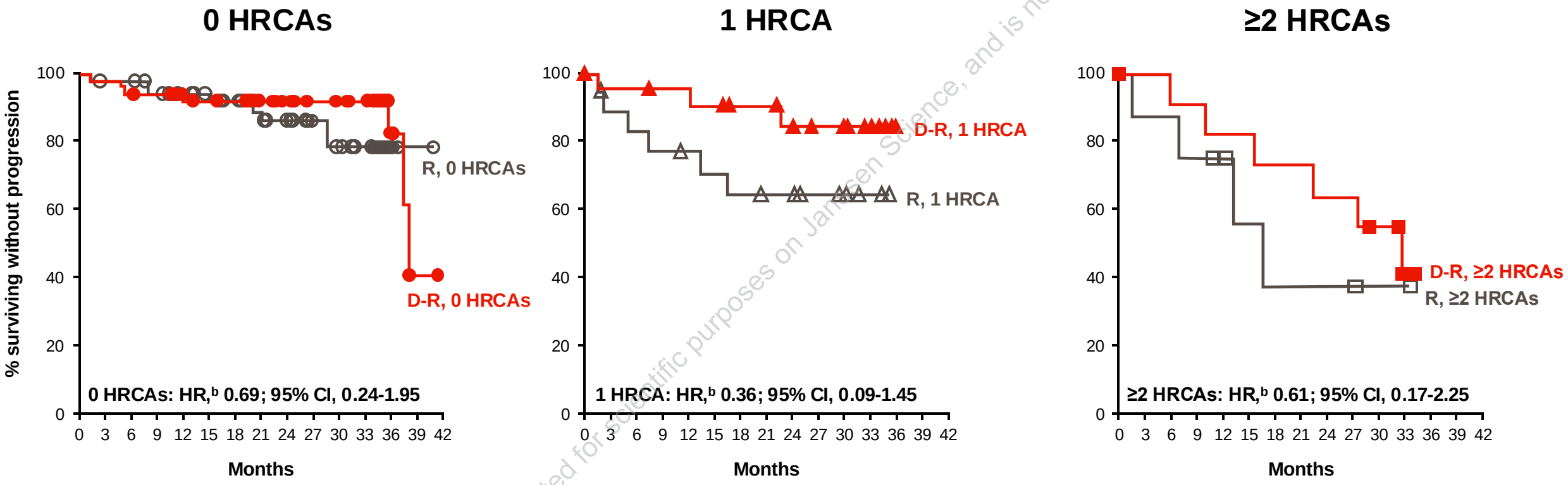
AURIGA: PFS by Revised HRCAs (0, 1, and ≥2)[a]



D-R maintenance led to a PFS benefit versus R regardless of the number of HRCAs

[a]HRCA numbers is defined as number of abnormalities from del(17p), t(4;14), t(14;16), t(14;20), or gain/amp(1q21). Cytogenetic results at diagnosis (based on CRF collected data from local labs) were used in the analysis.
[b]HR and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable. A HR <1 indicates an advantage for D-R.

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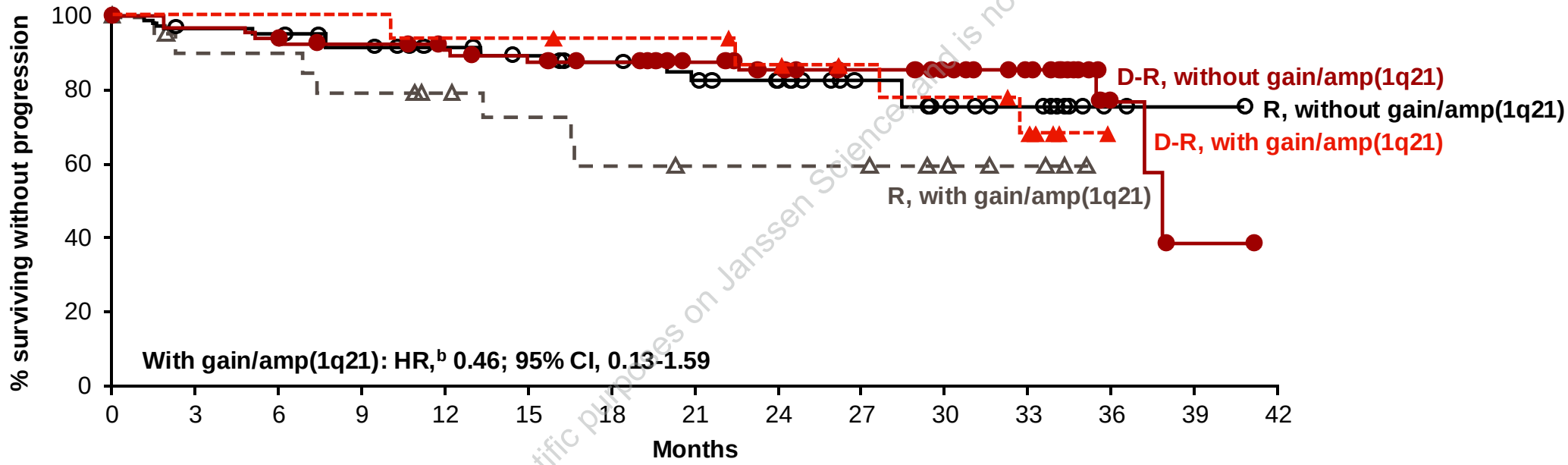
AURIGA: PFS by Gain/amp(1q21) Irrespective of Other HRCAs[a]



No. at risk															
R, with gain/amp(1q21)	22	17	17	15	13	11	9	8	8	8	6	3	0	0	0
D-R, with gain/amp(1q21)	16	16	16	16	15	15	14	14	12	10	9	7	0	0	0
R, without gain/amp(1q21)	61	56	55	51	47	42	40	34	31	23	19	15	2	1	0
D-R, without gain/amp(1q21)	68	64	62	59	56	53	50	44	40	37	34	29	4	1	0

D-R maintenance improved PFS versus R among patients with gain/amp(1q21)

[a]With (presence of) gain/amp(1q21) refers to gain/amp(1q21) abnormality regardless of status of the other HRCAs per the revised definition. Without gain/amp(1q21) refers to revised high-risk or revised standard-risk without gain/amp(1q21) abnormality. [b]HR and 95% CI from a Cox proportional hazards model with treatment as the sole explanatory variable. A HR <1 indicates an advantage for D-R.

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AURIGA: Safety by Age

- Among patients aged <65 years, median duration of therapy was 25.0 months (D-R, 30.5; R, 23.5 months)
- Among patients aged ≥65 years, median duration of therapy was 24.4 months (D-R, 32.7; R, 19.2 months)

Patients with ≥1TEAE, n (%)	D-R		R	
	<65 years (n = 59)	≥65 years (n = 37)	<65 years (n = 58)	≥65 years (n = 40)
Grade 3/4 TEAEs	45 (76.3)	26 (70.3)	37 (63.8)	29 (72.5)
Most common[a]				
Neutropenia[b]	26 (44.1)	19 (51.4)	25 (43.1)	16 (40.0)
Lymphopenia	7 (11.9)	3 (8.1)	3 (5.2)	2 (5.0)
Hypertension	6 (10.2)	1 (2.7)	3 (5.2)	1 (2.5)
Leukopenia	6 (10.2)	3 (8.1)	2 (3.4)	4 (10.0)
Hypokalemia	4 (6.8)	3 (8.1)	2 (3.4)	4 (10.0)
Pneumonia	1 (1.7)	4 (10.8)	1 (1.7)	3 (7.5)
Grade 3/4 cytopenias	31 (52.5)	21 (56.8)	27 (46.6)	19 (47.5)
Grade 3/4 infections	11 (18.6)	7 (18.9)	6 (10.3)	7 (17.5)
Serious TEAEs	14 (23.7)	15 (40.5)	7 (12.1)	15 (37.5)
COVID-19 events				
Any grade	19 (32.2)	9 (24.3)	22 (37.9)	7 (17.5)
Grade 3/4	1 (1.7)	0	3 (5.2)	0
TEAEs leading to discontinuation of any treatment component[c]	7 (11.9)	7 (18.9)	4 (6.9)	4 (10.0)
Death due to TEAEs	0	2 (5.4)	0	1 (2.5)

No increase in grade 3/4 infection or cytopenia rate among patients aged ≥65 years with the addition of DARA SC

TEAE, treatment-emergent adverse event; AE, adverse event. [a]Occurring in ≥10% of patients in either treatment group in either age category. [b]Preferred term grouping. [c]Includes those who had adverse events with action taken as drug withdrawn to ≥1 component of study treatment on "AE" complete report form page.

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AURIGA: Safety by Race

- Among White patients, median duration of therapy was 23.7 months (D-R, 29.3; R, 18.9 months)
- Among Black patients, median duration of therapy was 25.4 months (D-R, 28.3; R, 25.4 months)

Patients with ≥1TEAE, n (%)	D-R		R	
	White (n = 64)	Black (n = 20)	White (n = 65)	Black (n = 24)
Grade 3/4 TEAEs	49 (76.6)	15 (75.0)	46 (70.8)	16 (66.7)
Most common[a]				
Neutropenia[b]	29 (45.3)	10 (50.0)	28 (43.1)	11 (45.8)
Lymphopenia	9 (14.1)	0	5 (7.7)	0
Hypokalemia	6 (9.4)	1 (5.0)	3 (4.6)	3 (12.5)
Leukopenia	5 (7.8)	3 (15.0)	4 (6.2)	2 (8.3)
Diarrhea	2 (3.1)	1 (5.0)	2 (3.1)	3 (12.5)
Fatigue	0	2 (10.0)	2 (3.1)	1 (4.2)
Grade 3/4 cytopenias	35 (54.7)	10 (50.0)	31 (47.7)	12 (50.0)
Grade 3/4 infections	13 (20.3)	4 (20.0)	8 (12.3)	5 (20.8)
Serious TEAEs	20 (31.3)	6 (30.0)	14 (21.5)	7 (29.2)
COVID-19 events				
Any grade	18 (28.1)	7 (35.0)	20 (30.8)	5 (20.8)
Grade 3/4	1 (1.6)	0	1 (1.5)	2 (8.3)
TEAEs leading to discontinuation of any treatment component[c]	14 (21.9)	0	7 (10.8)	1 (4.2)
Death due to TEAEs	2 (3.1)	0	1 (1.5)	0

D-R maintenance did not lead to additional safety concerns in the Black patient population

[a]Occurring in ≥10% of patients in either treatment group in either racial group. [b]Preferred term grouping. [c]Includes those who had adverse events with action taken as drug withdrawn to ≥1 component of study treatment on "AE" complete report form page.

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AURIGA: Conclusions

- In this post hoc analysis of AURIGA, the addition of DARA SC to R maintenance in transplant-eligible patients with NDMM who were anti-CD38 naïve, in ≥VGPR, and MRD-positive post-ASCT resulted in:
  - An increase in MRD-negative (10^{-5}) conversion rates by 12 months of maintenance and overall, across all subgroups, among patients with standard-risk and high-risk multiple myeloma, including those with high cytogenetic risk
  - Favorable PFS benefits consistently observed across all subgroups, including patients with standard-risk and high-risk multiple myeloma
  - No unexpected safety concerns among patients ≥65 years of age or Black patients

This post hoc analysis shows the benefit of D-R maintenance in clinically relevant subgroups of patients with NDMM, including those with high- and standard-risk disease

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