2026 ASCO ANNUAL MEETING

Individualized Neoantigen Therapy Intismeran Autogene Plus Pembrolizumab in Resected Melanoma: 5-Year Update of the KEYNOTE-942 Study

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Key findings

- At **5 years of planned follow-up** analysis from the phase 2 KEYNOTE-942 study, intismeran plus pembrolizumab demonstrated durable treatment benefits vs pembrolizumab alone in patients with resected high-risk melanoma
  - There was a **49% reduction in risk of recurrence or death, a 59% reduction of distant metastasis or death**, and trend towards improved overall survival with intismeran plus pembrolizumab versus pembrolizumab alone
- The data continues to demonstrate a **favorable safety profile** of intismeran in combination with pembrolizumab
- Intismeran plus pembrolizumab compared to pembrolizumab alone **increased T-cell clonality** and enhanced the generation of novel T-cell clones
  - A trend towards **higher novel clone generation** was associated with reduced recurrence in patients receiving intismeran plus pembrolizumab

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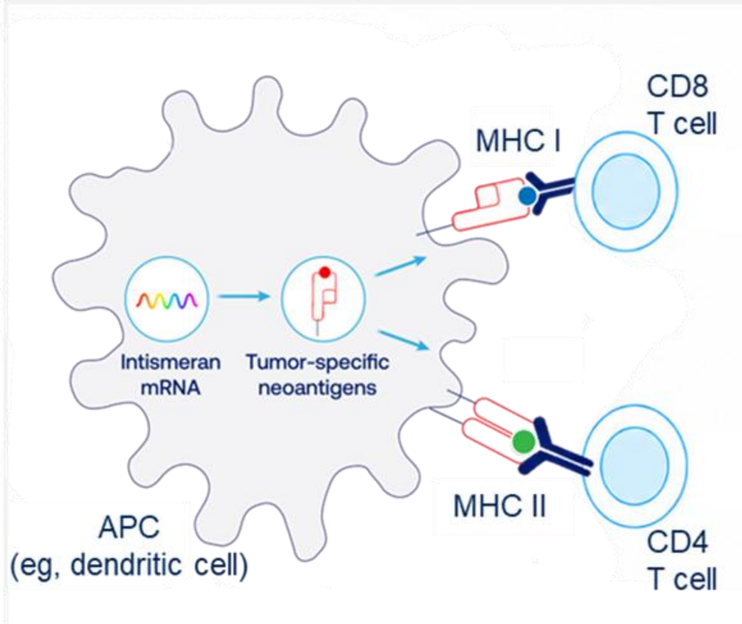
Intismeran autogene proposed mechanism of action

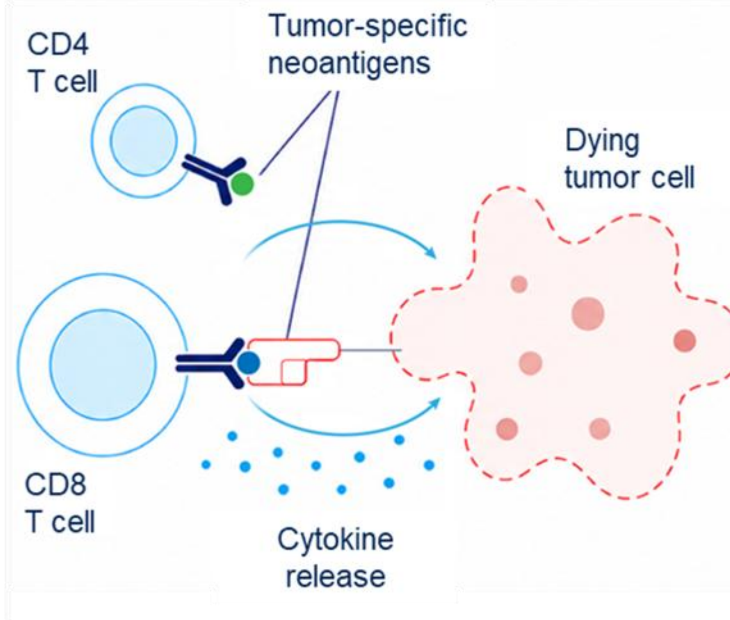
T-CELL ACTIVATION

APCs naturally process intismeran, then present tumor-specific neoantigens, generating de novo and activating pre-existing T-cell clones



TUMOR DESTRUCTION

Neoantigen-specific T-cells recognize and attack tumor cells



- Neoantigen-targeted therapies can **strengthen existing** and **create new** T-cell responses[1]
- **Intismeran autogene (intismeran)** is an mRNA-based individualized neoantigen therapy designed to **enhance endogenous antitumor T-cell responses** by targeting patient-specific tumor mutations[2]
- Combining intismeran with an immune checkpoint inhibitor may **enhance tumor destruction and support durable T-cell responses**

APC, antigen-presenting cell; CD, cluster of differentiation; MHC, major histocompatibility complex.
1. Gainor JF, et al. *Cancer Discov*. 2024;14(11):2209-2223. 2. Weber JS, et al. *Lancet*. 2024;403(10427):632-644.

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Background

- Despite PD-1 based adjuvant therapy, ~40%–50% of patients with high-risk melanoma experience recurrence, including progression to distant metastatic disease[1]
  - Improving DMFS by delaying/preventing metastasis is clinically meaningful, and can precede improvement in overall survival[2,3]
- To date, no randomized controlled trial evaluating adjuvant immunotherapy in stage III melanoma has demonstrated significantly improved outcomes with a combination regimen vs anti–PD-1 monotherapy
- In the primary analysis and 3-year supportive analysis of the phase 2 KEYNOTE-942 study, patients with completely resected, high-risk, stage IIIB–IV cutaneous melanoma had prolonged RFS and DMFS with intismeran plus pembrolizumab vs pembrolizumab alone[4,5]

Objective:

Assess the efficacy and safety of intismeran plus pembrolizumab and evaluate the combination's effects on T-cell receptor dynamics after 5 years of median planned follow-up (median [range], 60.3 [50.5–76.4] months)

DMFS, distant metastasis-free survival; RFS, recurrence-free survival.

1. Eggermont AMM, et al. *NEJM Evid*. 2022;1(11):EVIDoa2200214. 2. Eggermont AMM, et al. *Eur J Cancer*. 2019;119:1-10. 3. Eggermont AM, et al. *Eur J Cancer.* 2024;211:114327. 4. Weber JS, et al. *Lancet*. 2024;403(10427):632-644. 5. Carlino MS, et al. *JCO Oncol Adv*. 2026;3(1):e2500008

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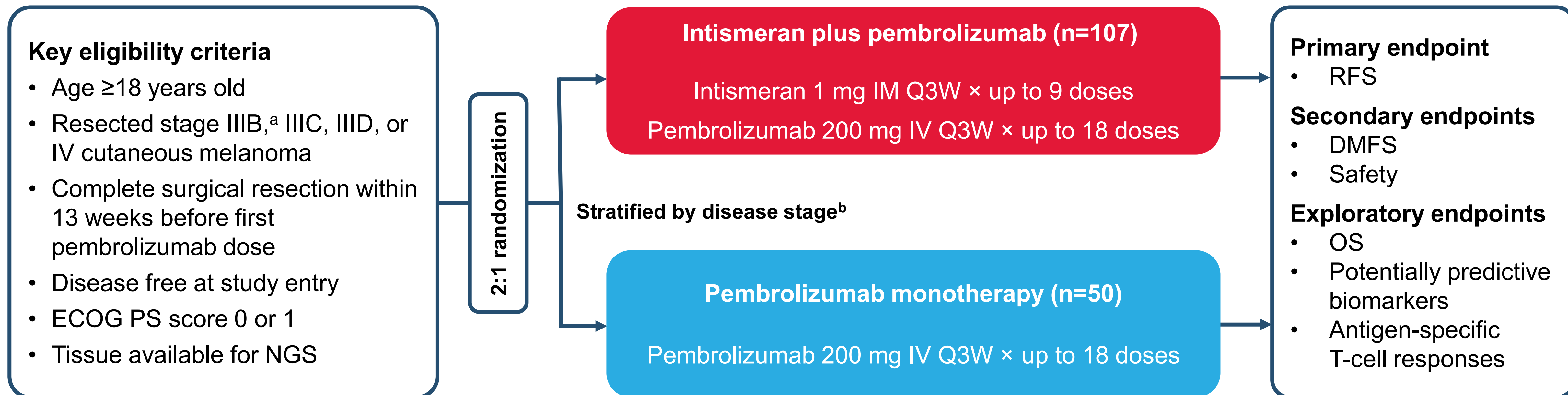
KEYNOTE-942 (NCT03897881) study design

Randomized, phase 2, open-label study of adjuvant therapy in patients with completely resected melanoma at high risk of recurrence



The 5-year analysis was conducted after the last enrolled patient had ≥4 years of planned follow-up (data cutoff: December 15, 2025); no α was assigned to this long-term follow-up analysis

IM, intramuscular; NGS, next-generation sequencing; TCR, T-cell receptor.
[a]Patients with stage IIIB disease were eligible if relapse occurred within 3 mo of prior surgery of curative intent. [b]According to the American Joint Committee on Cancer Staging Manual 8th edition.

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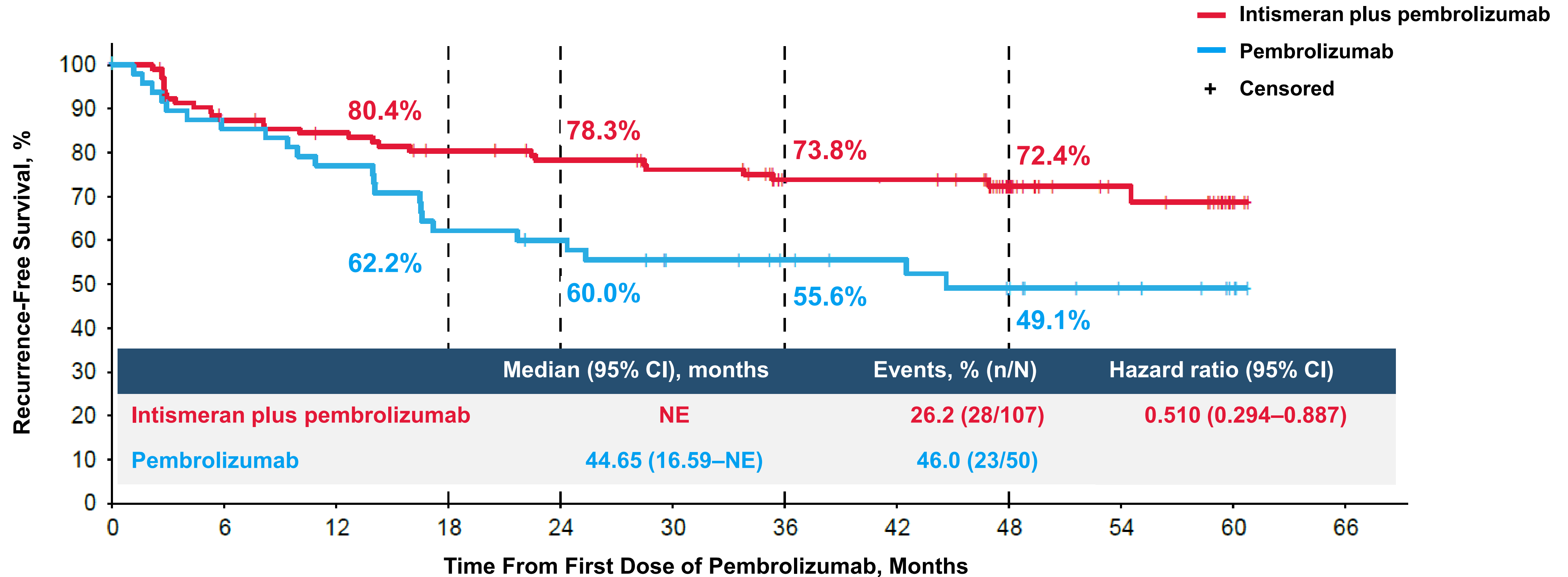
Durable benefit in RFS (primary endpoint)



	Median (95% CI), months	Events, % (n/N)	Hazard ratio (95% CI)
Intismeran plus pembrolizumab	NE	26.2 (28/107)	0.510 (0.294–0.887)
Pembrolizumab	44.65 (16.59–NE)	46.0 (23/50)	

No. at risk (no. censored)

	0	6	12	18	24	30	36	42	48	54	60	66
Intismeran plus pembrolizumab	107 (0)	89 (5)	84 (7)	78 (9)	74 (11)	70 (13)	57 (24)	55 (26)	39 (41)	20 (60)	3 (76)	0 (79)
Pembrolizumab	50 (0)	41 (2)	37 (2)	29 (3)	27 (4)	22 (7)	19 (10)	17 (12)	12 (15)	7 (20)	3 (24)	0 (27)

NE, not estimable.

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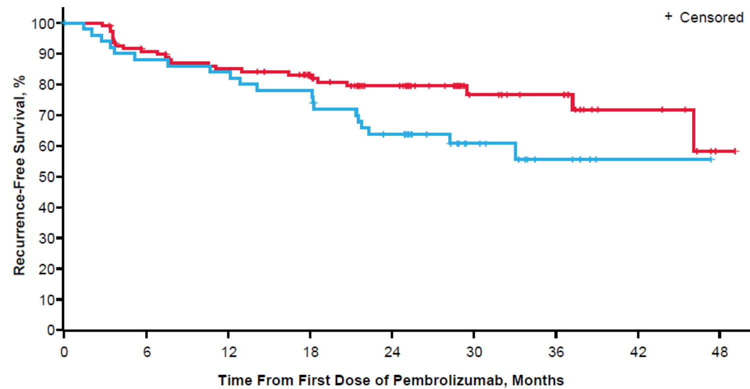
Consistent and durable RFS benefit across primary, 3-year, and 5-year analyses

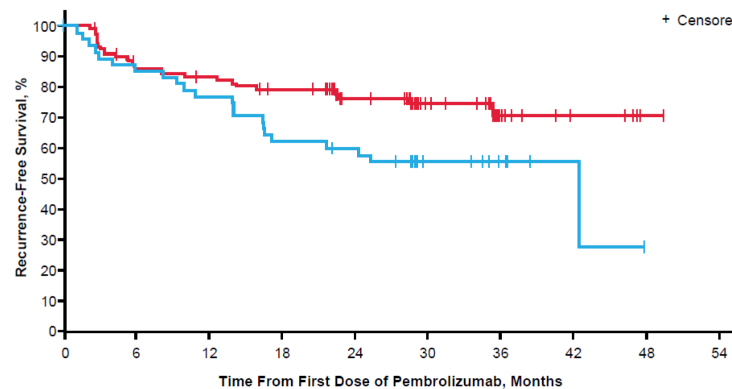
Primary Analysis: Nov 14, 2022[1]



	0	6	12	18	24	30	36	42	48
Intismeran plus pembrolizumab	107	88	82	49	24	8	3	0	0
Pembrolizumab	50	41	37	28	11	1	1	0	0

	Events, % (n/N)	Hazard Ratio (95% CI)
Intismeran plus pembrolizumab	22.4 (24/107)	0.561 (0.309–1.017) *P* = 0.0266[b]
Pembrolizumab	40.0 (20/50)	

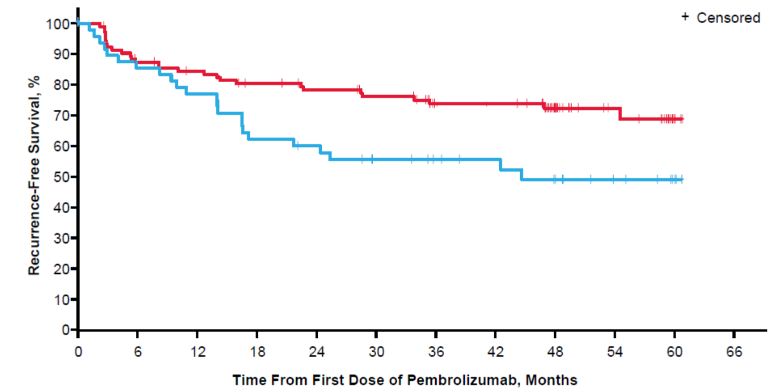
3-Year Analysis: Nov 3, 2023[2]



	0	6	12	18	24	30	36	42	48	54
Intismeran plus pembrolizumab	107	87	83	77	52	29	12	6	1	0
Pembrolizumab	50	41	37	29	27	10	5	2	0	0

	Events, % (n/N)	Hazard Ratio (95% CI)
Intismeran plus pembrolizumab	23.4 (25/107)	0.510 (0.288–0.906)
Pembrolizumab	44.0 (22/50)	

5-Year Analysis: Dec 15, 2025



	0	6	12	18	24	30	36	42	48	54	60	66
Intismeran plus pembrolizumab	107	89	84	78	74	70	57	55	39	20	3	0
Pembrolizumab	50	41	37	29	27	22	19	17	12	7	3	0

	Events, % (n/N)	Hazard Ratio (95% CI)
Intismeran plus pembrolizumab	26.2 (28/107)	0.510 (0.294–0.887)
Pembrolizumab	46.0 (23/50)	

[a]Formal hypothesis testing of RFS (overall one-sided α=0.10) was performed at primary analysis (Nov 2022 data cut).

1. Weber JS, et al. *Lancet*. 2024;403(10427):632-644. 2. Carlino MS, et al. *JCO Oncol Adv*. 2026;3(1):e2500008

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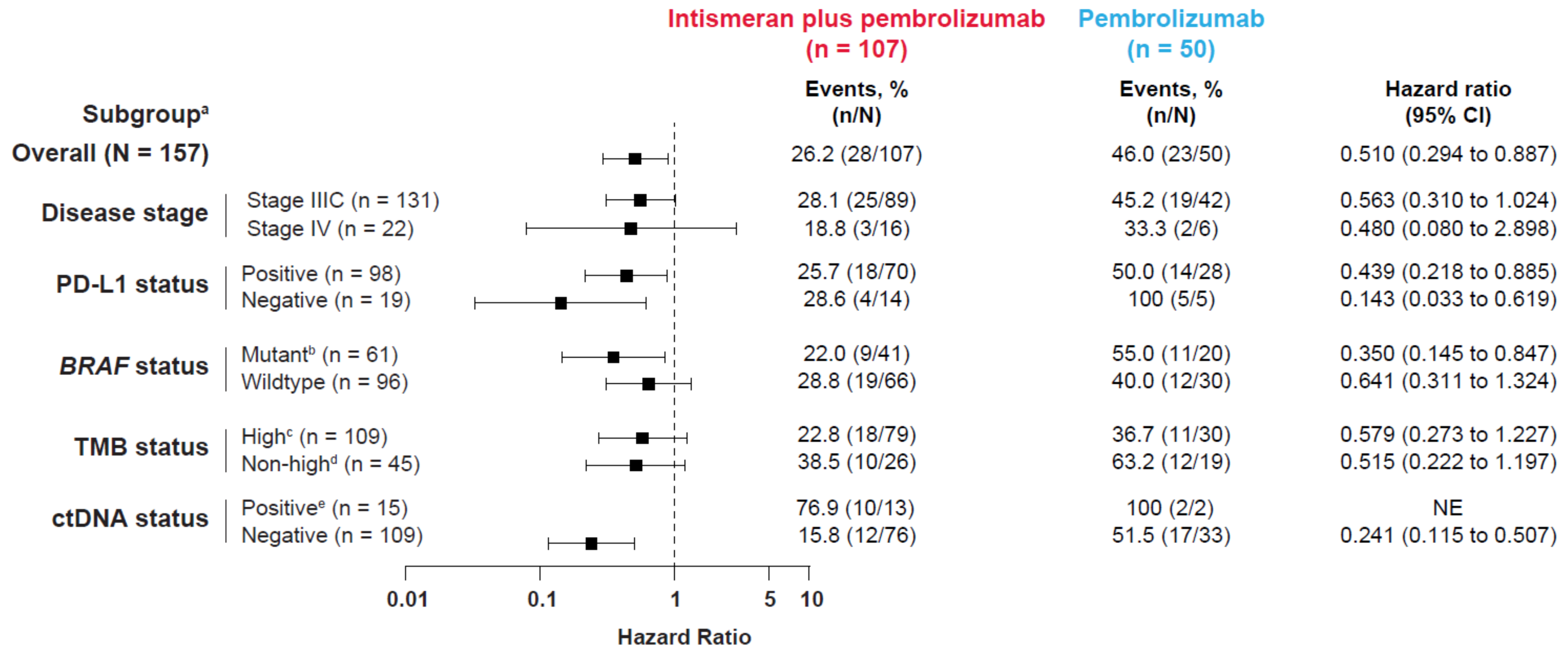
Subgroup analyses indicate RFS benefit is maintained across a broad patient population



[a]RFS in the overall population was estimated by a stratified Cox proportional hazards model; an unstratified analysis was used for subgroup analyses. [b]V600K or V600E mutation. [c]≥175 mutations/exome; [d]<175 mutations/exome. [e]Hazard ratio for the ctDNA-positive subgroup was NE as all patients in the pembrolizumab had a recurrence event. Subgroups were defined as previously described.[1]

1. Weber JS, et al. *Lancet*. 2024;403(10427):632-644

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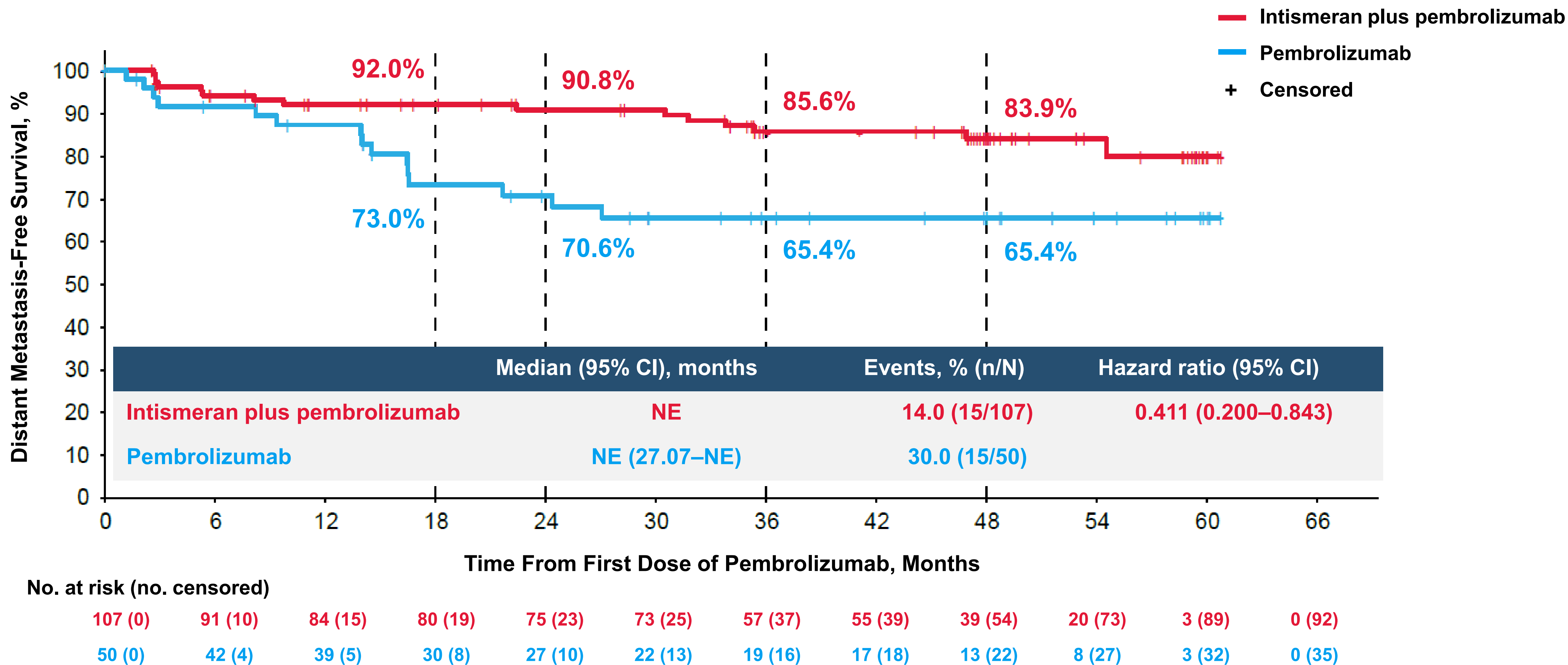
Durable benefit in DMFS (secondary endpoint)



	Median (95% CI), months	Events, % (n/N)	Hazard ratio (95% CI)
Intismeran plus pembrolizumab	NE	14.0 (15/107)	0.411 (0.200–0.843)
Pembrolizumab	NE (27.07–NE)	30.0 (15/50)	

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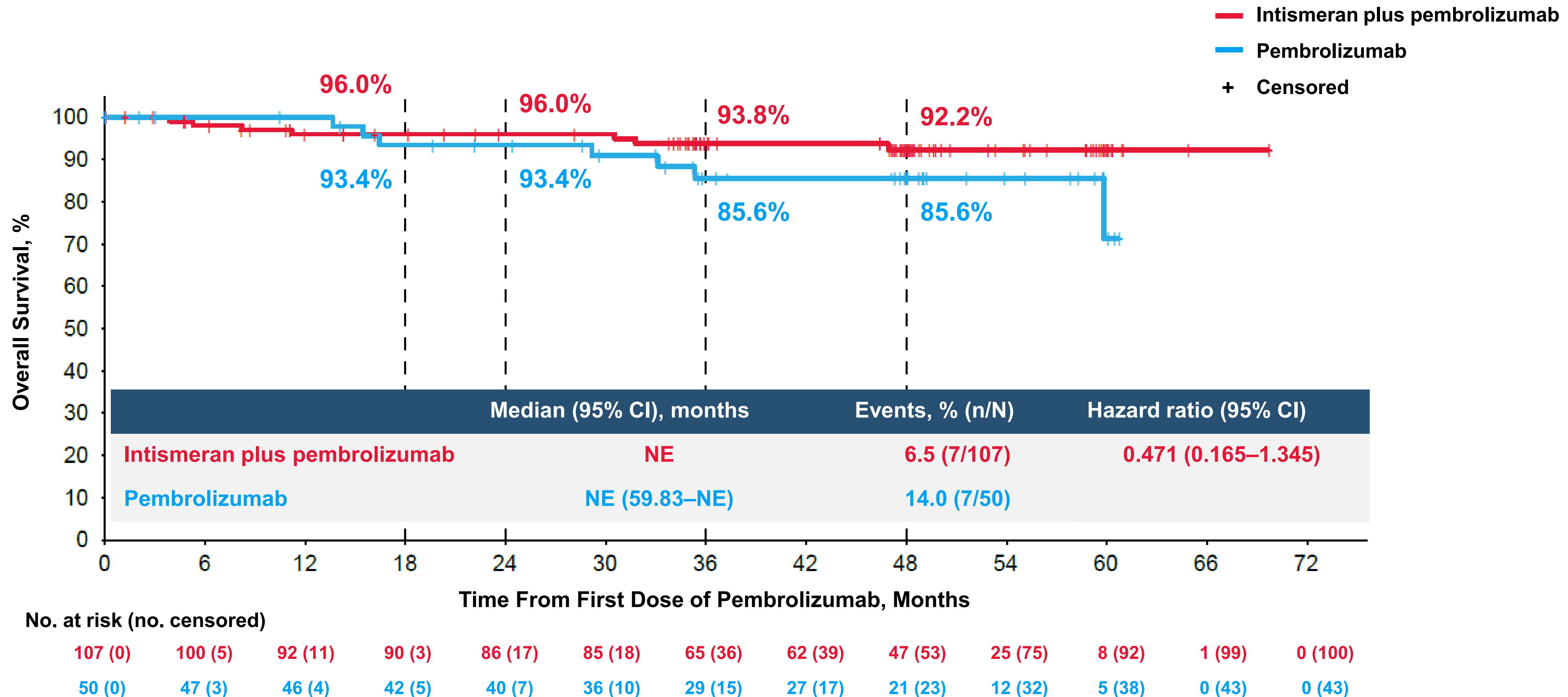
Overall survival shows an encouraging trend, but data remain immature



	Median (95% CI), months	Events, % (n/N)	Hazard ratio (95% CI)
Intismeran plus pembrolizumab	NE	6.5 (7/107)	0.471 (0.165–1.345)
Pembrolizumab	NE (59.83–NE)	14.0 (7/50)	

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At 5-year follow-up, established safety profile was maintained with no new safety signals

	Intismeran + Pembrolizumab (n=104)		Pembrolizumab (n=50)	
Event, n (%)	**Any grade**	**Grade ≥3**	**Any grade**	**Grade ≥3**
Any AE	104 (100)	35 (33.7)	47 (94.0)	15 (30.0)
Any treatment-related AE	104 (100)	26 (25.0)	42 (84.0)	7 (14.0)
Serious AE	14 (13.5)	13 (12.5)	5 (10.0)	4 (8.0)
Immune-mediated AEs[a]	38 (36.5)	11 (10.6)	19 (38.0)	6 (12.0)

Intismeran + pembrolizumab (n=104), n (%)	Grade 1	Grade 2	Grade 3	Grade 4/5	Total (n=104)
Patients with intismeran-related AE[b]	33 (31.7)	54 (51.9)	11 (10.6)	0	98 (94.2)
Fatigue	39 (37.5)	18 (17.3)	5 (4.8)	0	62 (59.6)
Injection site pain	37 (35.6)	25 (24.0)	0	0	62 (59.6)
Chills	49 (47.1)	4 (3.8)	0	0	53 (51.0)
Pyrexia	35 (33.7)	15 (14.4)	1 (1.0)	0	51 (49.0)
Injection site erythema	28 (26.9)	5 (4.8)	0	0	33 (31.7)
Headache	19 (18.3)	13 (12.5)	0	0	32 (30.8)
Influenza-like illness	21 (20.2)	10 (9.6)	0	0	31 (29.8)
Nausea	23 (22.1)	3 (2.9)	0	0	26 (25.0)
Myalgia	16 (15.4)	6 (5.8)	1 (1.0)	0	23 (22.1)

AE, adverse event; AEOSI, adverse event of special interest; CMQ, customized MedDRA queries.
Safety was analyzed in all randomized patients with ≥1 treatment dose. AEs were monitored throughout the study through 100 days after last intismeran dose and 30 days after last pembrolizumab dose (90 days for serious AEs). All patients completed study treatment before primary analysis (2022). Grading per NCI CTCAE v5.0. [a]Based on established list of pembrolizumab immune-related AEs (CMQ Pembrolizumab AEOSI); [b]Intismeran-related AEs included events attributed by investigators to intismeran alone and to both intismeran and pembrolizumab.

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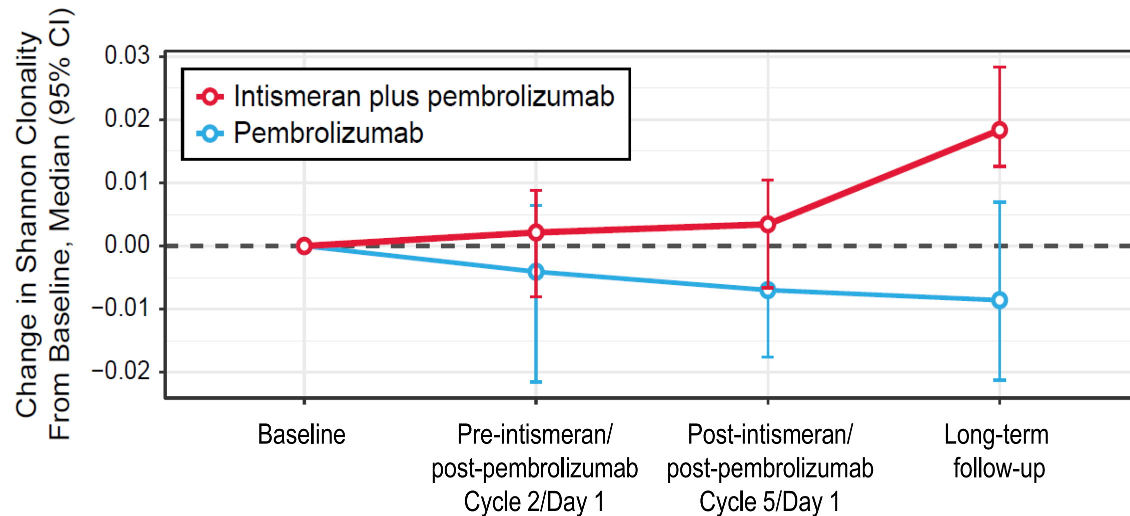
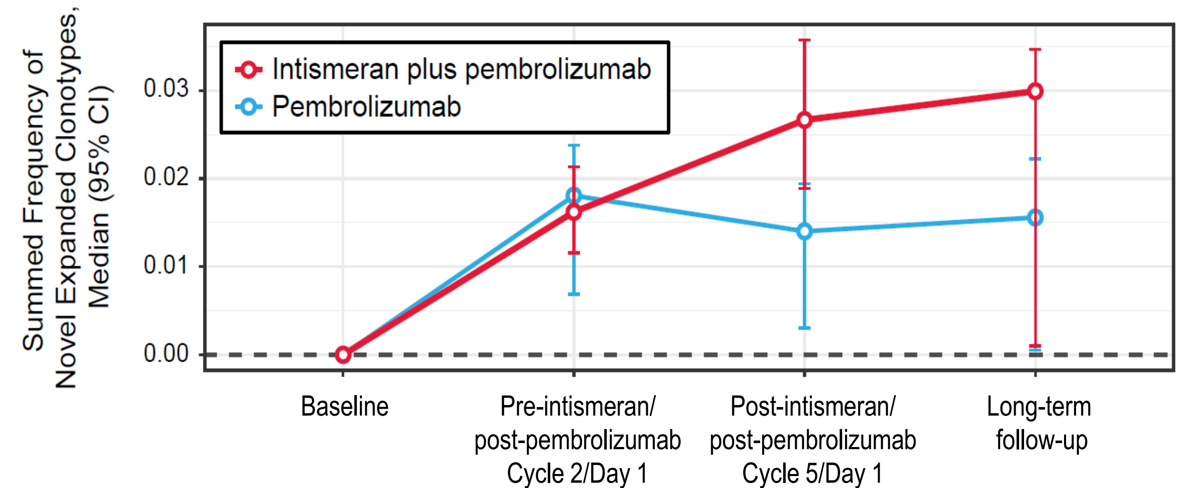
Intismeran plus pembrolizumab enhances T-cell clonal expansion and novel clone emergence

Combination therapy increased clonality, reflecting expansion of dominant T-cell clones



	Baseline	Pre-intismeran/post-pembrolizumab Cycle 2/Day 1	Post-intismeran/post-pembrolizumab Cycle 5/Day 1	Long-term follow-up
Intismeran plus pembrolizumab	n=78	n=69	n=73	n=56
Pembrolizumab	n=38	n=32	n=35	n=23

Combination therapy increased novel TCR clonotypes



	Baseline	Pre-intismeran/post-pembrolizumab Cycle 2/Day 1	Post-intismeran/post-pembrolizumab Cycle 5/Day 1	Long-term follow-up
Intismeran plus pembrolizumab	n=78	n=69	n=73	n=56
Pembrolizumab	n=38	n=32	n=35	n=23

Data are median (bootstrapped 95% CI). Whole blood TCR RNA sequencing at baseline, pre-intismeran/post-pembrolizumab (Cycle 2/Day 1), post-intismeran/post-pembrolizumab (Cycle 5/Day 1), and 30 days after the last pembrolizumab dose. Analyses used downsampled TCRβ chains normalized to 10,000 clones. Novel clones identified by absence at baseline. Differential clone abundance between baseline and on-treatment used 2-sample exact tests and *P* value adjusted for false discovery rates to identify novel-expanded clones.

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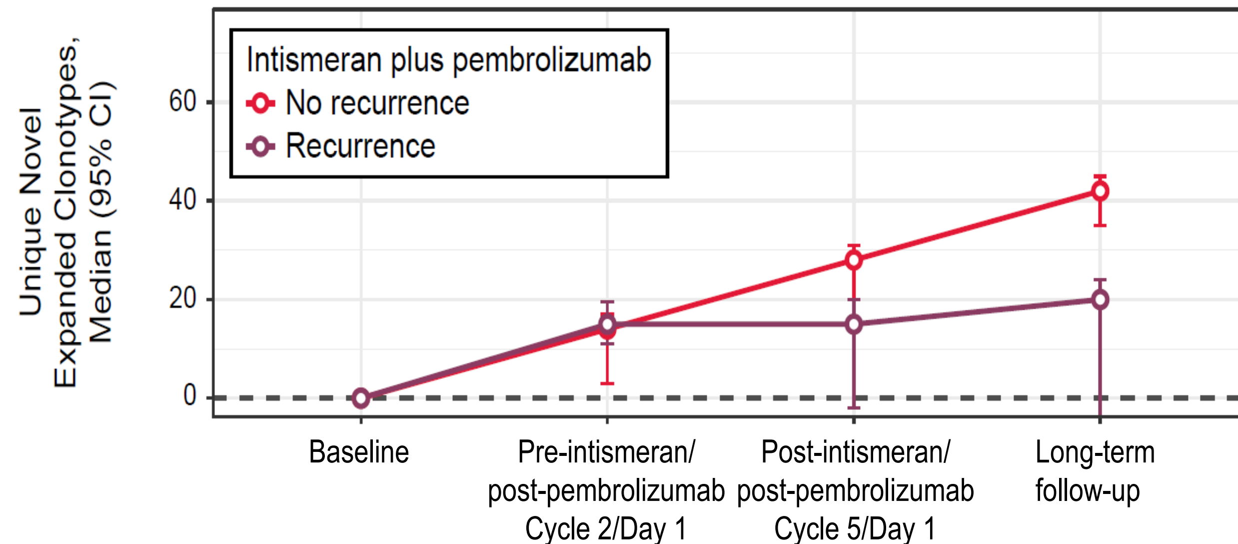
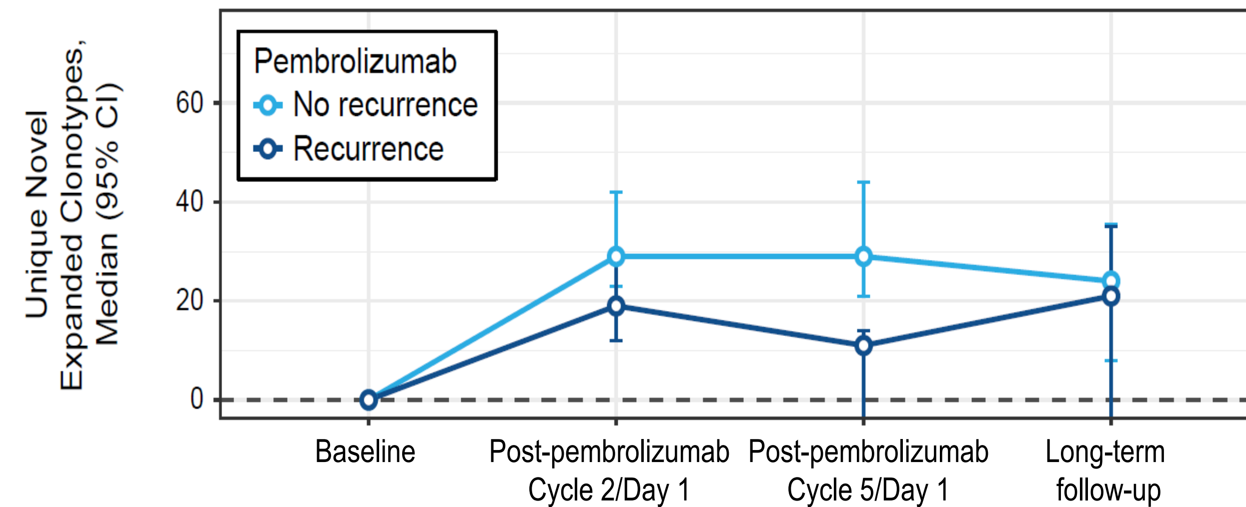
Greater novel clone expansion was associated with lower recurrence in the intismeran plus pembrolizumab arm

Intismeran Plus Pembrolizumab



	Baseline	Pre-intismeran/post-pembrolizumab Cycle 2/Day 1	Post-intismeran/post-pembrolizumab Cycle 5/Day 1	Long-term follow-up
No recurrence	n=57	n=49	n=54	n=43
Recurrence	n=21	n=20	n=19	n=13

Pembrolizumab



	Baseline	Post-pembrolizumab Cycle 2/Day 1	Post-pembrolizumab Cycle 5/Day 1	Long-term follow-up
No recurrence	n=21	n=17	n=19	n=14
Recurrence	n=17	n=15	n=16	n=9

Data are shown as median and bootstrapped 95% CI. Whole blood TCR RNA sequencing at baseline, pre-intismeran/post-pembrolizumab (Cycle2/Day1), post-intismeran/post-pembrolizumab (Cycle5/Day1), and 30 days after the last pembrolizumab dose. Long-term follow-up data were collected at >170 days after last intismeran dose.

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Conclusions

- Intismeran plus pembrolizumab demonstrated **durable and clinically significant improvements in RFS and DMFS** vs standard-of-care pembrolizumab in high-risk resected melanoma at 5 years of follow-up
  - 49% reduction in risk of recurrence or death and 59% reduction in distant metastasis or death
  - Encouraging trend in overall survival
- Intismeran plus pembrolizumab maintained a **manageable safety profile** without potentiation of immune-related AEs vs pembrolizumab monotherapy
- Intismeran plus pembrolizumab generated **sustained novel T-cell clonotype expansion,** which was associated with lack of recurrence, supporting a durable immune surveillance mechanism
- Deep immune profiling established a **direct mechanistic link between these novel T-cell clonotypes and intismeran-encoded neoantigens** (*Sullivan, R et al; poster #9564*)
- Study limitations include the small sample size of this phase 2 study, immature overall survival results, and translational findings requiring validation in larger cohorts. **The phase 3 INTerpath-001 study (NCT05933577) of adjuvant melanoma is fully enrolled**; additional studies are ongoing across tumor types

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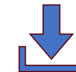
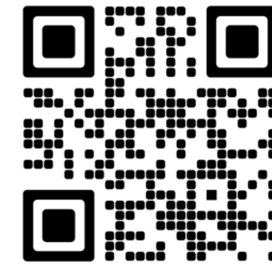
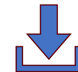
We thank the patients, families, investigators, site staff, researchers, and collaborators who made this work possible.

We honor the memory of Dr. Jeffrey Weber, a lead investigator on this study and a giant in advancing melanoma treatment.

The following were members of the INT Research and Development Group:

George Ansstas, Victoria Atkinson, Elizabeth I. Buchbinder, Matteo S. Carlino, C. Lance Cowey, Mark Faries, Geoffrey T. Gibney, Omid Hamid, Julie Howle, Azim Khan, Adnan Khattak, Kevin B. Kim, Georgina V. Long, Jason J. Luke, Meredith McKean, Theresa Medina, Janice M. Mehnert, Tarek Meniawy, Meghan J. Mooradian, Andrew Pecora, Jennifer Segar, Montaser Shaheen, Ryan J. Sullivan, Matthew H. Taylor, Sajeve Thomas, Thuy T. Tran, Jeffrey S. Weber*, and Merck & Co., Inc., and Moderna, Inc. study teams.

**In memoriam*

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Intismeran Autogene Plus Pembrolizumab Versus Pembrolizumab Alone in High-Risk Resected Melanoma: 5-Year Update of the Randomized Phase 2b KEYNOTE-942 Study

https://ascopubs.org/doi/10.1200/JCO-26-00835

Dr. Matteo S. Carlino

Listen to the accompanying podcast with Drs. Grant McArthur and Ash Gurumurthi linked from the article or at asco.org/podcasts

Join Dr. Grant McArthur for a Journal Club Discussion in JCO Central (S402a) on Monday, June 1, 2026, 4pm CDT

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Plain Language Summary

- Intismeran is a cancer therapy that is personalized for each patient and is designed to help the body's immune system find and attack cancer cells
- In a study of people with high-risk melanoma, a serious type of skin cancer that has a high probability of coming back, intismeran was given in combination with pembrolizumab, another cancer medicine
- People who received both medicines were less likely to have their cancer come back than people who received pembrolizumab alone
- There were early signs that people who received both medicines may live longer, but more follow-up is needed to fully understand this
- Side effects were manageable, and most side effects linked to intismeran were mild or moderate
- The two medicines working together may help immune cells find and fight cancer cells

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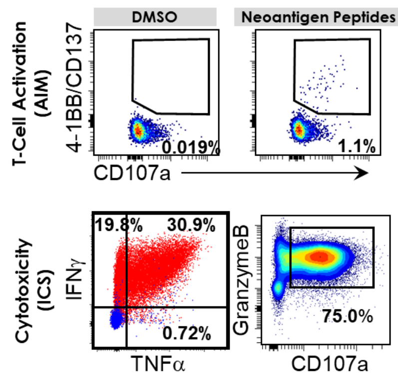
On-treatment expanded novel T cells target intismeran-encoded neoantigens and in circulation

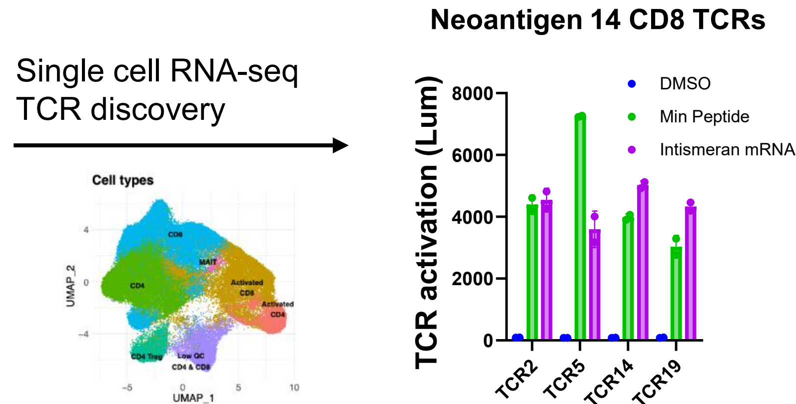
Enrichment of Neoantigen-Reactive T cells



Neoantigen-reactive T cells were polyfunctional, cytotoxic, and predominantly exhibited an effector-memory phenotype

Functional TCR Validation

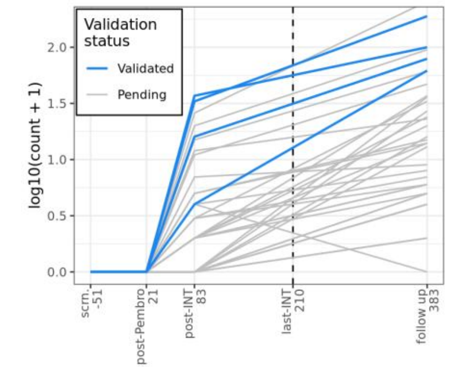
Single cell RNA-seq TCR discovery



Polyclonal T-cell response was functionally confirmed in NFAT-luciferase reporter Jurkat cell assays

Neoantigen-reactive T Cells Expand and in Circulation

Track TCRs in peripheral blood



Intismeran-encoded neoantigen-reactive $CD4^+$ and $CD8^+$ T cells expanded with treatment and were maintained in circulation for >150 days after the last intismeran dose

AIM, activation-induced marker; DMSO, dimethyl sulfoxide; ICS, intracellular cytokine staining; IFNγ, interferon-gamma; LUM, luminescence; NFAT, a nuclear factor of activated T cells; PBMC, peripheral blood mononuclear cells; TCR, T-cell receptor; TNFα, tumor necrosis factor–alpha.

Sullivan, R et al; poster #9564,

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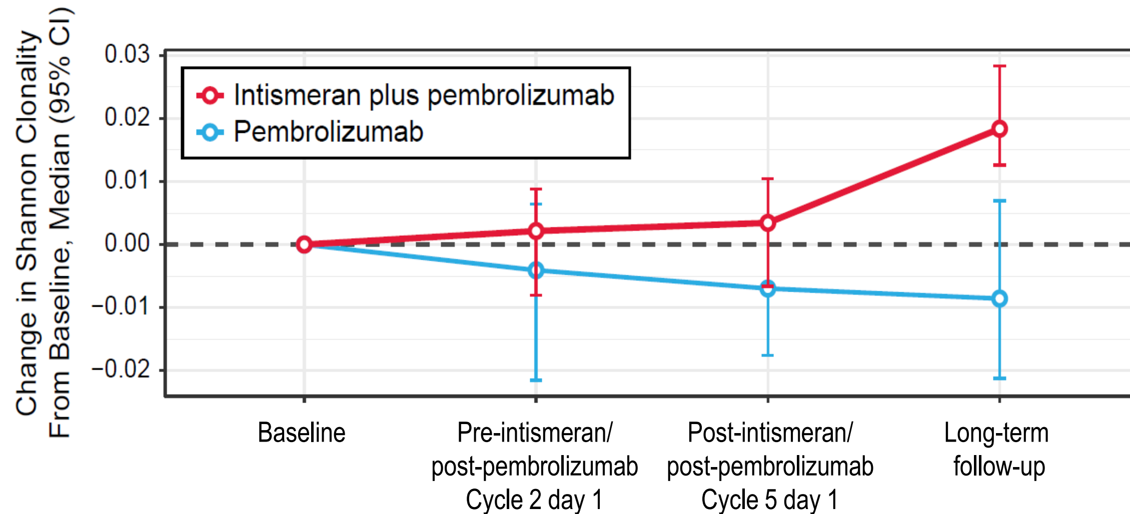
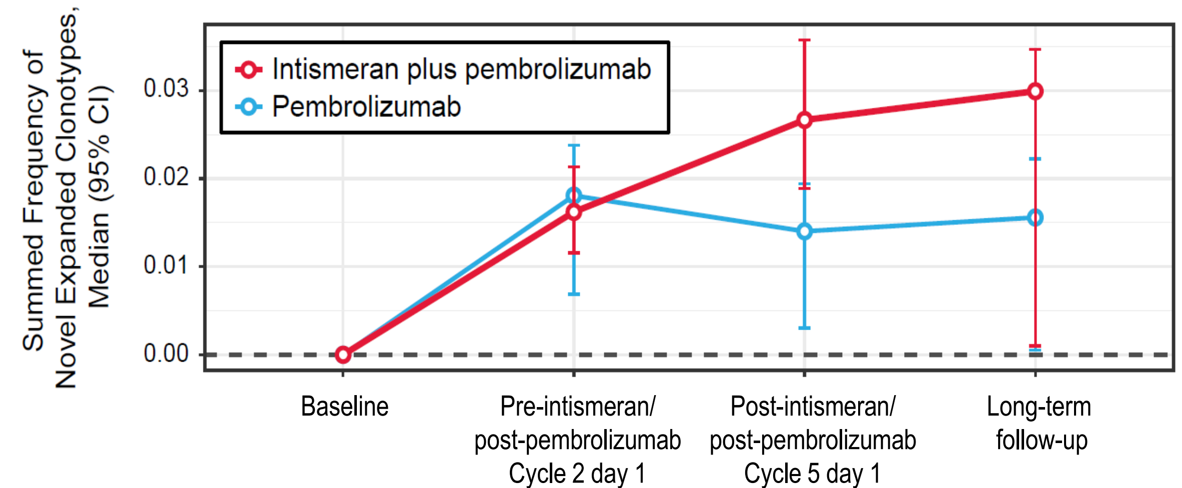
Intismeran plus pembrolizumab enhances T cell clonal expansion and novel clone emergence

Combination therapy increased clonality, reflecting expansion of dominant T-cell clones



	Baseline	Pre-intismeran/post-pembrolizumab Cycle 2 day 1	Post-intismeran/post-pembrolizumab Cycle 5 day 1	Long-term follow-up
Intismeran plus pembrolizumab	n=78	n=69	n=73	n=56
Pembrolizumab	n=38	n=32	n=35	n=23

Combination therapy increased novel TCR clonotypes



	Baseline	Pre-intismeran/post-pembrolizumab Cycle 2 day 1	Post-intismeran/post-pembrolizumab Cycle 5 day 1	Long-term follow-up
Intismeran plus pembrolizumab	n=78	n=69	n=73	n=56
Pembrolizumab	n=38	n=32	n=35	n=23

Data are median (bootstrapped 95% CI). Whole blood TCR RNA sequencing at baseline, pre-intismeran/post-pembrolizumab (cycle 2/day 1), post-intismeran/post-pembrolizumab (cycle 5/day 1), and 30 days after the last pembrolizumab dose. Analyses used downsampled TCRβ chains normalized to 10,000 clones. Novel clones identified by absence at baseline. Differential clone abundance between baseline and on-treatment used 2-sample exact tests and *P* value adjusted for false discovery rates to identify novel-expanded clones.

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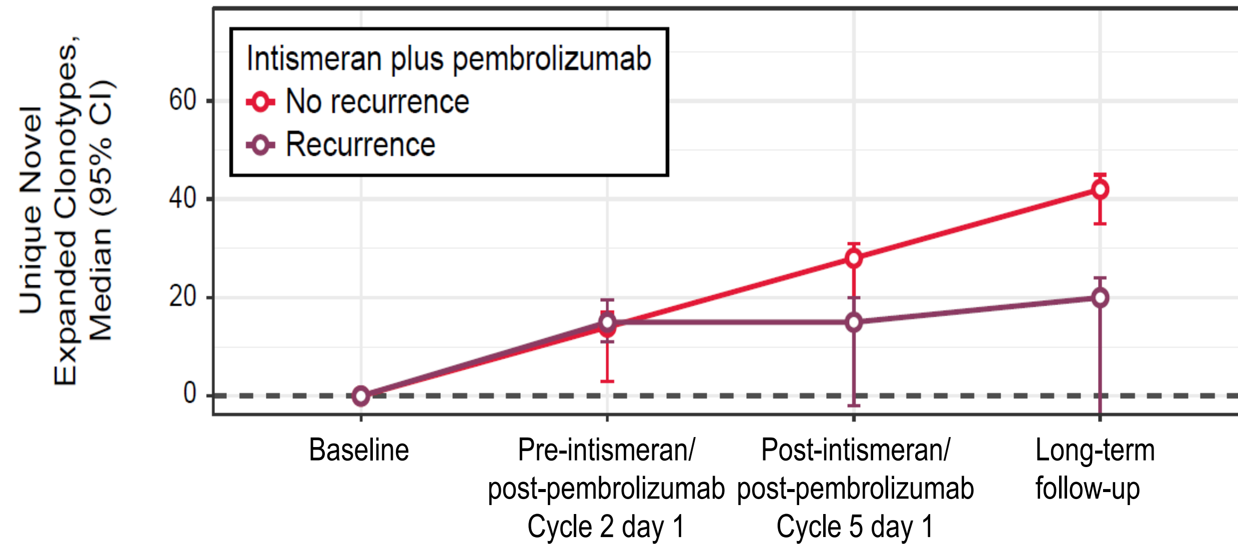
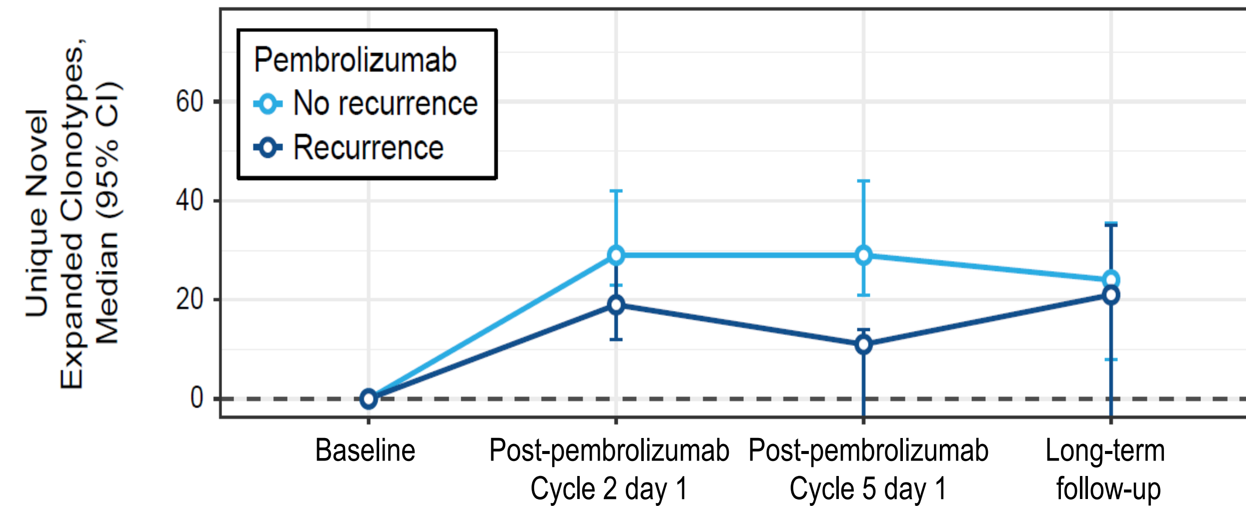
Greater novel clone expansion was associated with lower recurrence in the intismeran plus pembrolizumab arm





No recurrence	n=57	n=49	n=54	n=43
Recurrence	n=21	n=20	n=19	n=13

No recurrence	n=21	n=17	n=19	n=14
Recurrence	n=17	n=15	n=16	n=9

Data are shown as median and bootstrapped 95% CI. Whole blood TCR RNA sequencing at baseline, pre-intismeran/post-pembrolizumab (cycle 2/day 1), post-intismeran/post-pembrolizumab (cycle 5/day 1), and 30 days after the last pembrolizumab dose. Long-term follow-up data were collected at >170 days after last intismeran dose.

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