Teclistamab Plus Daratumumab (Tec-Dara) in Patients (Pts) With Relapsed Refractory Multiple Myeloma (RRMM): Analysis of MajesTEC-3 Based on Cytogenetic and Functional Risk

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https://www.congresshub.com/EHA2026/Oncology/Teclistamab/Banerjee

MajesTEC-3: Background

- Tec-Dara significantly improved PFS and OS and increased MRD-negativity rates vs DPd/DVd in patients with RRMM and 1 to 3 prior LOTs in the phase 3 MajesTEC-3 study[1,2]
  - Benefits with Tec-Dara were consistently observed across prespecified subgroups, including patients with high-risk cytogenetics[a]
- Based on these unprecedented results, Tec-Dara received US approval for the treatment of RRMM with ≥1 prior LOT including a PI and IMiD[3]
- Patients with RRMM and high-risk characteristics have poorer disease outcomes,[4-6] highlighting the need for more effective therapies in such subgroups

We present an in-depth, post hoc analysis of MajesTEC-3 outcomes in high-risk subgroups, including expanded[b] HRCAs and FHR status

DPd/DVd, daratumumab with dexamethasone and pomalidomide or bortezomib; FHR, functional high-risk; HRCA, high-risk cytogenetic abnormality; IMiD, immunomodulatory drug; LOT, line of therapy; MRD, minimal residual disease; OS, overall survival; PFS, progression-free survival; PI, proteasome inhibitor; RRMM, relapsed refractory multiple myeloma; Tec-Dara, teclistamab plus daratumumab. [a]Prespecified standard risk: none of del(17p), t(4;14), or t(14;16). Prespecified high risk: ≥1 of del(17p), t(4;14), or t(14;16). [b]Expanded risk abnormalities include the following: del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21). 1. Costa LJ, et al. *N Engl J Med*. 2026;394(8):739-752. 2. Mateos MV, et al. Presented at: 67th ASH Annual Meeting and Exposition; December 6-9, 2025; Orlando, FL, USA. Oral (LBA-6). 3. TECVAYLI® (teclistamab-cqyv) injection, for subcutaneous use [package insert]. Janssen Biotech; 2026. 4. Raab MS, et al. *EJHaem*. 2023;4(4):1117-1131. 5. Hanamura I. *Int J Hematol*. 2022;115(6):762-777. 6. Banerjee R, et al. *Frontiers Oncol*. 2023;13:1240966.

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MajesTEC-3: Phase 3 Study Design

Key inclusion criteria

- RRMM
- 1-3 prior LOTs including a PI and lenalidomide
  - Patients with only 1 prior LOT must have been lenalidomide refractory per IMWG criteria
- ECOG PS score of 0-2

Key exclusion criteria

- Prior BCMA-directed therapy
- Refractory to anti-CD38 mAbs[a]

1:1 randomization N=587

22 Oct 2021-29 Sept 2023[b]

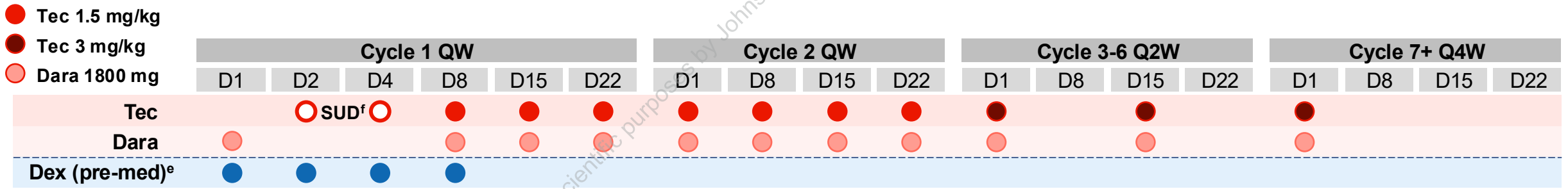
Tec-Dara N=291
SC dosing following Dara schedule

DPd/DVd N=296
by investigator's choice[c]

Primary end point
- PFS per IRC

Key secondary end points
- ≥CR[d] and ORR[d]
- MRD negativity (10^{-5})
- OS
- MySIm-Q Total Symptom score

Other secondary end points
- Safety
- PK and immunogenicity



Steroid sparing after Cycle 1 Day 8, and SC dosing aligned with approved Dara schedule

BCMA, B-cell maturation antigen; ≥CR, complete response or better; D, Day; Dara, daratumumab; Dex, dexamethasone; ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; IRC, independent review committee; mAb, monoclonal antibody; MySIm-Q, Multiple Myeloma Symptom and Impact Questionnaire; ORR, overall response rate; PK, pharmacokinetics; pre-med, pre-medication; QW, weekly; Q2W, every 2 weeks; Q4W, every 4 weeks; SC, subcutaneous; SUD, step-up dosing; Tec, teclistamab. [a]Prior exposure to anti-CD38 mAbs was permitted. [b]During the COVID-19 pandemic. [c]DPd/DVd were administered per approved schedules. [d]Response and disease progression were assessed by a blinded IRC per IMWG criteria. [e]Dexamethasone, acetaminophen, and diphenhydramine pre-medication was required for the first 2 weeks; subsequent dexamethasone was not required thereafter. [f]Patients received SUD of 0.06 mg/kg and 0.3 mg/kg on Days 2 and 4, respectively.

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MajesTEC-3: Subgroup Analysis

Cytogenetic Risk[a]

Prespecified and expanded definitions

Prespecified high risk (≥1 HRCA)

Expanded high risk (≥1 HRCA)

- del(17p)
- t(4;14)
- t(14;16)
- Gain(1q21)
- Amp(1q21)

Prespecified definition	Expanded definition
Standard risk (0 HRCAs)	Expanded standard risk (0 HRCAs)
High risk (≥1 HRCA)	Expanded high risk (≥1 HRCA)
	Number of expanded HRCAs: 0, 1, ≥2[b]

Functional High Risk

Explored in patients with 1 prior LOT only

FHR definition

Patients with 1 prior LOT with progressive disease within 18 months of ASCT or start of initial therapy

Endpoints: PFS and MRD-negative ≥CR rate[c] (10^{-5} and 10^{-6})

ASCT, autologous stem-cell transplant; CR/sCR, complete response/stringent complete response; FISH, fluorescence in situ hybridization; NGF, next-generation flow; NGS, next-generation sequencing; [a]Cytogenetic risk was assessed centrally with FISH or on local FISH or karyotype testing if central FISH was not available. [b]Also referred to as "ultra high-risk". [c]MRD-negative ≥CR refers to MRD negativity achieved within 3 months prior to achieving CR/sCR or at any time after CR/sCR and before progression or subsequent therapy. Assessed in the MRD NGS primary analysis set, defined as all randomized patients except those recruited in China (due to China instead utilizing NGF for MRD assessment).

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MajesTEC-3: Disease Characteristics

Characteristic, n (%)	Tec-Dara (n = 291)	DPd/DVd (n = 296)
Baseline cytogenetic risk[a,b] per prespecified definition		
Standard risk	126 (43.3)	145 (49.0)
High risk	104 (35.7)	104 (35.1)
Baseline cytogenetic risk[a,c] per expanded definition		
Expanded standard risk (0 HRCAs)	52 (17.9)	55 (18.6)
Expanded high risk (≥1 HRCA)	169 (58.1)	180 (60.8)
1 HRCA	105 (36.1)	111 (37.5)
≥2 HRCAs	64 (22.0)	69 (23.3)
Functional high-risk status		
No. of patients with 1 prior LOT only	108	114
Yes	26 (24.1)	20 (17.5)
No	82 (75.9)	94 (82.5)

- Median follow-up, 34.5 months
- A high proportion of patients were classified as having high-risk by the expanded definition
- 24% of Tec-Dara patients had progressed within 18 months of ASCT or initial treatment

Baseline risk profile was inclusive of real-world high-risk disease biology characteristics

[a]Cytogenetic risk was assessed centrally with FISH or on local FISH or karyotype testing if central FISH was not available. [b]Prespecified standard risk: none of del(17p), t(4;14), or t(14;16). Prespecified high risk: ≥1 of del(17p), t(4;14), or t(14;16). [c]Expanded standard risk: none of del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21). Expanded high risk: ≥1 of del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21).

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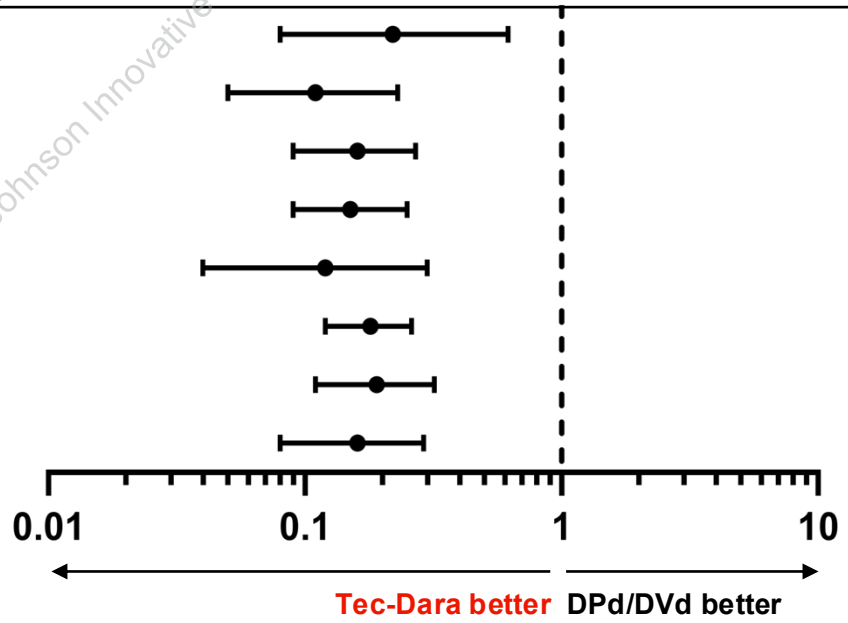
MajesTEC-3: PFS By Risk Status (ITT)

	Tec-Dara		DPd/DVd		HR (95% CI)
	Events n/N	Median PFS (mo)	Events n/N	Median PFS (mo)	
Functional high risk	5/26	NE	14/20	23.2	0.22 (0.08-0.62)
Non-functional high risk	8/82	NE	57/94	20.8	0.11 (0.05-0.23)
Prespecified std. risk[a]	15/126	NE	84/145	24.7	0.16 (0.09-0.27)
Prespecified high risk[a]	20/104	NE	78/104	14.4	0.15 (0.09-0.25)
Expanded std. risk[b]	5/52	NE	34/55	24.2	0.12 (0.04-0.30)
Expanded high risk[b]	30/169	NE	122/180	15.8	0.18 (0.12-0.26)
1 HRCA	17/105	NE	69/111	17.9	0.19 (0.11-0.32)
≥2 HRCAs	13/64	NE	53/69	14.4	0.16 (0.08-0.29)



Tec-Dara consistently improved PFS vs DPd/DVd regardless of disease biology

CI, confidence interval; HR hazard ratio; ITT, intent-to-treat; NE, not estimable; Std., standard. [a]Prespecified standard risk: none of del(17p), t(4;14), or t(14;16). Prespecified high risk: ≥1 of del(17p), t(4;14), or t(14;16). [b]Expanded standard risk: none of del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21). Expanded high risk: ≥1 of del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21).

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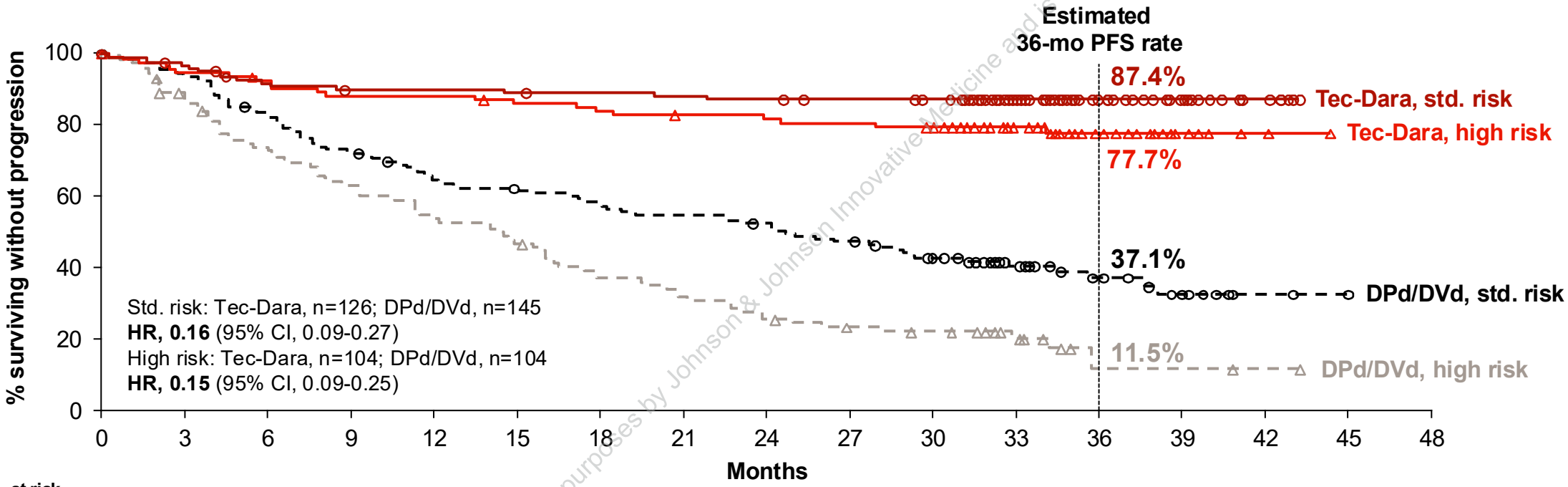
MajesTEC-3: PFS by Prespecified[a] Cytogenetic Risk



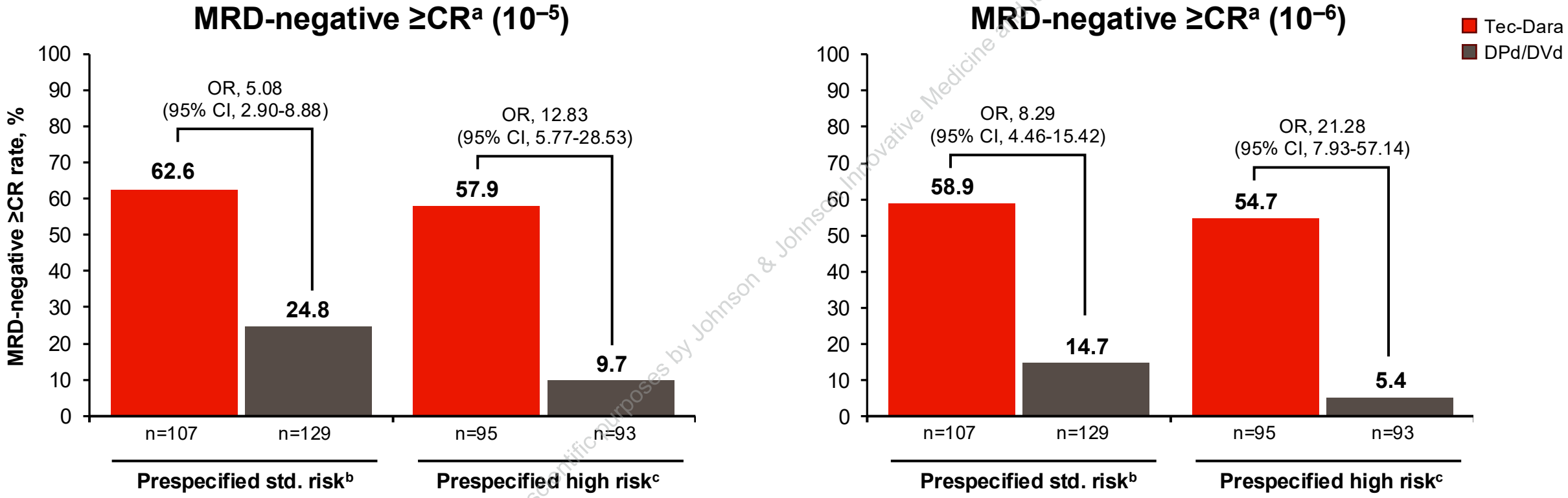
No. at risk																	
Tec-Dara, std. risk	126	116	108	105	105	104	103	102	101	99	97	64	36	17	6	0	0
DPd/DVd, std. risk	145	131	115	99	87	82	78	73	69	62	53	34	20	10	2	1	0
Tec-Dara, high risk	104	89	86	82	82	79	77	75	74	73	71	47	31	10	3	0	0
DPd/DVd, high risk	104	85	71	61	53	45	35	30	24	20	18	10	2	2	1	0	0

Tec-Dara demonstrated superior PFS vs DPd/DVd regardless of cytogenetic risk and mirroring the overall study effect (HR 0.17)[1]

[a]Prespecified standard risk: none of del(17p), t(4;14), or t(14;16). Prespecified high risk: ≥1 of del(17p), t(4;14), or t(14;16).

1. Costa LJ, et al. *N Engl J Med*. 2026;394(8):739-752.

MajesTEC-3: MRD-Negative ≥CR by Prespecified Cytogenetic Risk



Tec-Dara substantially increased MRD-negative ≥CR rates, with an MRD-negative ≥CR (10^{-6}) rate that was 10-fold that of DPd/DVd

OR, odds ratio. [a]MRD-negative ≥CR refers to MRD negativity achieved within 3 months prior to achieving CR/sCR or at any time after CR/sCR and before progression or subsequent therapy. Assessed in the MRD NGS primary analysis set, defined as all randomized patients except those recruited in China (due to China instead utilizing NGF for MRD assessment). [b]Prespecified standard risk: none of del(17p), t(4;14), or t(14;16). [c]Prespecified high risk: ≥1 of del(17p), t(4;14), or t(14;16).

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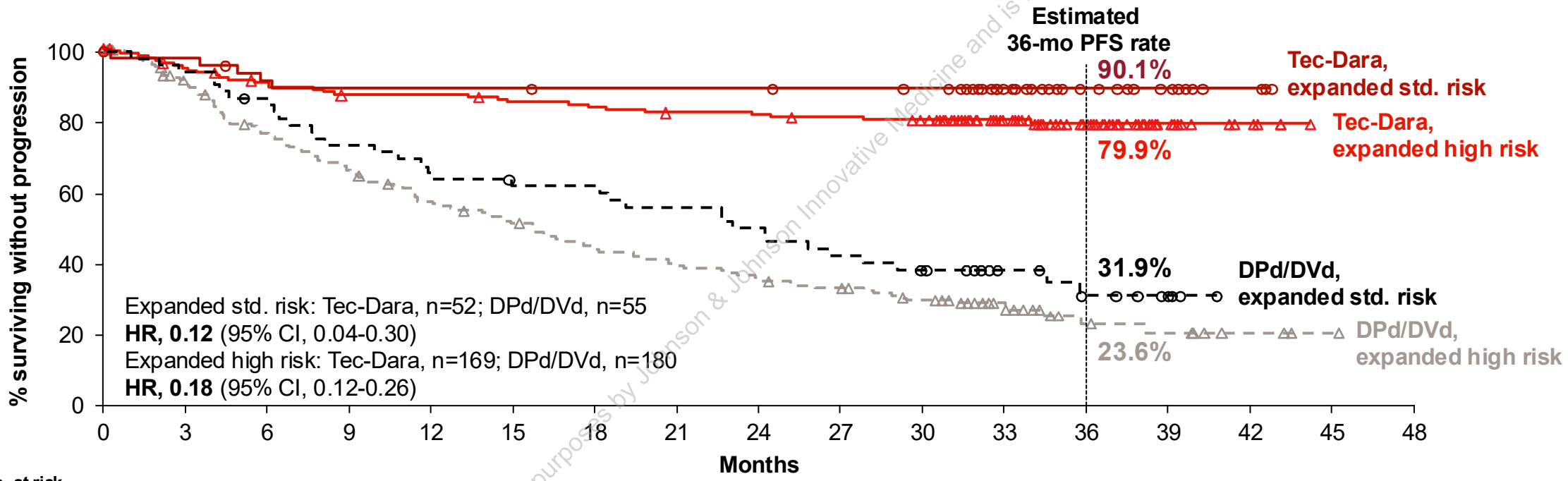
MajesTEC-3: PFS by Expanded[a] Cytogenetic Risk



No. at risk																	
Tec-Dara, expanded std. risk	52	50	46	45	45	45	44	44	44	43	42	28	15	8	3	0	-
DPd/DVd, expanded std. risk	55	51	46	39	34	32	32	29	26	22	19	12	8	3	0	0	-
Tec-Dara, expanded high risk	169	147	139	133	133	129	127	124	123	121	119	80	53	19	6	0	0
DPd/DVd, expanded high risk	180	153	129	110	95	84	71	64	57	52	45	27	11	8	3	1	0

Tec-Dara maintained superior PFS vs DPd/DVd across expanded cytogenetic risk groups, consistent with the overall study effect[1]

[a]Expanded standard risk: none of del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21). Expanded high risk: ≥1 of del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21).

1. Costa LJ, et al. *N Engl J Med*. 2026;394(8):739-752.

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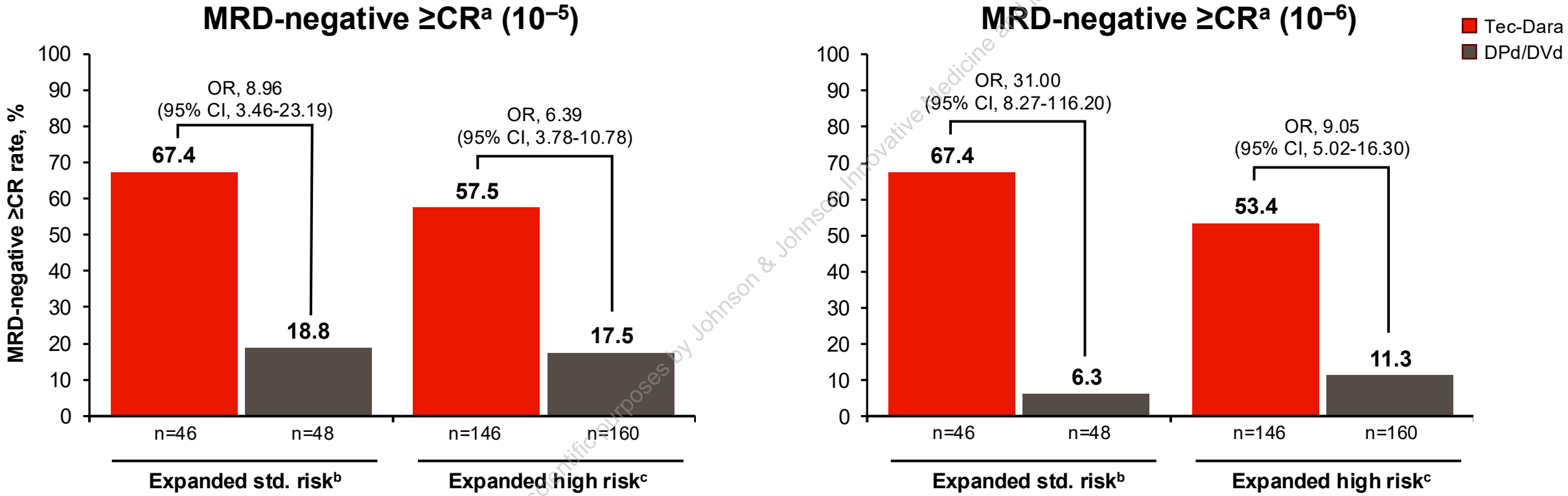
MajesTEC-3: MRD-Negative ≥CR by Expanded Cytogenetic Risk



Tec-Dara substantially increased MRD-negative ≥CR rates, with an MRD-negative ≥CR (10^{-6}) rate that was ~5-fold that of DPd/DVd

[a]MRD-negative ≥CR refers to MRD negativity achieved within 3 months prior to achieving CR/sCR or at any time after CR/sCR and before progression or subsequent therapy. Assessed in the MRD NGS primary analysis set, defined as all randomized patients except those recruited in China (due to China instead utilizing NGF for MRD assessment). [b]Expanded standard risk: none of del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21). [c]Expanded high risk: ≥1 of del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21).

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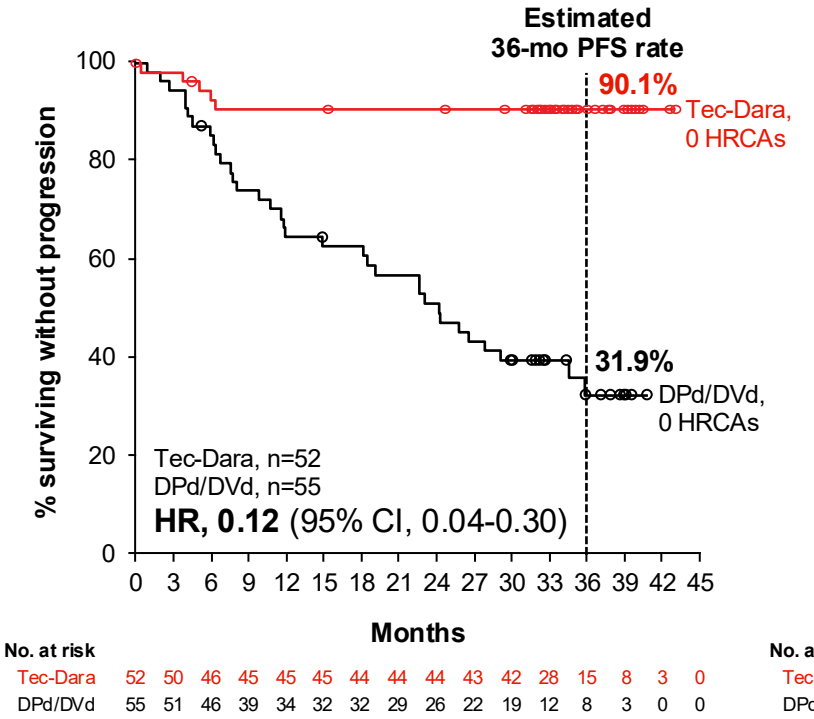
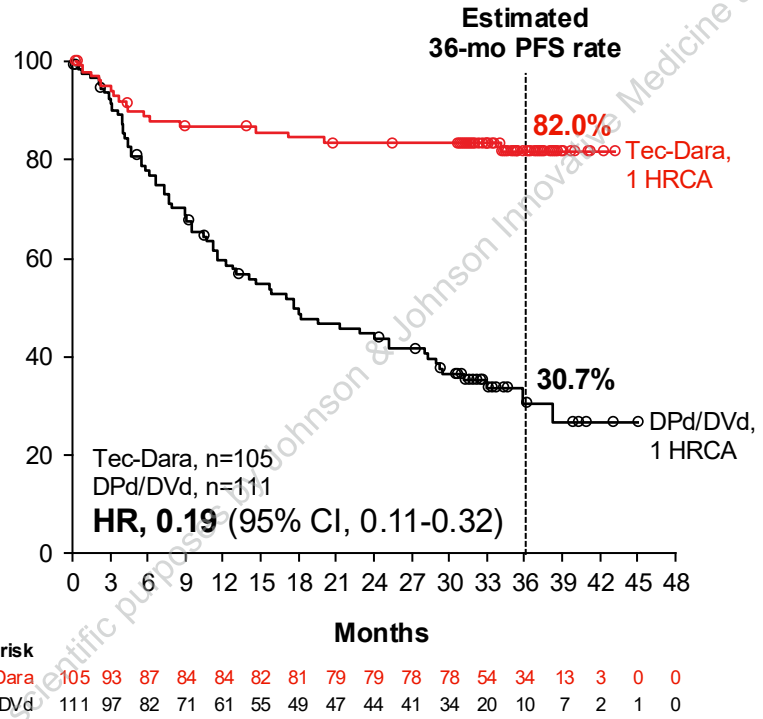
MajesTEC-3: PFS by Number of Expanded[a] HRCAs

0 HRCAs



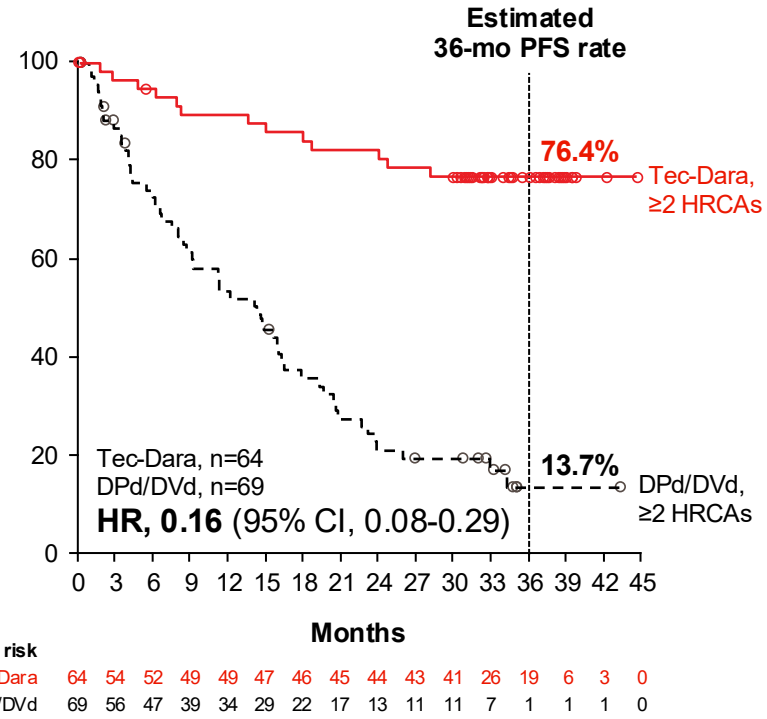
No. at risk																
Tec-Dara	52	50	46	45	45	45	44	44	44	43	42	28	15	8	3	0
DPd/DVd	55	51	46	39	34	32	32	29	26	22	19	12	8	3	0	0

1 HRCA



No. at risk																	
Tec-Dara	105	93	87	84	84	82	81	79	79	78	78	54	34	13	3	0	0
DPd/DVd	111	97	82	71	61	55	49	47	44	41	34	20	10	7	2	1	0

≥2 HRCAs



No. at risk																
Tec-Dara	64	54	52	49	49	47	46	45	44	43	41	26	19	6	3	0
DPd/DVd	69	56	47	39	34	29	22	17	13	11	11	7	1	1	1	0

Tec-Dara consistently improved PFS vs DPd/DVd, including in patients with ultra high-risk RRMM

[a]HRCA number is defined as the number of abnormalities present from the following: del(17p), t(4;14), t(14;16), amp(1q21), or gain(1q21).

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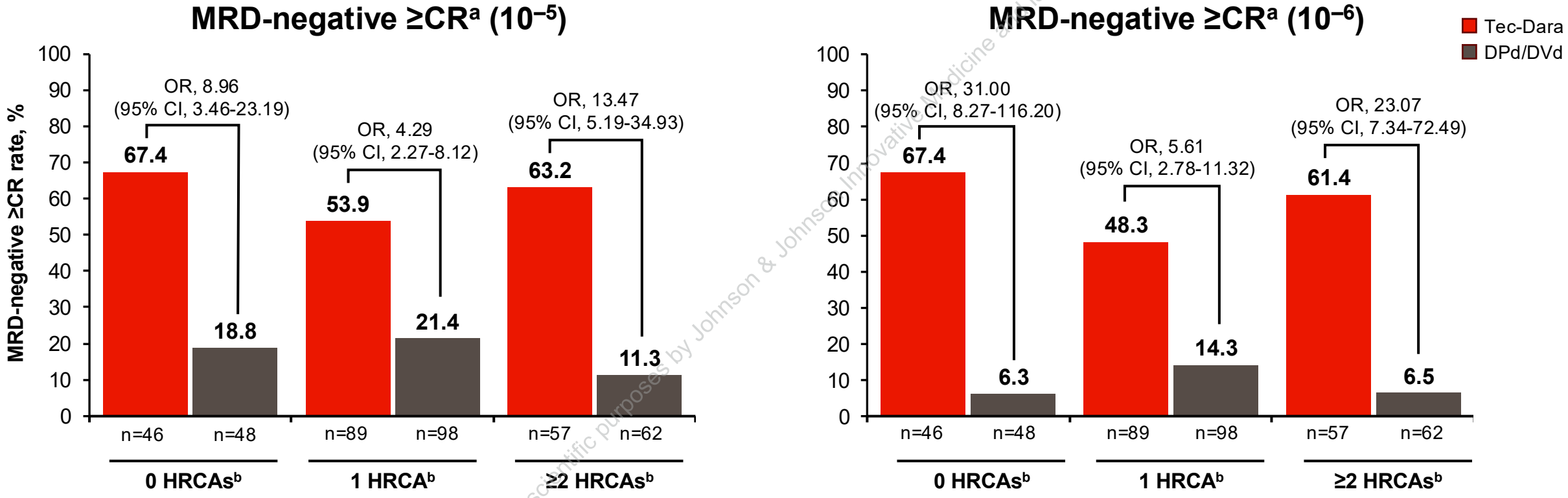
MajesTEC-3: MRD-Negative ≥CR by Number of Expanded HRCAs



Tec-Dara substantially increased MRD-negative ≥CR rates, with an MRD-negative ≥CR (10^{-6}) rate that was >9-fold that of DPd/DVd in ultra high-risk patients

[a]MRD-negative ≥CR refers to MRD negativity achieved within 3 months prior to achieving CR/sCR or at any time after CR/sCR and before progression or subsequent therapy. Assessed in the MRD NGS primary analysis set, defined as all randomized patients except those recruited in China (due to China instead utilizing NGF for MRD assessment). [b]Expanded risk abnormalities include the following: del(17p), t(4;14), t(14;16), amp(1q21),and gain(1q21).

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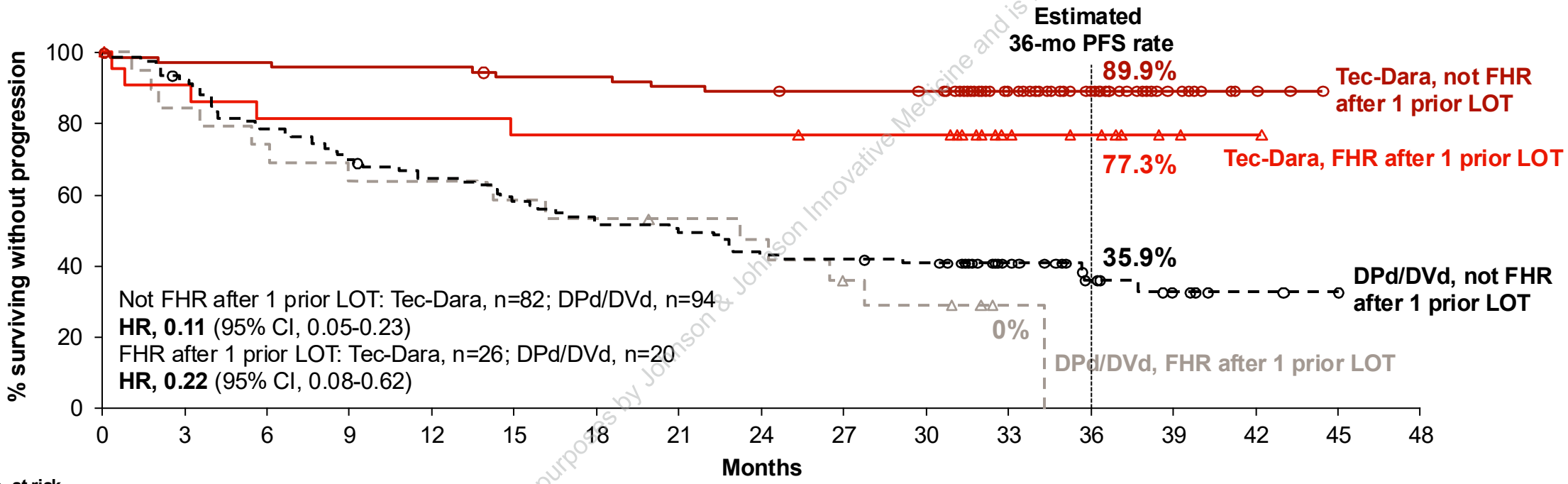
MajesTEC-3: PFS by Functional High-Risk Status[a]



No. at risk																	
Tec-Dara, not FHR after 1PL	82	78	78	77	77	74	74	72	71	70	69	46	30	15	3	0	0
DPd/DVd, not FHR after 1PL	94	86	73	65	59	53	47	45	39	38	36	24	13	7	2	1	0
Tec-Dara, FHR after 1PL	26	20	18	18	18	17	17	17	17	16	16	8	6	2	1	0	0
DPd/DVd, FHR after 1 PL	20	16	14	12	12	11	10	9	8	5	4	1	0	0	0	0	0

Tec-Dara substantially prolonged PFS vs DPd/DVd in patients with FHR MM, surpassing inferior outcomes historically seen with traditional therapies[1]

1PL, 1 prior LOT; MM, multiple myeloma. [a]Functional high-risk status defined as patients with 1 prior LOT and progressive disease within 18 months of ASCT or start of initial therapy. 1. Banerjee R, et al. *Frontiers Oncol.* 2023;13:1240966.

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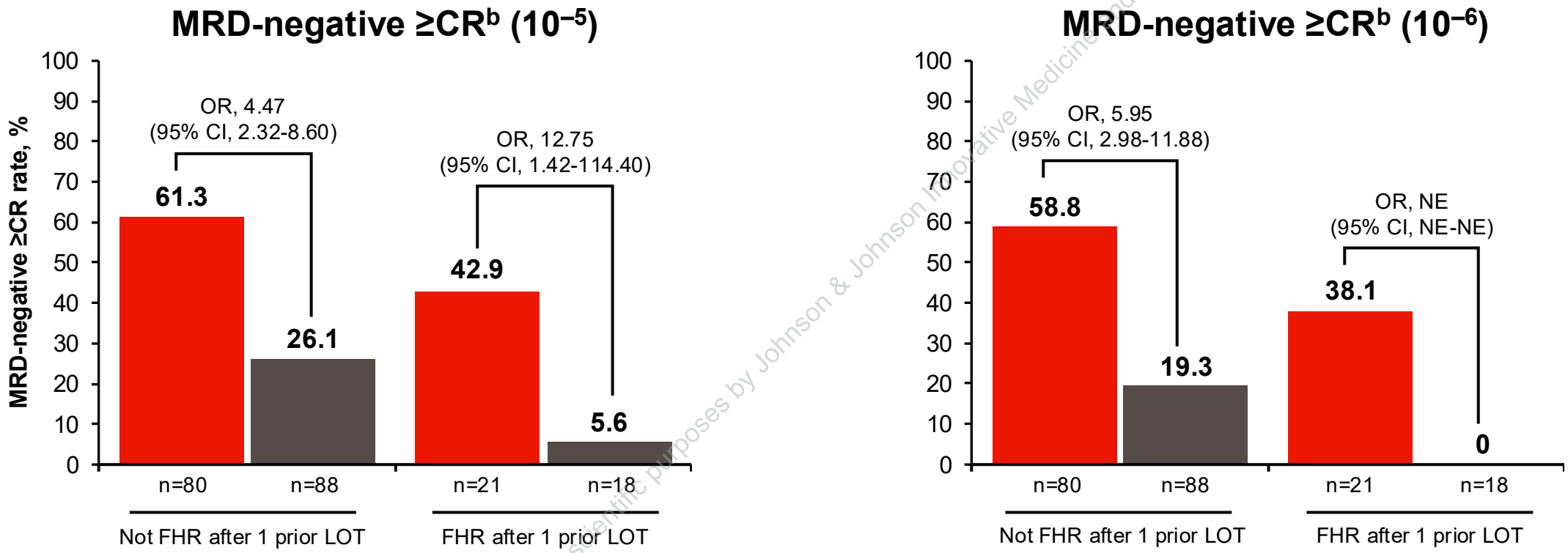
MajesTEC-3: MRD-Negative ≥CR by Functional High-Risk Status[a]



Tec-Dara consistently increased MRD-negative >CR rates vs DPd/DVd at both 10^{-5} and the more stringent 10^{-6} threshold in patients with FHR MM

[a]Functional high-risk status defined as patients with 1 prior LOT and progressive disease within 18 months of ASCT or start of initial therapy. [b]MRD-negative ≥CR refers to MRD negativity achieved within 3 months prior to achieving CR/sCR or at any time after CR/sCR and before progression or subsequent therapy. Assessed in the MRD NGS primary analysis set, defined as all randomized patients except those recruited in China (due to China instead utilizing NGF for MRD assessment).

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MajesTEC-3: Analysis by Risk Status Conclusions

- Tec-Dara, a steroid-sparing synergistic combination, improved outcomes vs DPd/DVd regardless of prespecified or expanded cytogenetic risk, presence of ultra high-risk MM, and FHR
  - Tec-Dara improved estimated 3-year PFS in standard-risk[a] (87-90%), high-risk[b] (76-82%), and FHR (77%)
  - Tec-Dara improved MRD-negative ≥CR 10^{-6} in standard-risk[a] (59-67%), high-risk[b] (48-61%), and FHR (38%)
- Patients with standard-risk disease have the greatest chance for functional cure in MM with Tec-Dara
- The trajectory of PFS with Tec-Dara in high-risk disease through 36 months is unprecedented and suggests that Tec-Dara mitigates the adverse prognostic impact historically seen with high-risk disease

Tec-Dara should be considered a new SoC from 2L across all risk groups and practice settings

2L, second line; SoC, standard of care. [a]Includes ranges from standard-risk patients per the prespecified (none of del[17p], t[4;14], or t[14;16]) and expanded (none of del[17p], t[4;14], t[4;16], amp[1q21], or gain[1q21]) definition. [b]Includes ranges from high-risk patients per the prespecified (≥1 of del[17p], t[4;14], or t[14;16]) or expanded definition (≥1 of del[17p], t[4;14], t[4;16], amp[1q21], or gain[1q21]), or presence of 1 or ≥2 expanded HRCAs.

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