



Immunotherapy in Advanced and Metastatic Non-Small Cell Lung Cancer

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First Line Lung Cancer Therapy with no actionable genes

NSQCC:

- Carboplatin/Pemetrexed/Pembrolizumab [Keynote 189]
- Carboplatin/Paclitaxel/Bevacizumab/Atezolizumab [IMPOWER 150]

SQCC:

- Carboplatin/Paclitaxel or nab-paclitaxel/Pembrolizumab [Keynote 407]

NSQCC and SQCC:

- Cemiplimab/Chemotherapy [Empower Lung-3]

IO single Agent (NSQCC OR SQCC)

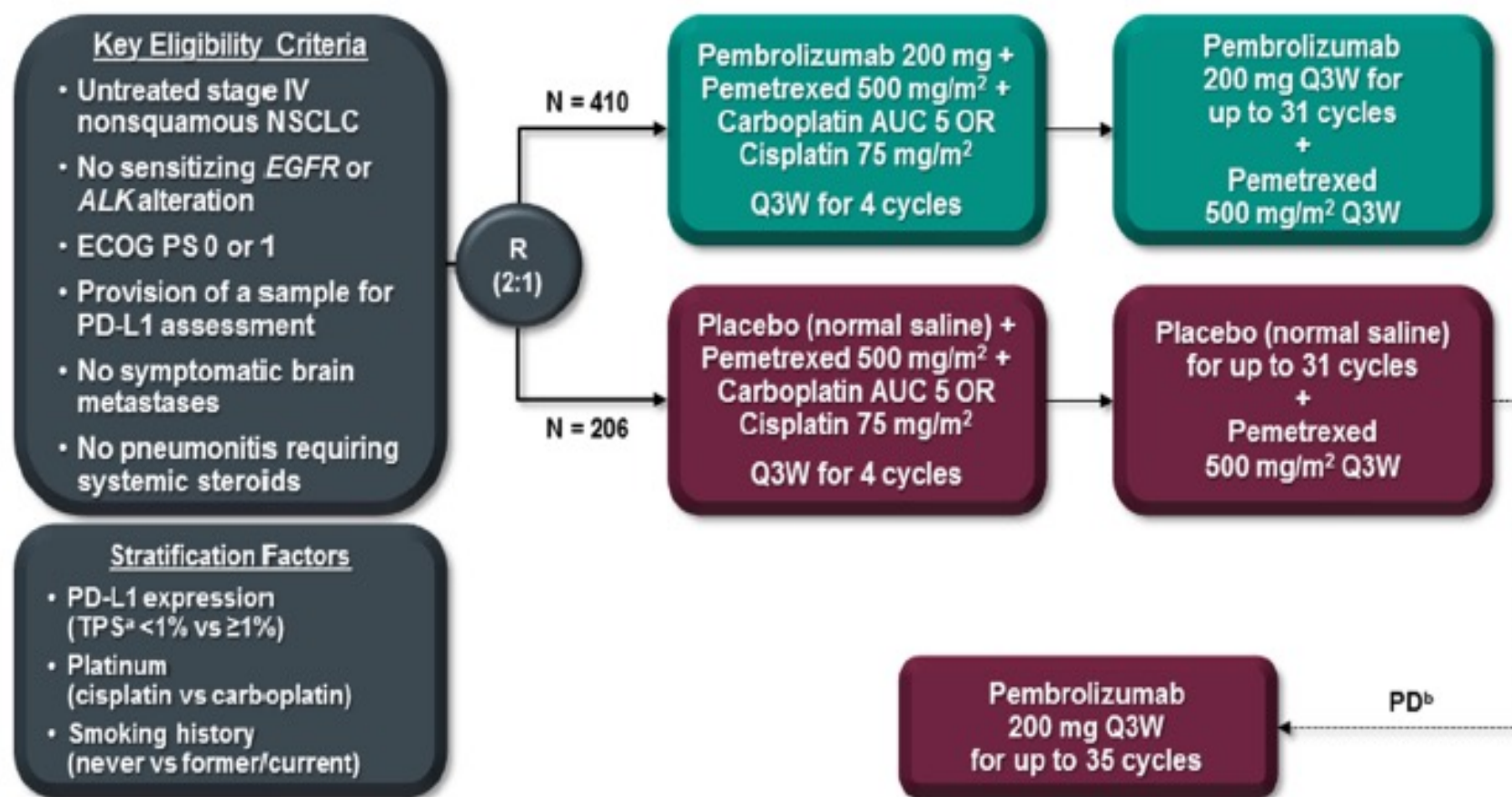
- Pembrolizumab [Keynote 024 and 042]
- Atezolizumab [IMPOWER 110]
- Cemiplimab [Empower Lung-1]

Immunotherapy combinations:

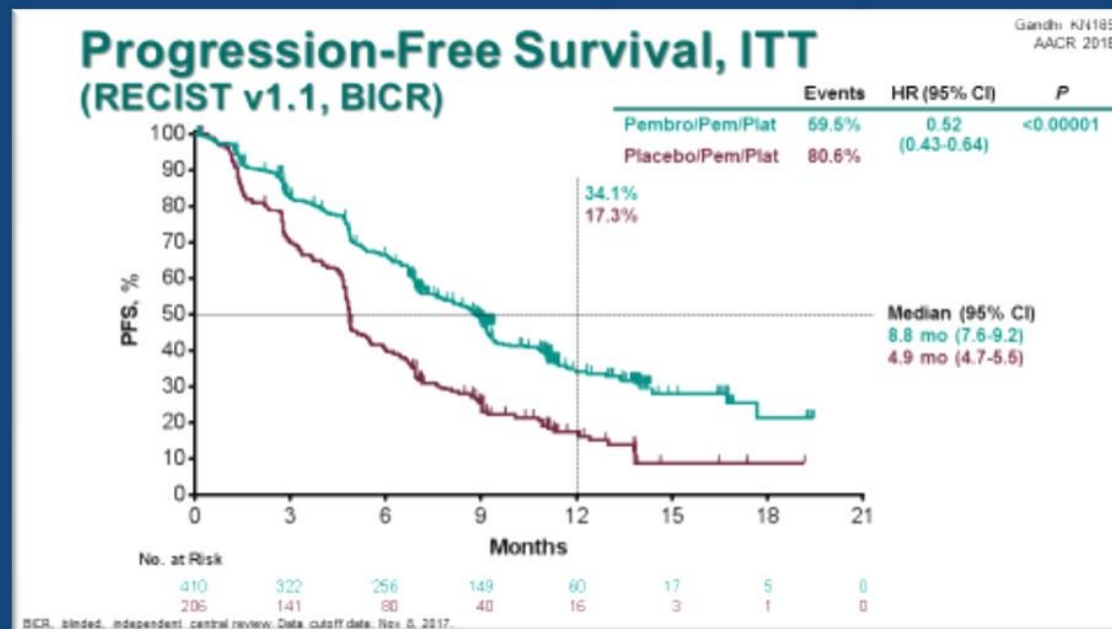
- Ipilimumab and Nivolumab [Checkmate 227]
- Ipilimumab and Nivolumab plus 2 cycles of chemotherapy [Checkmate 9LA]

KEYNOTE 189

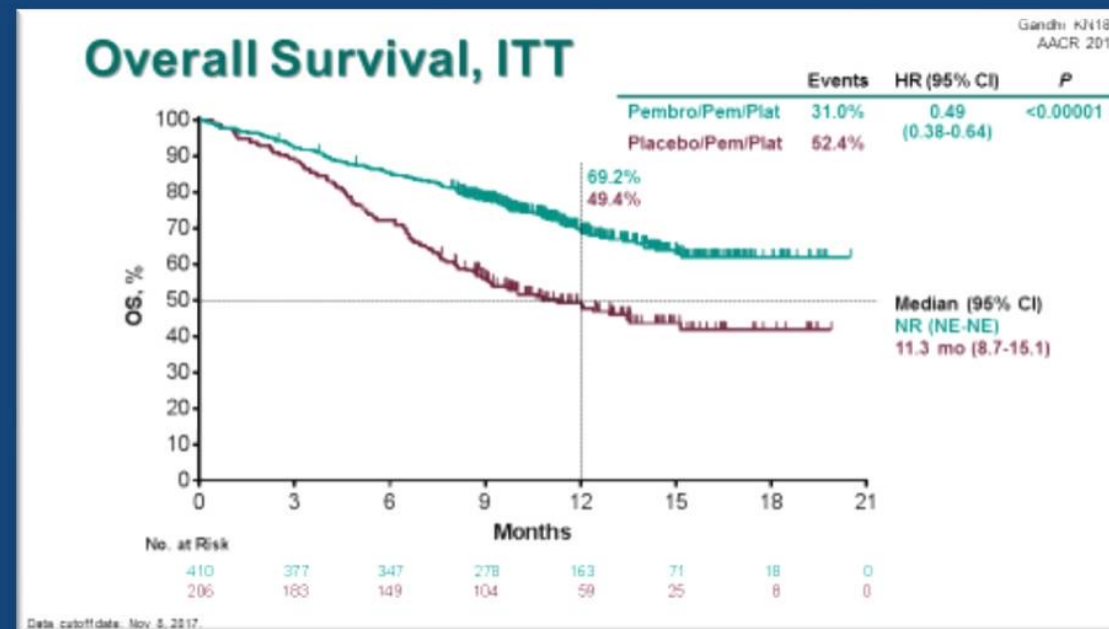
RANDOMIZED, DOUBLE-BLIND, PHASE III STUDY OF PLATINUM+PEMETREXED CHEMOTHERAPY WITH OR WITHOUT PEMBROLIZUMAB IN FIRST LINE METASTATIC NON-SQUAMOUS NON-SMALL CELL LUNG CANCER SUBJECTS



KEYNOTE 189 Co-primary endpoints: mPFS and mOS



	CPP	Control
mPFS (mo)	8.8 (7.6-9.2)	4.9 (4.7-5.5)
HR, 95% CI, p value	0.52 (0.43-0.64) P = <0.00001	



	CPP	Control
mOS (mo)	NR	11.3 (8.7-15.1)
HR, 95% CI, p value	0.49 (0.38-0.64) P = <0.00001	

ORR^a and OS

Patients Who Completed 35 Cycles (2 Years) of Pembrolizumab

Best response

N = 56

Objective response, n (%) 49 (87.5)

Best objective response, n (%)

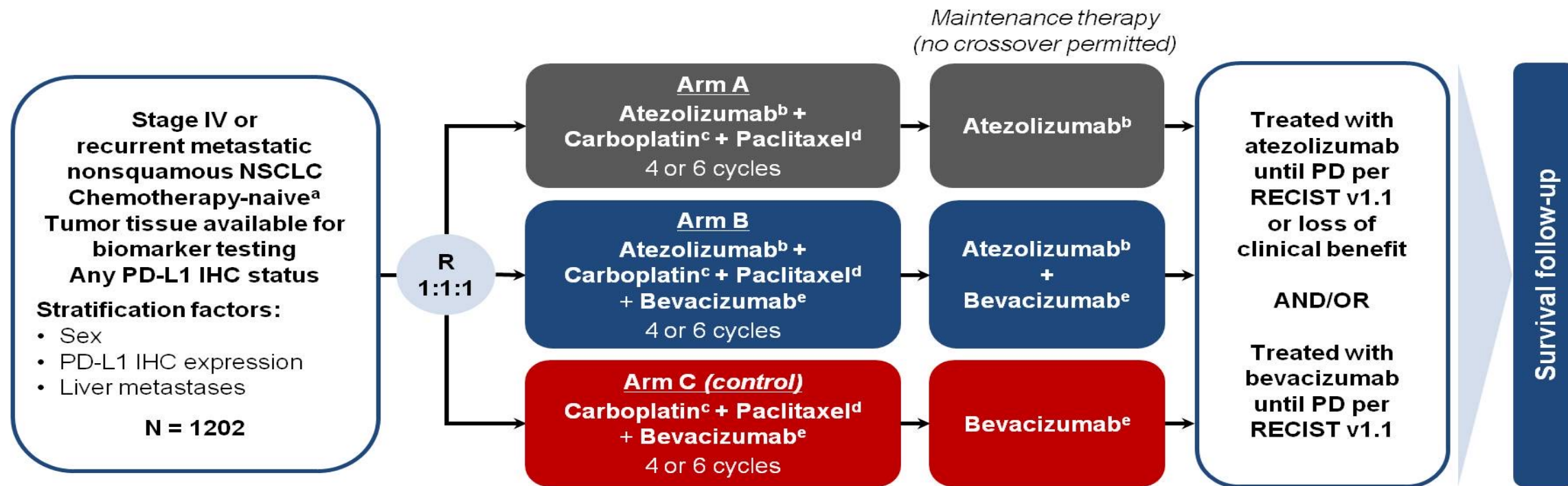
CR 6 (10.7)

PR 43 (76.8)

SD 7 (12.5)

- 2-year OS rate from completion of 35 cycles (2 years) was 79.6%
- At data cutoff, 45/56 patients (80.4%) were alive, 28 without PD
- 7 patients started second-course pembrolizumab
 - 2 had a second-course best response of SD by investigator assessment
 - 2 had best response of PD, and 3 were not assessed as of data cutoff

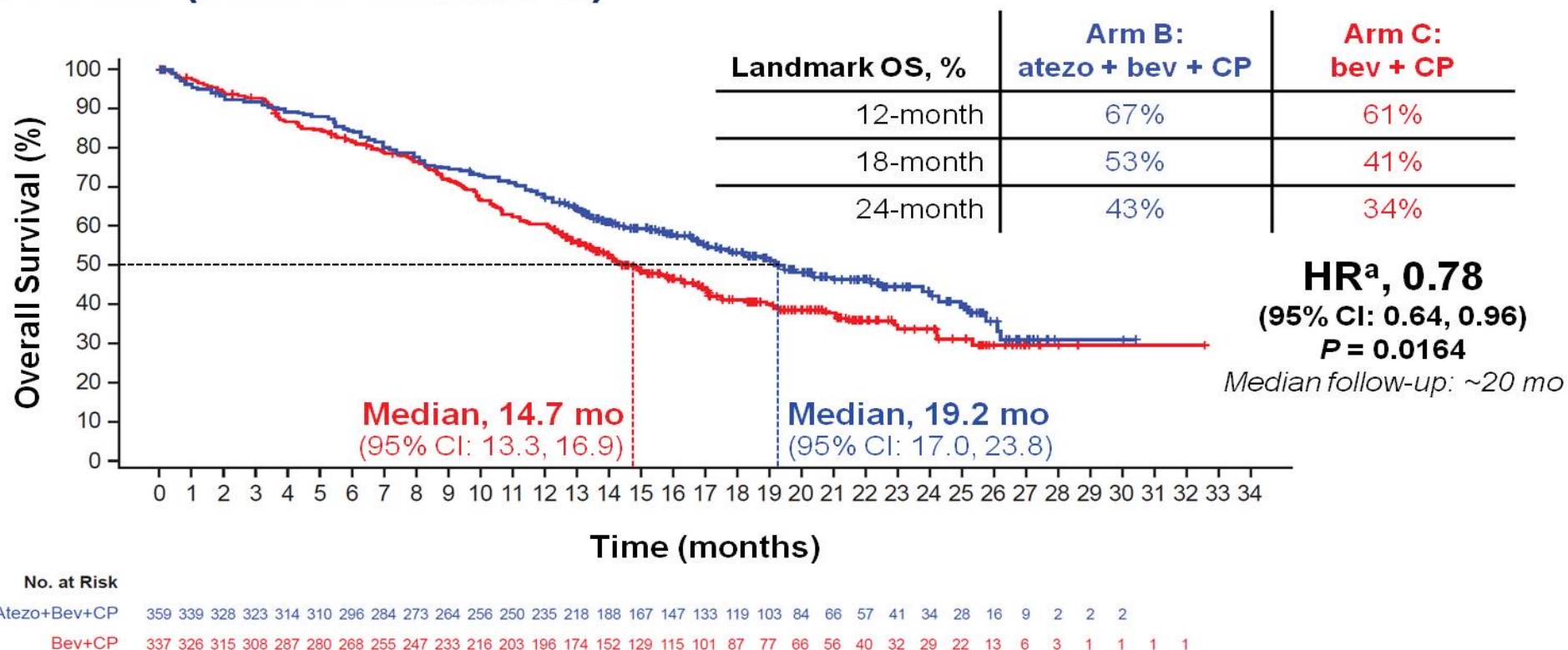
IMpower150 Study Design



^a Patients with a sensitizing *EGFR* mutation or *ALK* translocation must have disease progression or intolerance of treatment with one or more approved targeted therapies.

^b Atezolizumab: 1200 mg IV q3w. ^c Carboplatin: AUC 6 IV q3w. ^d Paclitaxel: 200 mg/m² IV q3w. ^e Bevacizumab: 15 mg/kg IV q3w.

OS in the ITT-WT (Arm B vs Arm C)



- Statistically significant and clinically meaningful OS benefit with atezolizumab + bevacizumab + chemotherapy vs bevacizumab + chemotherapy was observed

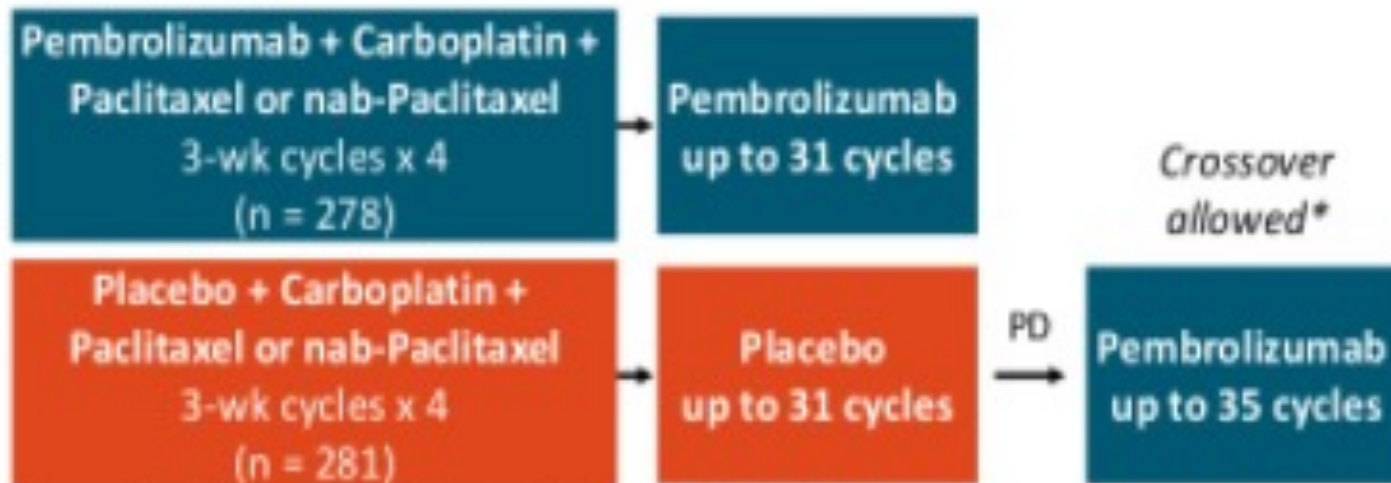
^a Stratified HR.
 Data cutoff: January 22, 2018

KEYNOTE-407: Study Design

- Randomized, double-blind phase III trial

Stratified by PD-L1 TPS (< 1% vs ≥ 1%), taxane (paclitaxel vs nab-paclitaxel), region (east Asia vs other)

Patients with untreated stage IV squamous NSCLC, ECOG PS 0/1, available tumor biopsy for PD-L1 assessment, no brain mets, and no pneumonitis requiring systemic steroids (N = 559)

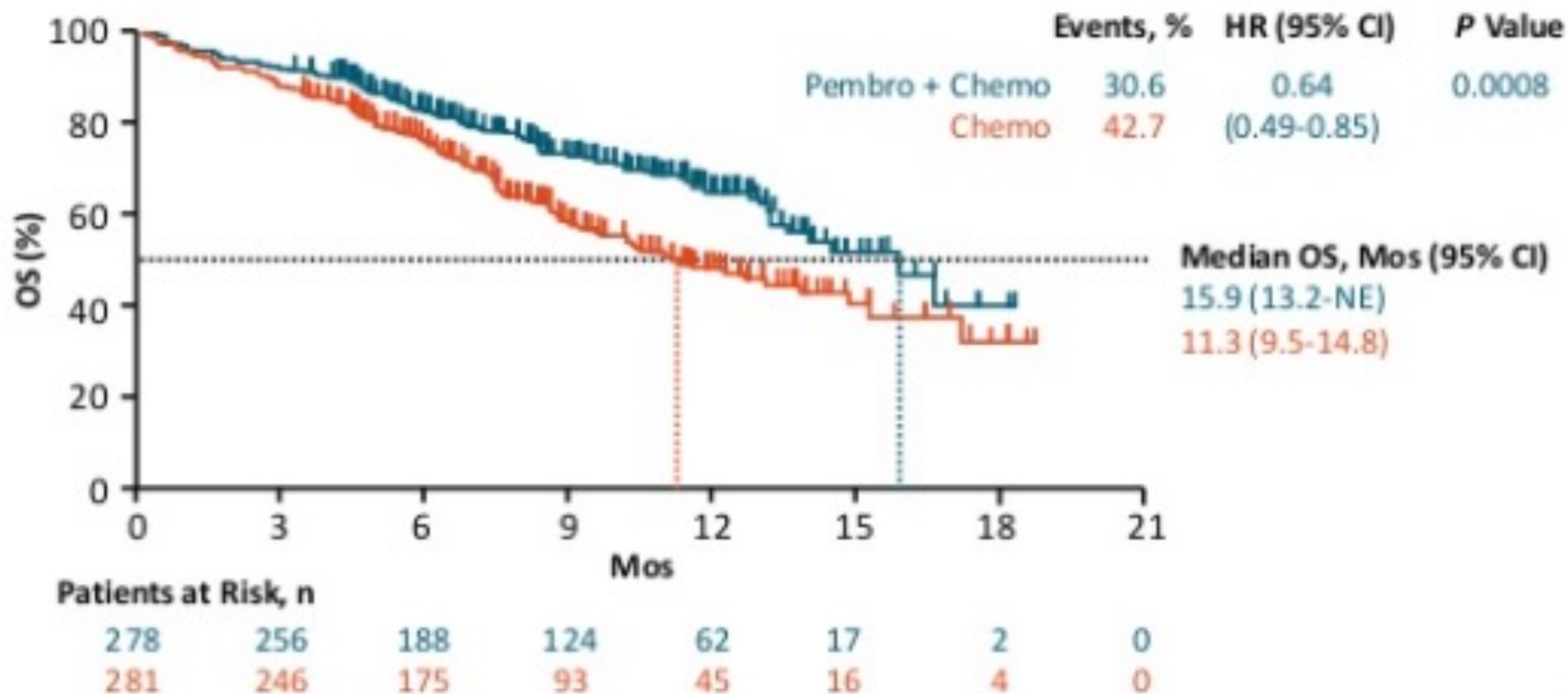


Carboplatin AUC 6 Q3W, nab-paclitaxel 100 mg/m² QW, paclitaxel 200 mg/m² Q3W, pembrolizumab 200 mg Q3W.

*Upon confirmation of PD and safety criteria by BICR, optional crossover could occur during combination or monotherapy.

- Primary endpoint: PFS by RECIST v1.1 (BICR), OS
- Secondary endpoints: ORR and DoR by RECIST v1.1 (BICR), safety

KEYNOTE-407: OS in ITT Population



EMPOWER-Lung 3 (Part 2) Study Design (NCT03409614)

Background: Cemiplimab (a high-affinity, fully human anti-PD-1) is approved as first-line monotherapy for advanced NSCLC with PD-L1 $\geq 50\%$ (EMPOWER-Lung 1 Study¹)

Key eligibility criteria

- Treatment-naïve advanced NSCLC (non-squamous and squamous histology; Stage IIIb/c[†], IV)
- Any PD-L1 expression
- No EGFR, ALK, or ROS1 mutations
- ECOG PS 0 or 1
- Treated, clinically stable CNS metastases[‡]

Stratification factors

- PD-L1 expression: <1% vs 1–49% vs $\geq 50\%$
- Histology: non-squamous vs squamous

Endpoints

- Primary: OS
- Key secondary: PFS and ORR
- Additional secondary: DOR, BOR, safety, and PRO

R 2:1

Arm A

Cemiplimab 350 mg Q3W + investigator's choice platinum-doublet chemo Q3W for 4 cycles[§]

PD or 108 weeks

Arm B

Placebo Q3W + investigator's choice platinum-doublet chemo Q3W for 4 cycles[§]

PD or 108 weeks

Follow-up

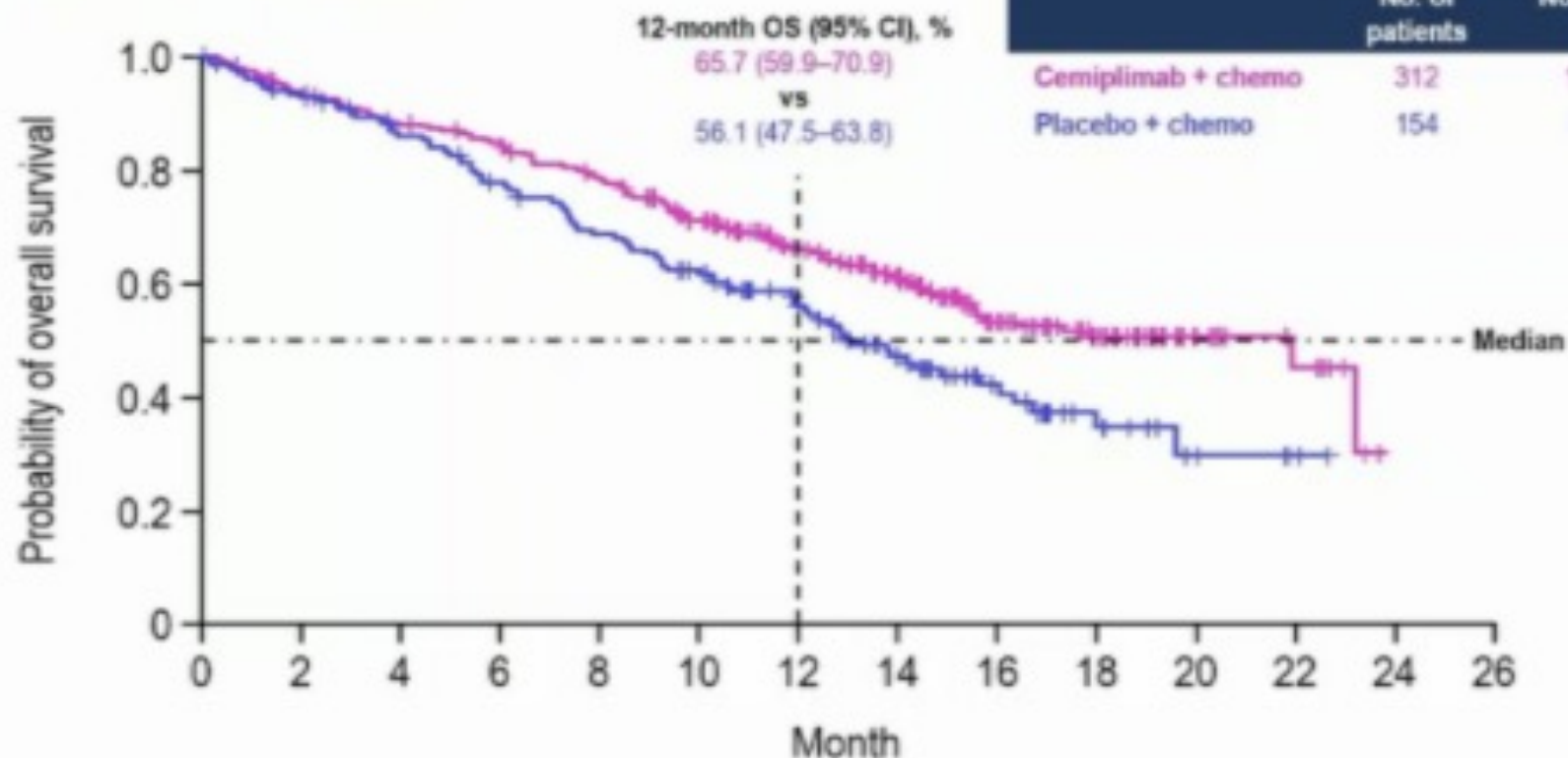
N=466

Two interim analyses were prespecified per protocol
Second interim analysis (14 June 2021) presented here

[†]Patient not a candidate for definitive chemoradiation. [‡]Patient must have neurologically returned to baseline (except for residual signs or symptoms related to the CNS treatment). [§]For patients with non-squamous NSCLC, pemetrexed is mandatory as maintenance therapy for those patients initially assigned to receive a pemetrexed-containing regimen. ALK, anaplastic lymphoma kinase gene; BOR, best overall response: chemo, chemotherapy; CNS, central nervous system; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor gene; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PRO, patient-reported outcomes; Q3W, every 3 weeks; R, randomised; ROS1, c-ros oncogene 1.
1. Sezer A et al. Lancet 2021;397:592–604.

Overall Survival

Median duration of follow-up (range): 16.4 (8.5–24.0) months



	No. of patients	No. of events, n (%)	OS, median (95% CI), months
Cemiplimab + chemo	312	132 (42.3)	21.9 (15.5–NE)
Placebo + chemo	154	82 (53.2)	13.0 (11.9–16.1)

HR (95% CI) = 0.71 (0.53–0.93); $P=0.014$

No. at risk:

Cemiplimab + chemo	312	289	269	256	233	199	162	131	86	52	18	8	0	0
Placebo + chemo	154	141	126	112	98	85	65	46	26	14	5	2	0	0



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SQCC:

- Carboplatin/Paclitaxel or nab-paclitaxel/Pembrolizumab [Keynote 407]

NSQCC OR SQCC

- Pembrolizumab [Keynote 024 and 042]
- Atezolizumab [IMPOWER 110]
- Cemiplimab **

Immunotherapy combinations:

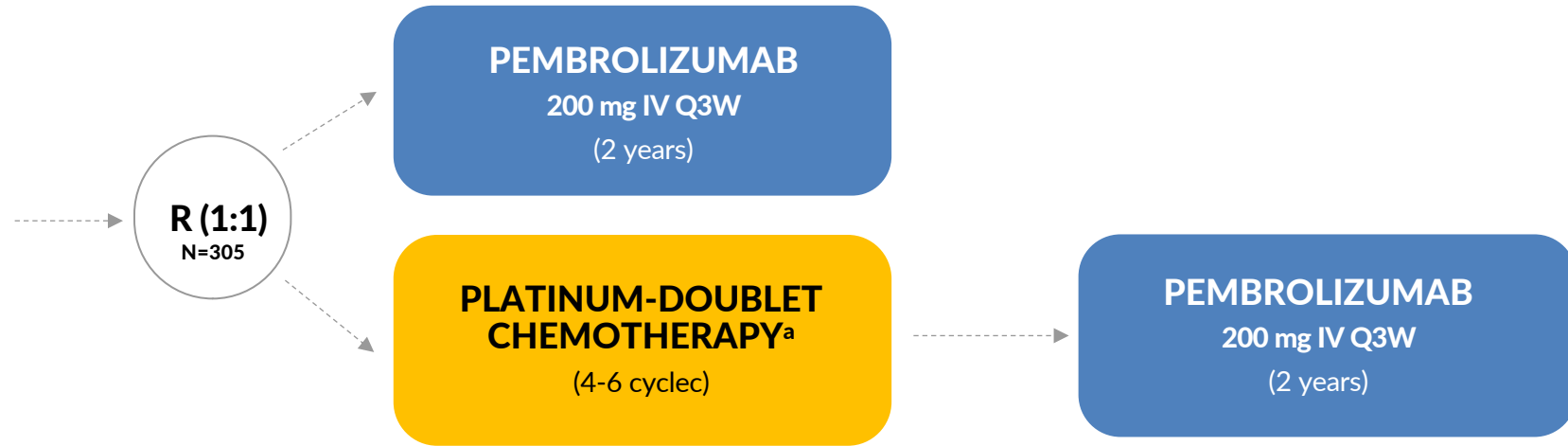
- Ipilimumab and Nivolumab [Checkmate 227]
- Ipilimumab and Nivolumab plus 2 cycles of chemotherapy [Checkmate 9LA]

KEYNOTE 024

PD-L1 >50%

KEY ELIGIBILITY CRITERIA

- Untreated stage IV NSCLC
- PD-L1 PS 0-1
- No activating EGFR mutation or ALK translocation
- No untreated brain metastases
- No active autoimmune disease requiring systemic therapy



Primary endpoint

- PFS (RECIST v1.1, blinded independent central review)

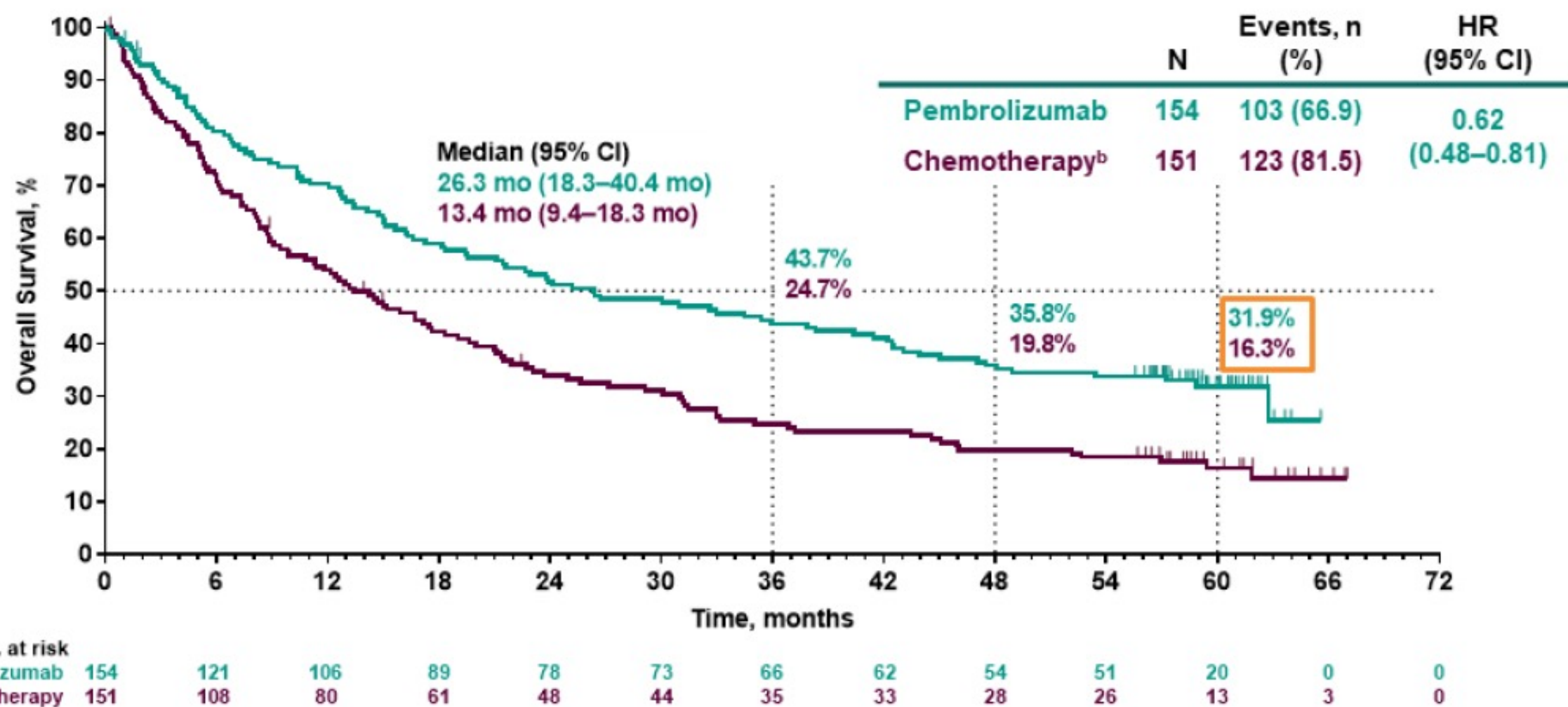
Secondary endpoint

- OS, ORR, Safety

Exploratory endpoint

- DOR, PFS2

Overall Survival^a



^aITT population.

^bEffective crossover rate from chemotherapy to anti-PD-(L)1 therapy, 66.0% (99 patients in total crossed over to anti-PD-[L]1 therapy: 83 patients crossed over to pembrolizumab during the study, and 16 patients received subsequent anti-PD-[L]1 therapy outside of crossover; patients may have received >1 subsequent anti-PD-[L]1 therapy). Data cutoff: June 1, 2020.

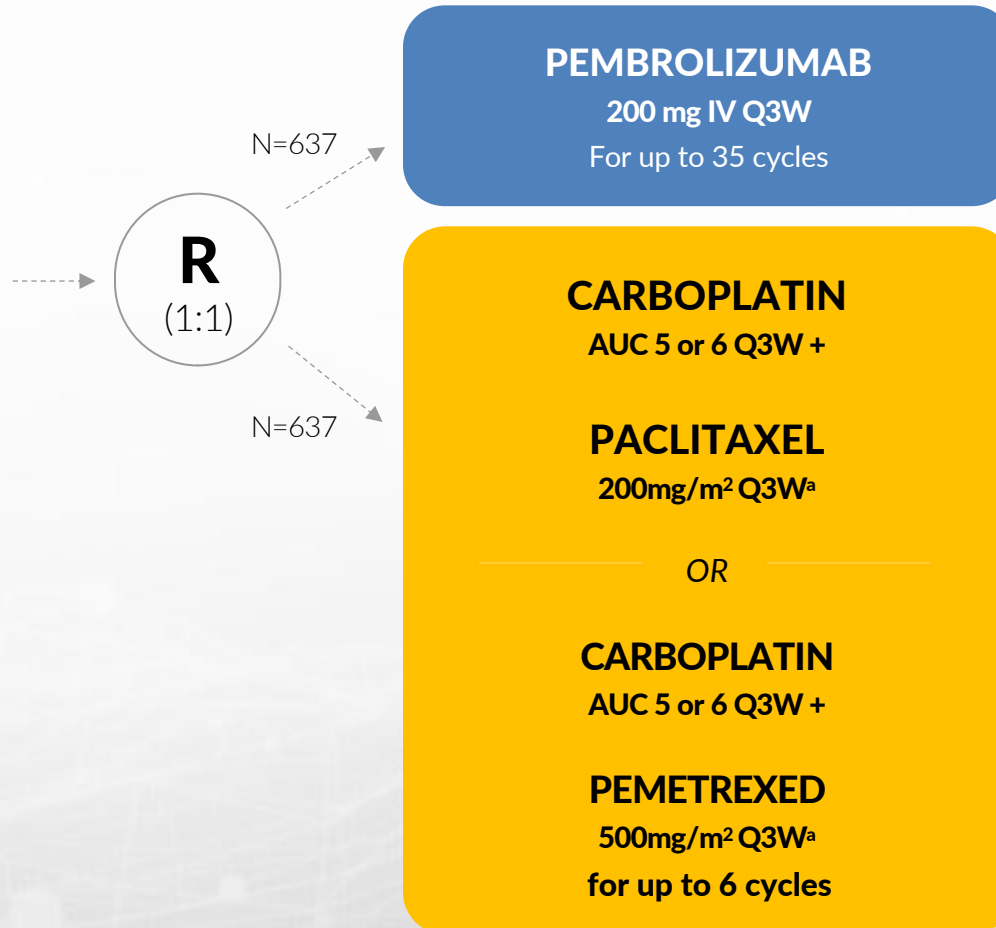
KEYNOTE 042

KEY ELIGIBILITY CRITERIA

- Untreated locally advanced or metastatic NSCLC of any histology
- PD-L1 TPS $\geq 1\%$
- No sensitizing EGFR or ALK alterations
- ECOG PS 0 or 1
- No untreated or unstable CNS metastases
- No history of pneumonitis that required systemic corticosteroids

STRATIFICATION FACTORS

- Region (east Asia vs rest of the world)
- ECOG PS (0 vs 1)
- Histology (squamous vs nonsquamous)
- PD-L1 TPS ($\geq 50\%$ vs 1-49%)



Primary endpoint

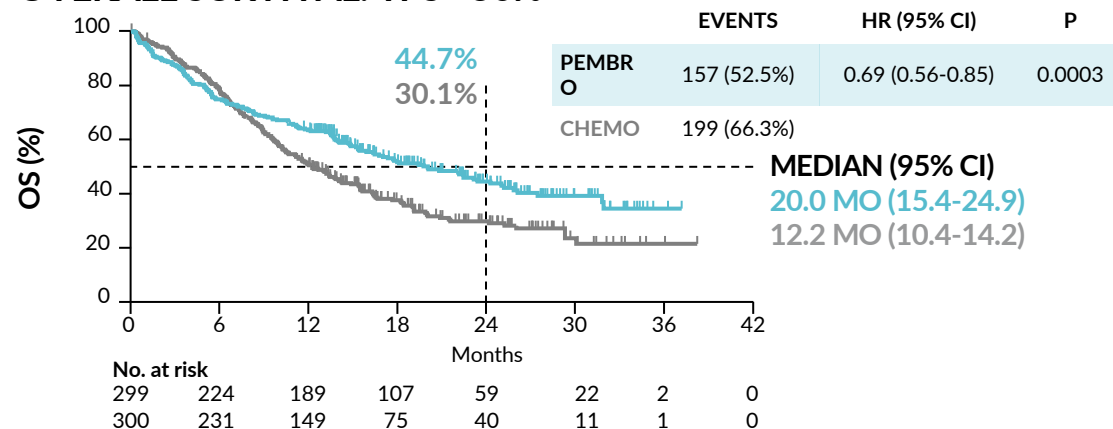
- OS in PD-L1 TPS $\geq 50\%$, $\geq 20\%$, and $\geq 1\%$

Secondary endpoint

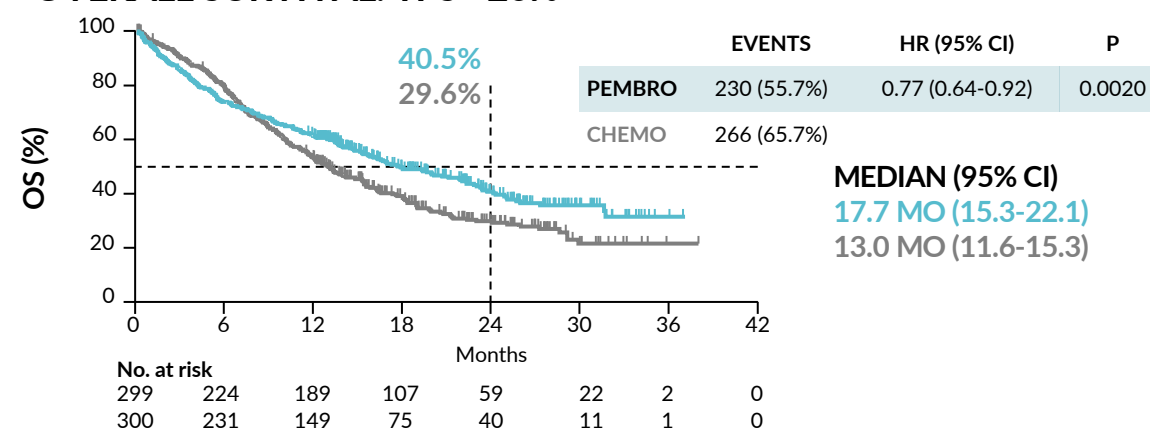
- PFS and ORR in TPS $\geq 50\%$, $\geq 20\%$, and $\geq 1\%$; safety in TPS $\geq 1\%$

KEYNOTE 042

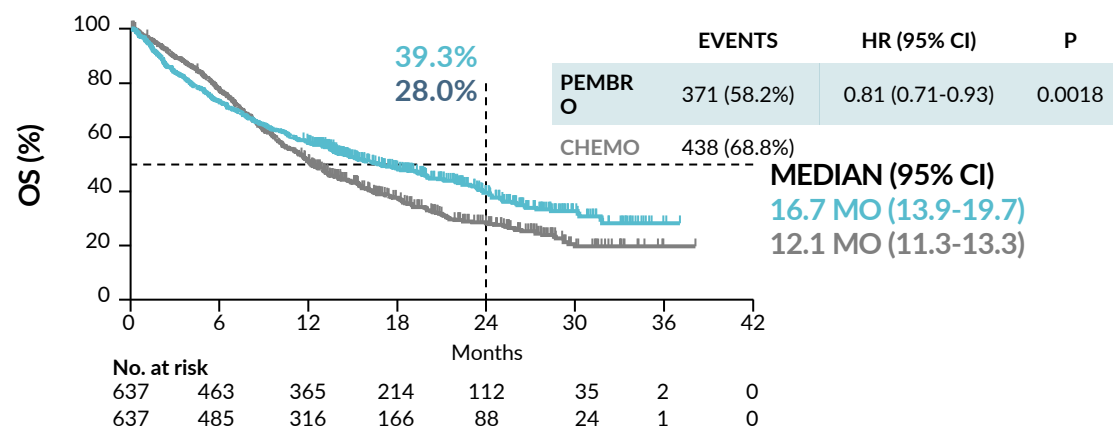
OVERALL SURVIVAL: TPS ≥50%



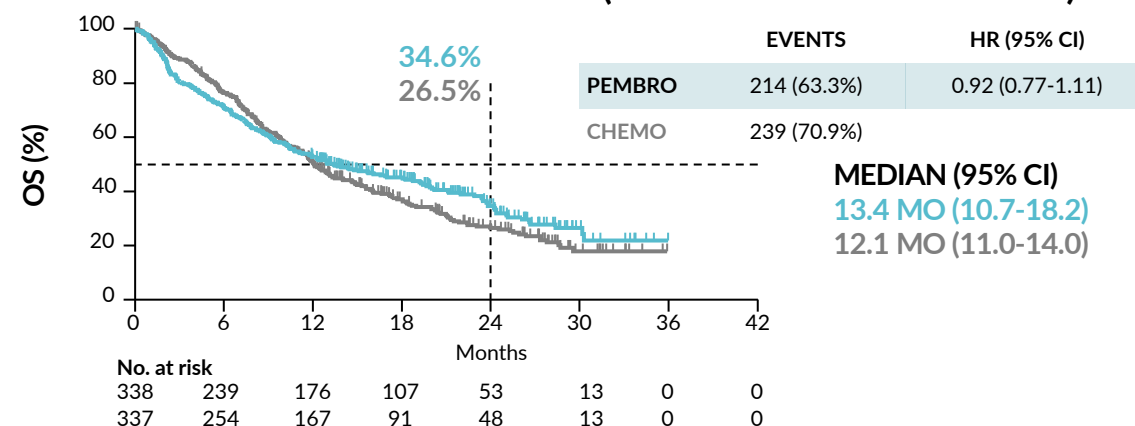
OVERALL SURVIVAL: TPS ≥20%



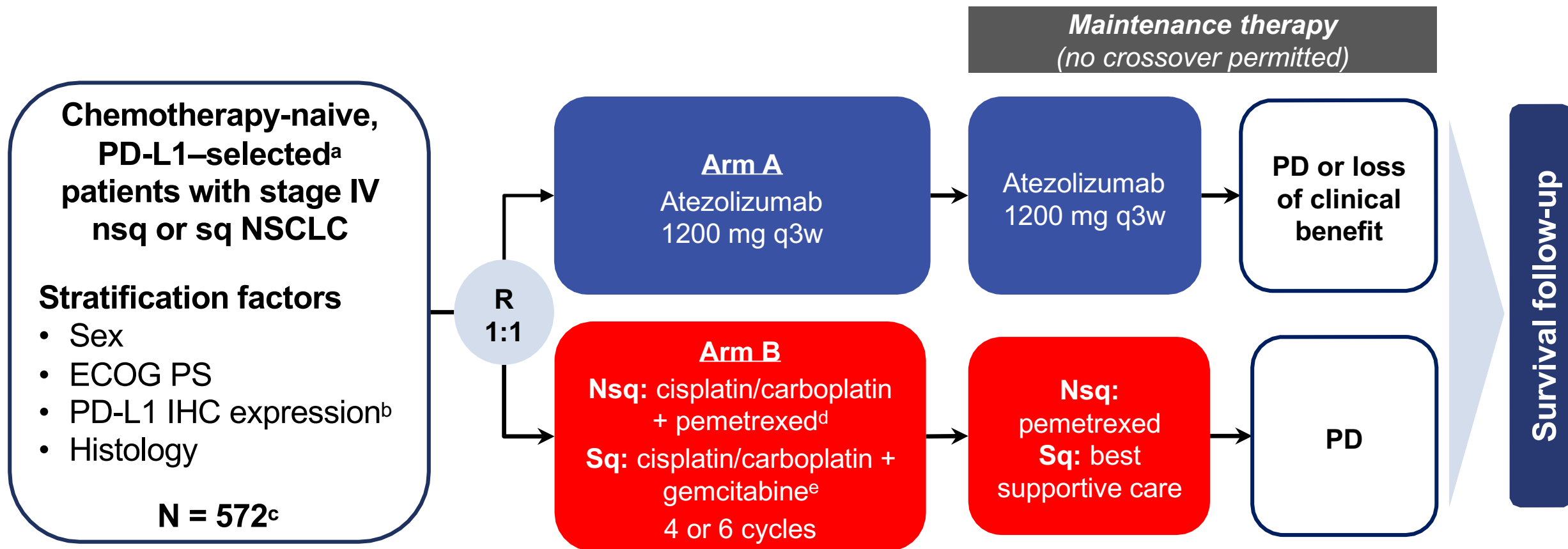
OVERALL SURVIVAL: TPS ≥1%



OVERALL SURVIVAL: TPS ≥1-49% (EXPLORATORY ANALYSIS^A)



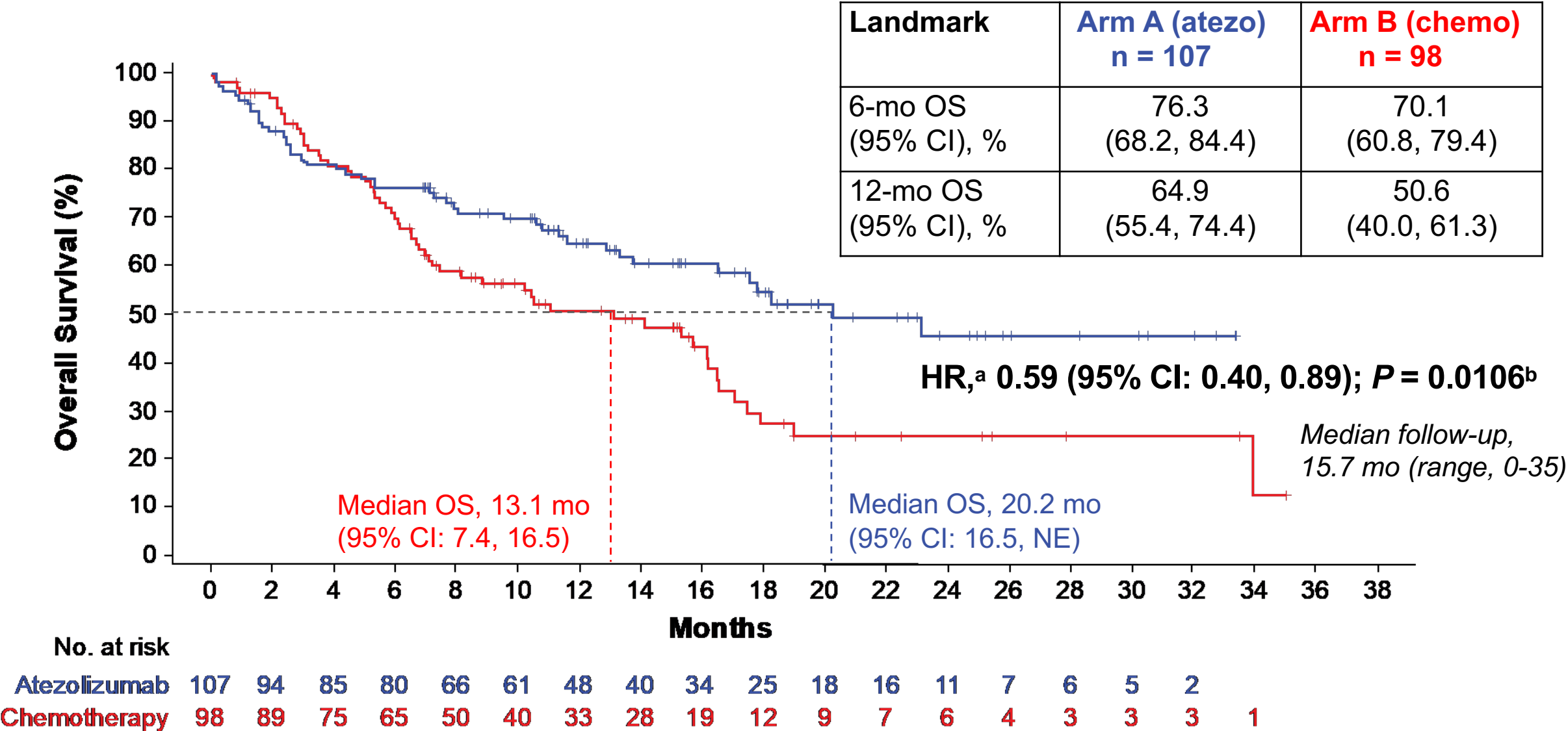
IMpower110 Study Design



- Primary endpoint: OS in WT population^f
- Key secondary endpoints: investigator-assessed PFS, ORR and DOR (per RECIST version 1.1)

IC, tumour-infiltrating immune cells; IHC, immunohistochemistry; nsq, non-squamous; PD, progressive disease; q3w, every 3 weeks; R, randomised; sq, squamous; TC, tumour cells; WT, wild-type. ^a PD-L1 expression (VENTANA SP142 IHC assay) ≥ 1% on TC or IC. ^b TC1/2/3 and any IC vs TC0 and IC1/2/3. ^c 554 patients in the WT population. ^d Cisplatin 75 mg/m² or carboplatin area under the curve (AUC) 6 + pemetrexed 500 mg/m² IV q3w. ^e Cisplatin 75 mg/m² + gemcitabine 1250 mg/m² or carboplatin AUC 5 + gemcitabine 1000 mg/m² IV q3w. ^f WT population excludes patients with EGFR+ and/or ALK+ NSCLC.

OS: TC3 or IC3 WT



Key Eligibility Criteria

- Treatment-naïve advanced NSCLC
- PD-L1 $\geq 50\%$
- No *EGFR*, *ALK* or *ROS1* mutations
- ECOG PS 0 or 1
- Treated, clinically stable CNS metastases and controlled hepatitis B or C or HIV were allowed

Stratification Factors:

- Histology (squamous vs non-squamous)
- Region (Europe, Asia or ROW)

N=710

Five interim analyses were prespecified per protocol
Second interim analysis (1 March 2020) presented here

R 1:1**Arm A**

Cemiplimab monotherapy IV
350 mg Q3W
Treat until PD or 108 weeks

PD

Optional
continuation of
cemiplimab + 4
cycles of
chemotherapy

Arm B

4–6 cycles of investigator's choice
chemotherapy

PD

Optional crossover
to cemiplimab
monotherapy

Follow-up**Endpoints:**

- Primary: OS and PFS
- Secondary: ORR (key), DOR, HRQoL and safety

Top Line Survival Results

ITT

	No. of Patients	Median OS (95% CI) mo
Cemiplimab	356	22.1 (95% CI, 17.7–NE)
Chemotherapy	354	14.3 (95% CI, 11.7–19.2)

HR, 0.68 (95% CI, 0.53–0.87); P=0.0022



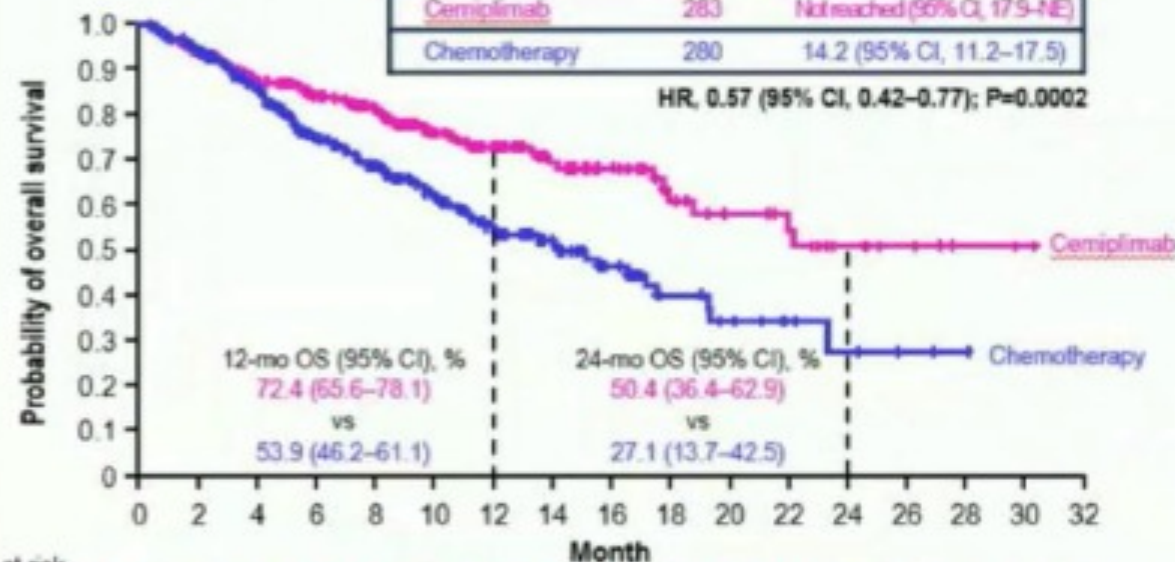
at risk

Cemiplimab	356	304	254	223	198	147	120	87	71	48	37	27	18	8	3	1	0
Chemotherapy	354	303	254	205	172	126	93	73	52	41	27	12	7	4	3	0	0

PD-L1 ≥50% ITT

	No. of Patients	Median OS (95% CI) mo
Cemiplimab	283	Not reached (95% CI, 17.9–NE)
Chemotherapy	280	14.2 (95% CI, 11.2–17.5)

HR, 0.57 (95% CI, 0.42–0.77); P=0.0002



No. at risk

Cemiplimab	283	244	203	177	154	108	83	55	42	24	18	15	10	6	3	1	0
Chemotherapy	280	239	198	153	125	87	57	41	25	15	11	6	4	2	1	0	0

Two Populations: In 235 patients the first PD-L1 assay had some issues and needed to be repeated. Of these, 88 were eventually included upon retest



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NSQCC:

- Carboplatin/Pemetrexed/Pembrolizumab [Keynote 189]
- Carboplatin/Paclitaxel/Bevacizumab/Atezolizumab [IMPOWER 150]

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- Carboplatin/Paclitaxel or nab-paclitaxel/Pembrolizumab [Keynote 407]

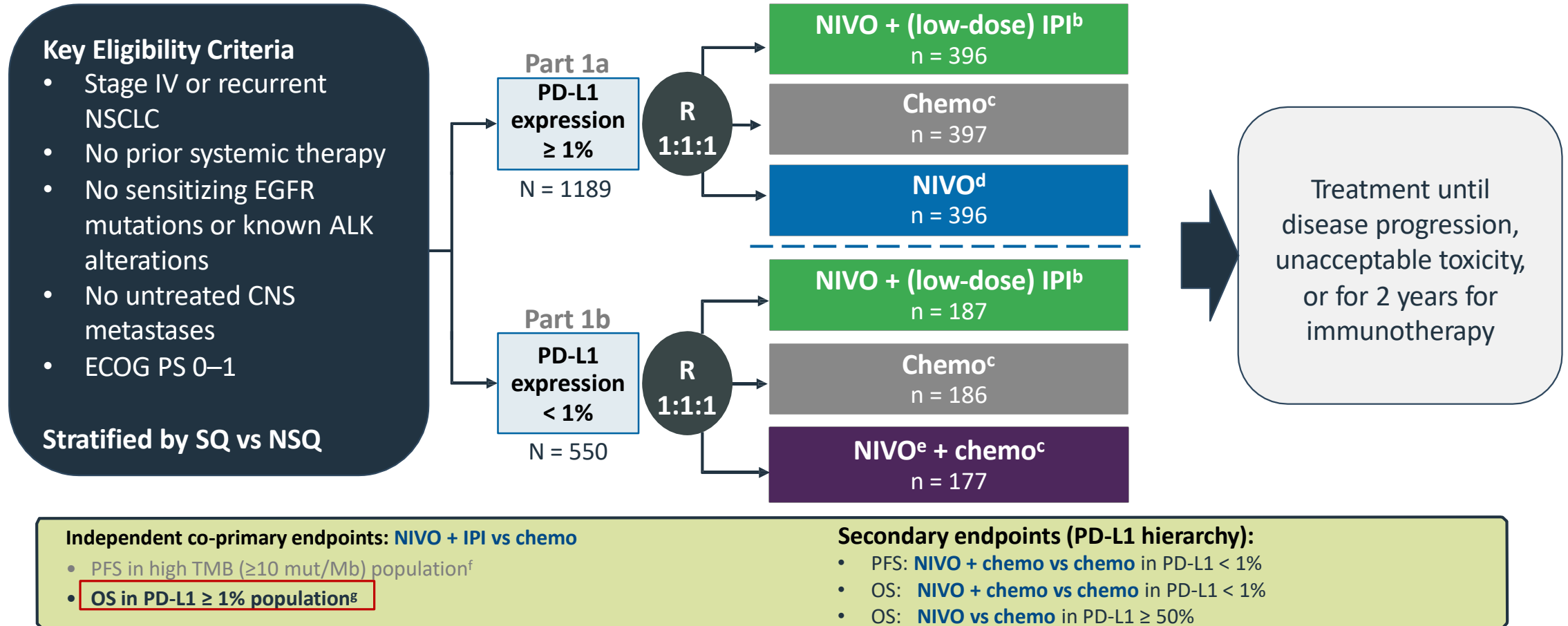
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Immunotherapy combinations:

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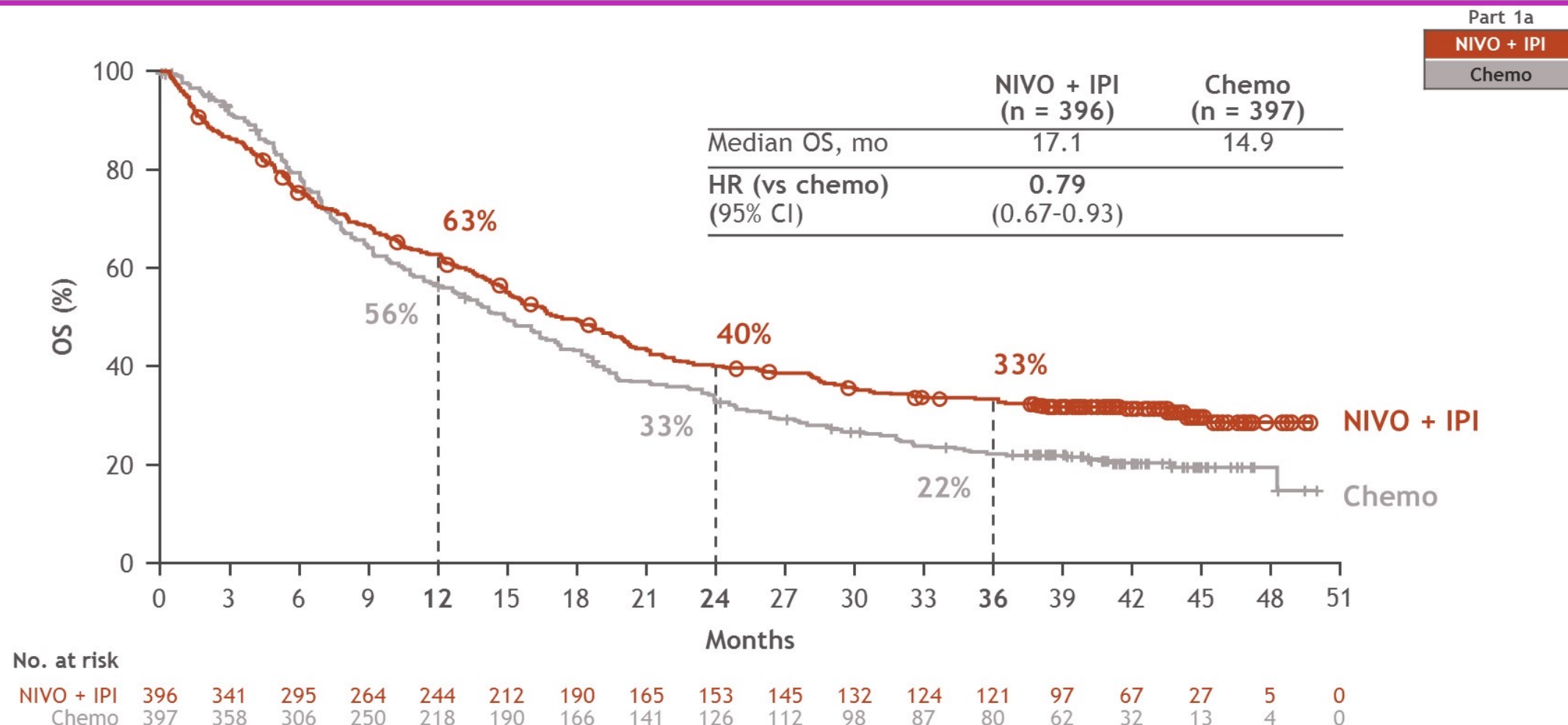
CheckMate 227: Part 1 final analysis of nivolumab + low-dose ipilimumab vs platinum-doublet chemotherapy in 1L advanced NSCLC



Database lock: July 2, 2019; minimum follow-up for primary endpoint: 29.3 months

^aNCT02477826; ^bNIVO (3 mg/kg Q2W) + IPI (1 mg/kg Q6W); ^cNSQ: pemetrexed + cisplatin or carboplatin, Q3W for ≤ 4 cycles, with optional pemetrexed maintenance following chemo or NIVO + pemetrexed maintenance following NIVO + chemo; ^dNSQ: gemcitabine + cisplatin, or gemcitabine + carboplatin, Q3W for ≤ 4 cycles; ^eNIVO (240 mg Q2W); ^fNIVO (360 mg Q3W); ^gTMB primary endpoint analysis conducted at January 24, 2018 database lock in subset of patients randomized to NIVO + IPI or chemo; alpha allocated was 0.025; ^hAlpha allocated was 0.025 overall (0.023 for final analysis)

3-year update: OS with NIVO + IPI vs chemo (PD-L1 $\geq 1\%$)



Database lock: February 28, 2020; minimum follow-up for OS: 37.7 months.

Dosages were NIVO (3 mg/kg Q2W) + IPI (1 mg/kg Q6W). Among patients who were alive at 3 years, subsequent systemic therapy was received by 35% in the NIVO + IPI arm and 76% in the chemo arm; subsequent immunotherapies were received by 13% and 71%, respectively, and subsequent chemotherapy was received by 28% and 30%, respectively.



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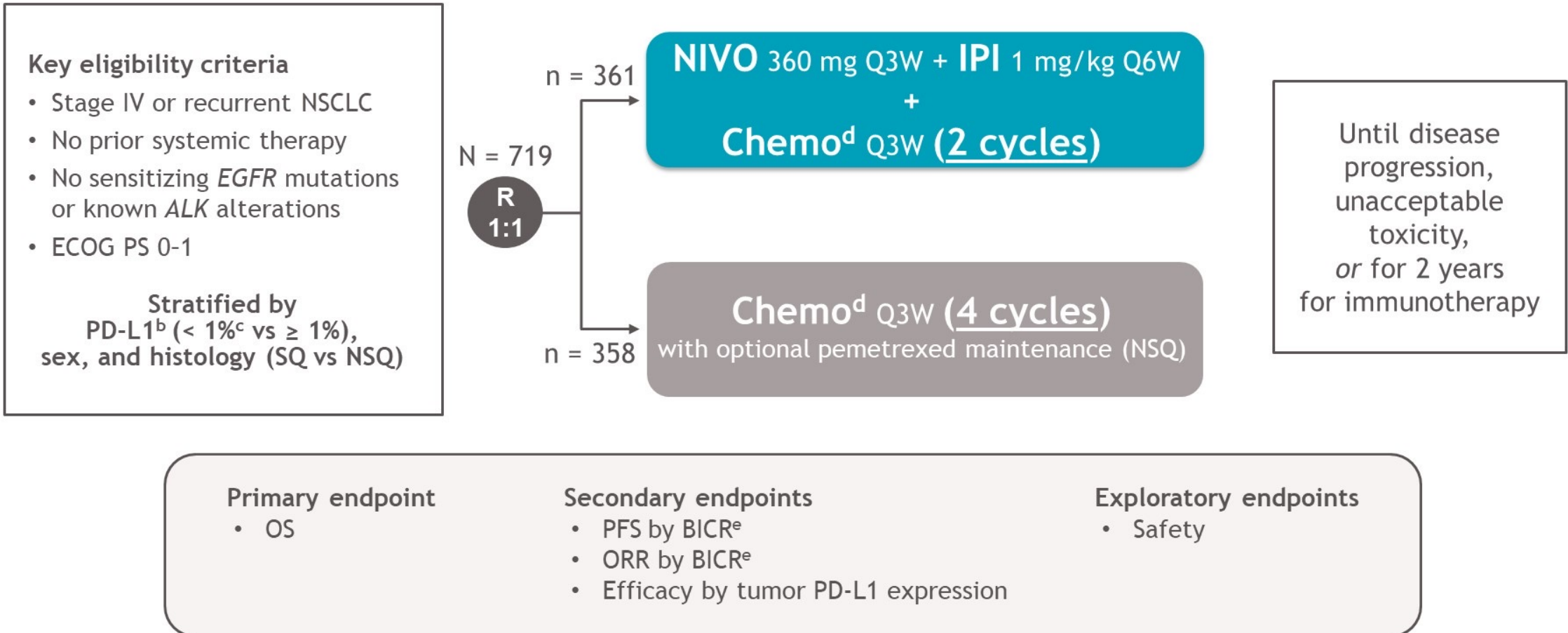
NSQCC OR SQCC

- Pembrolizumab [Keynote 024 and 042]
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- Cemiplimab

Immunotherapy combinations:

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- **Ipilimumab and Nivolumab plus 2 cycles of chemotherapy [Checkmate 9LA]**

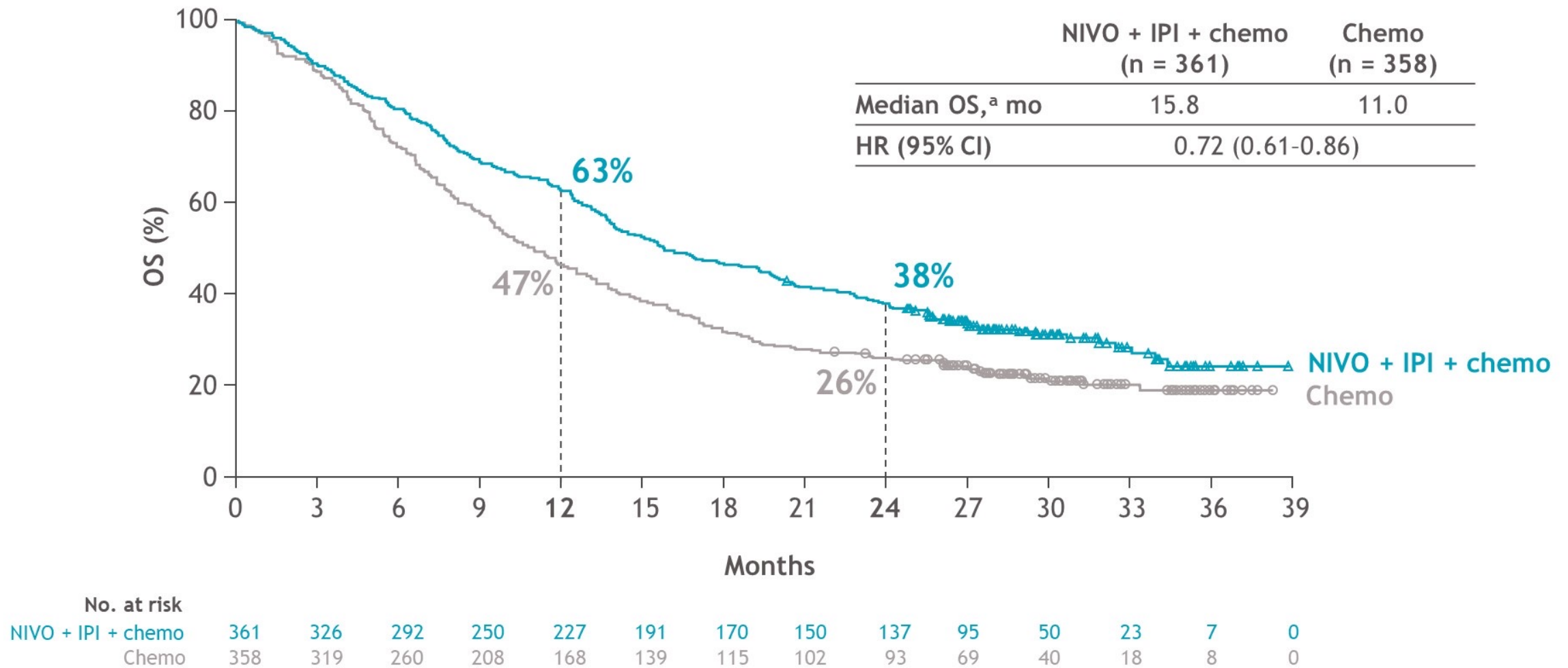
CheckMate 9LA study design^a



DBL: February 18, 2021; minimum / median follow-up for OS: 24.4 months / 30.7 months.

^aNCT03215706; ^bDetermined by the PD-L1 IHC 28-8 pharmDx assay (Dako); ^cPatients unevaluable for PD-L1 were stratified to PD-L1 < 1% and capped to 10% of all randomized patients; ^dNSQ: pemetrexed + cisplatin or carboplatin; SQ: paclitaxel + carboplatin; ^eHierarchically statistically tested.

2-Year update: OS in all randomized patients



Minimum follow-up: 24.4 months.

^a95% CI = 13.9-19.7 (NIVO + IPI + chemo) and 9.5-12.7 (chemo).

ORR slightly in favor of combination

	KN 24 (TPS > 50%)	KN 42 (TPS > 50%)	IMPW 10 TC3/IC3 (>50% and >10%)	KN 407 (TPS > 50%)	KN 189 (TPS > 50%)
ORR	45%	39.5%	30.7%	60.3%	61.4%
DOR	Nr (1.8-20.6 m)	20.2 m	Nr (1.8-29.3m)	7.7 m (all patients)	11.2 m (all patients)



Adverse Events

	KN-42		KN-24		KN-189		KN-407	
	Pembro	CT	Pembro	CT	Pembro + CT	CT	Pembro + CT	CT
All TRAE (%)	62.7%	89.9%	76.6%	90.0%	99.8%	99.0%	98.2%	97.9%
Grade 3-5 TRAE (%)	17.8%	41%	31.2%	53.3%	67.2%	65.0%	69.8%	68.2%
Discontinuation rate (any) (%)	9%	9.4%	13.6%	10.7%	27.7%	14.9%	23.4%	11.8%
Led to death	0.2%	0%	1.3%	2.0%	6.7%	5.9%	8.3%	6.4%

Outcomes of anti-PD-(L)1 therapy with or without chemotherapy (chemo) for first-line (1L) treatment of advanced non-small cell lung cancer (NSCLC) with PD-L1 score $\geq 50\%$: FDA Pooled Analysis

Oladimeji Akinboro¹, Jonathon Vallejo¹, Erica Nakajima¹, Yi Ren¹, Pallavi Mishra-Kalyani¹, Erin Larkins¹, Paz Vellanki¹, Nicole Drezner¹, Mathieu Luckson¹, Shenghui Tang¹, Martha Donoghue^{1,2}, Richard Pazdur^{1,2}, Julia A. Beaver^{1,2}, Harpreet Singh^{1,2}

¹Center for Drug Evaluation and Research, U.S. Food and Drug Administration

²Oncology Center of Excellence, U.S. Food and Drug Administration

Oladimeji Akinboro, MD, MPH

Clinical trials of first-line Chemo-IO and IO regimens included in FDA pooled analysis



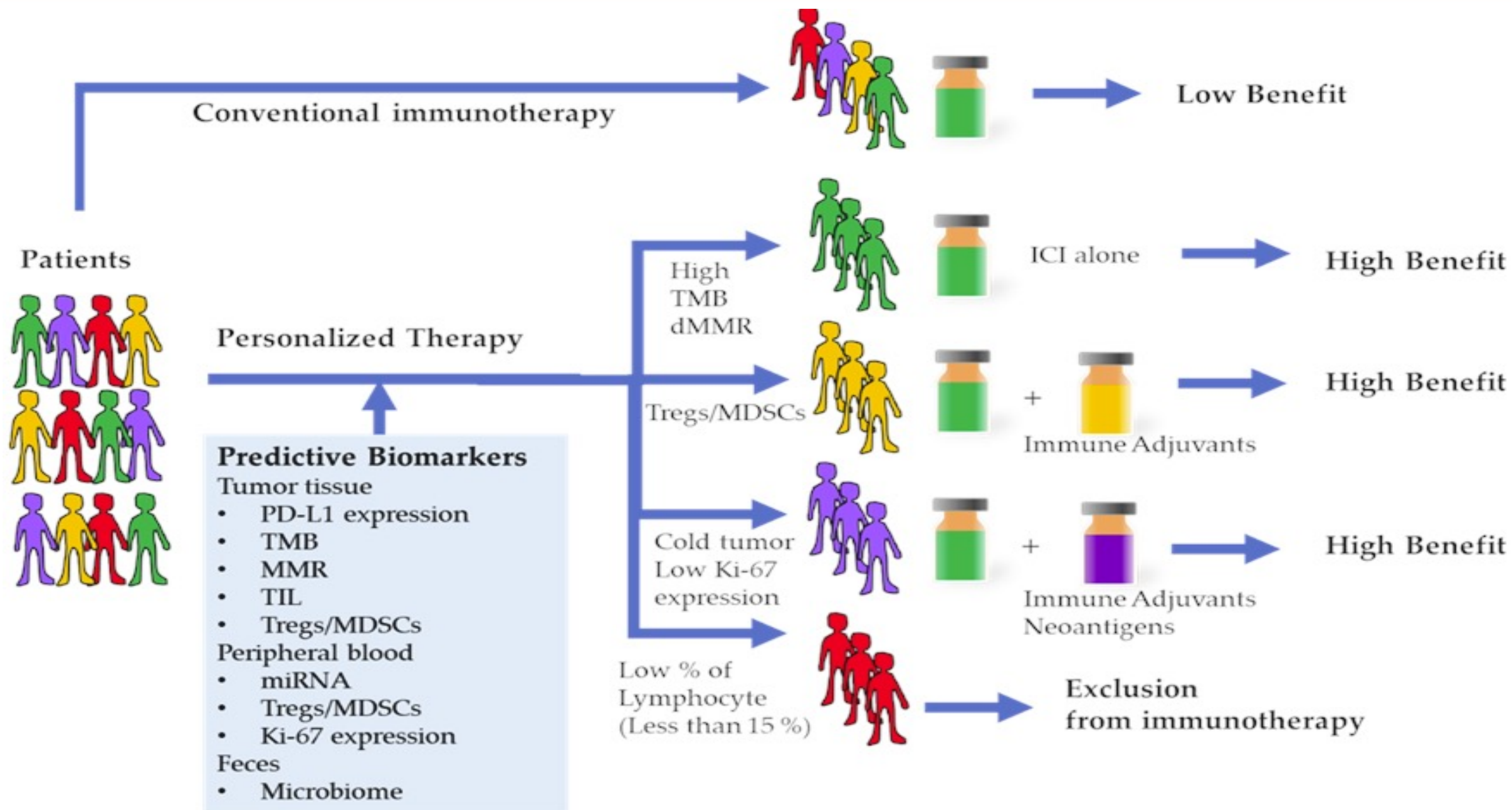
Chemo-IO Trials		IO-only Trials	
Trial	Investigational Regimen	Trial	Investigational Regimen
KEYNOTE-021*	Pembrolizumab + Chemo**	CheckMate 026	Nivolumab**
KEYNOTE-189	Pembrolizumab + Chemo**	KEYNOTE-024	Pembrolizumab**
KEYNOTE-407	Pembrolizumab + Chemo**	KEYNOTE-042	Pembrolizumab**
IMpower150	Atezolizumab + Bevacizumab + Chemo***	IMpower110	Atezolizumab**
IMpower130	Atezolizumab + Chemo**	CheckMate 227	Nivolumab + Ipilimumab**
CheckMate-9LA	Nivolumab + Ipilimumab + Chemo**	EMPOWER-Lung 1	Cemiplimab**
Abbreviations: Chemo-IO=platinum-based doublet chemotherapy immunotherapy; IO=immunotherapy. * Cohort G ** Control arms: Platinum-based doublet chemotherapy *** Control arm in IMpower150: Bevacizumab plus platinum-based doublet chemotherapy			

Exploratory OS, PFS, and ORR: NSCLC PD-L1 $\geq 50\%$



	Chemo-IO (N=455)	IO-alone (N=1,298)
OS		
Median, months (95% CI)	25.0 (19.0, NE)	20.9 (18.5, 23.1)
HR (95% CI)		0.82 (0.62, 1.08)
PFS		
Median, months (95% CI)	9.6 (8.4, 11.1)	7.1 (6.3, 8.3)
HR (95% CI)		0.69 (0.55, 0.87)
ORR		
% (95% CI)	61 (56, 66)	43 (41, 46)
Odds ratio		1.2 (1.1, 1.3)
Abbreviations: Chemo-IO=platinum-based doublet chemotherapy plus immunotherapy; CI=confidence interval; HR=hazards ratio; IO=immunotherapy; N=number; NSCLC=non-small-cell lung cancer; NE=not estimable; ORR=objective response rate; OS=overall survival; PD-L1=programmed death ligand-1; PFS=progression-free survival.		





STK11/LKB1, KRAS mutations and immune-related adverse events as predictors of response to immunotherapy in lung cancer

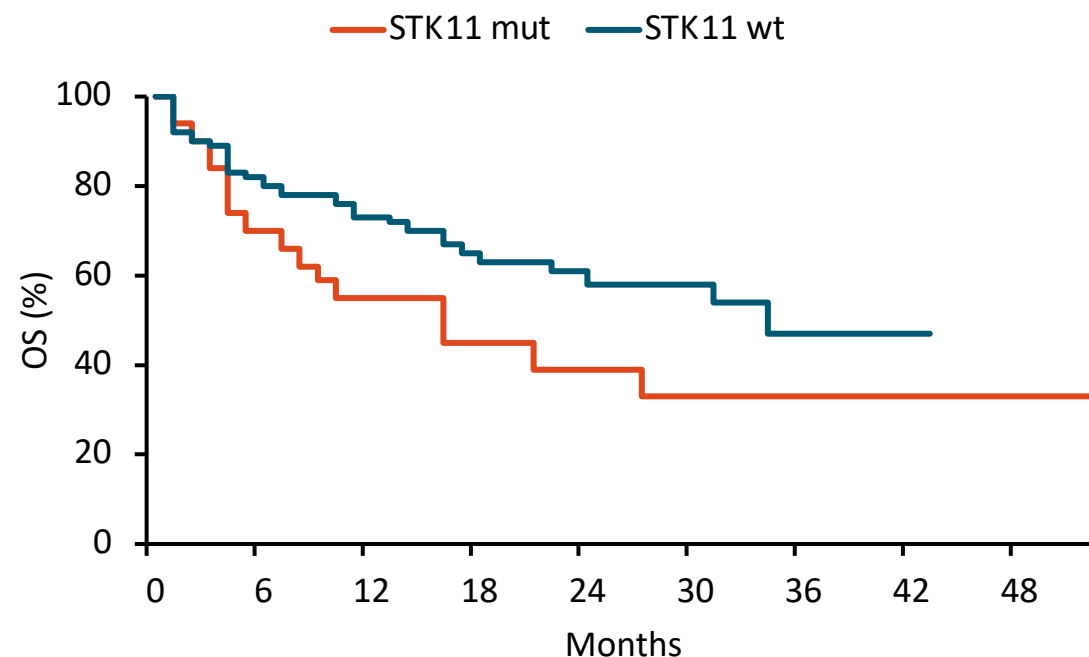
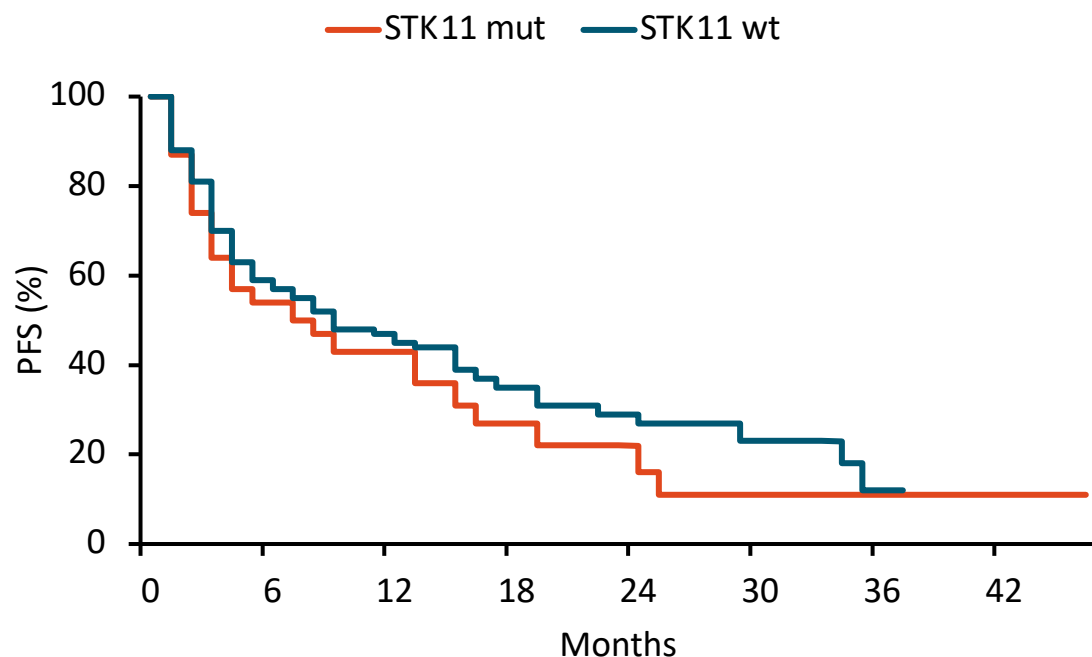
Luis E. Raez, MD¹; Richie Uba, PharmD^{2,3}; Aaron North, PharmD^{2,3};
Katerine Dumais, PharmD, MPH¹; Hermán W. Powery II, PharmD, BCOP¹;
Gelenis Domingo, MD¹; Brian Hunis, MD¹; Paola Izquierdo, ARNP¹;
Frank Gentile, PharmD, BCOP¹

¹Memorial Cancer Institute, Pembroke Pines, FL; ²Florida A&M University, Davie, FL;

³Memorial Regional Hospital, Hollywood, FL



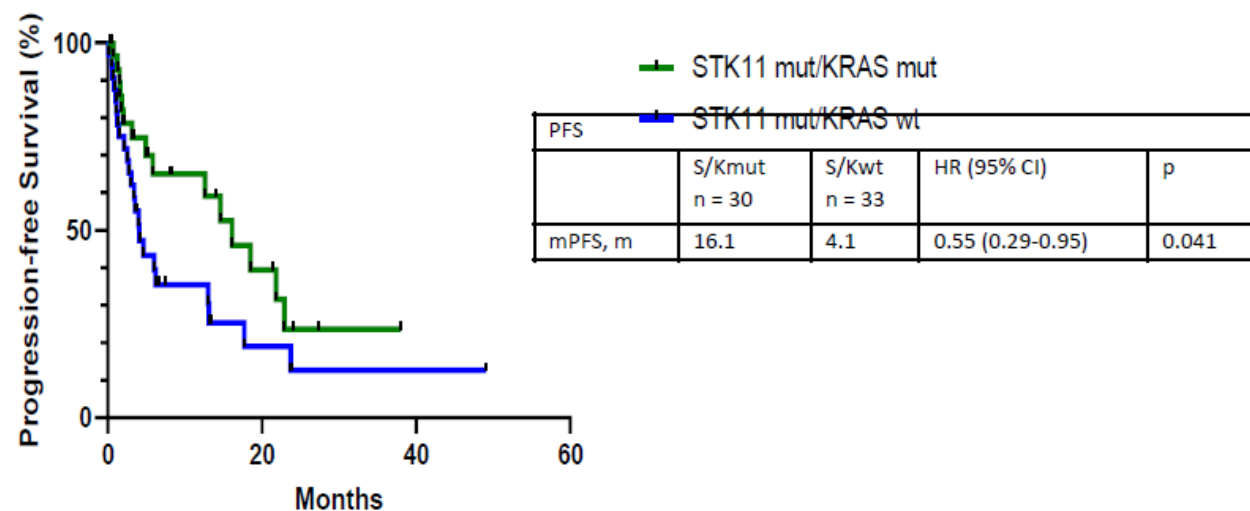
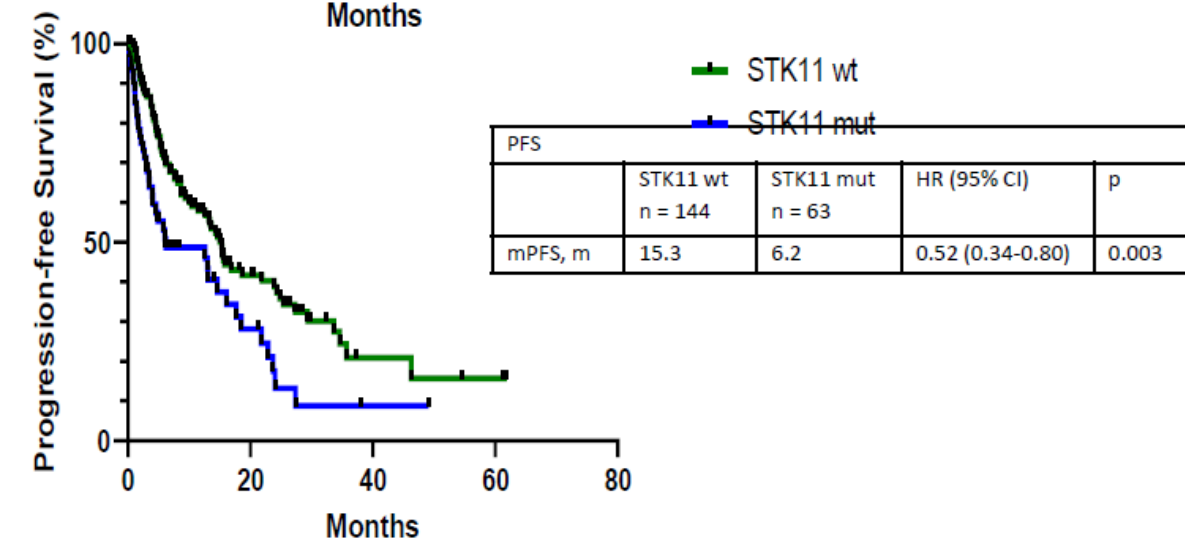
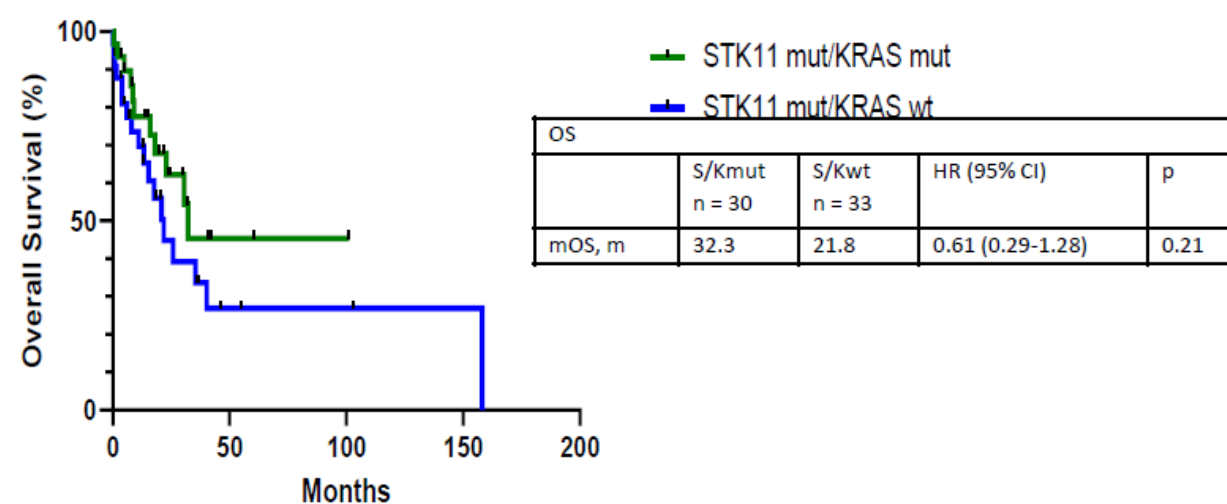
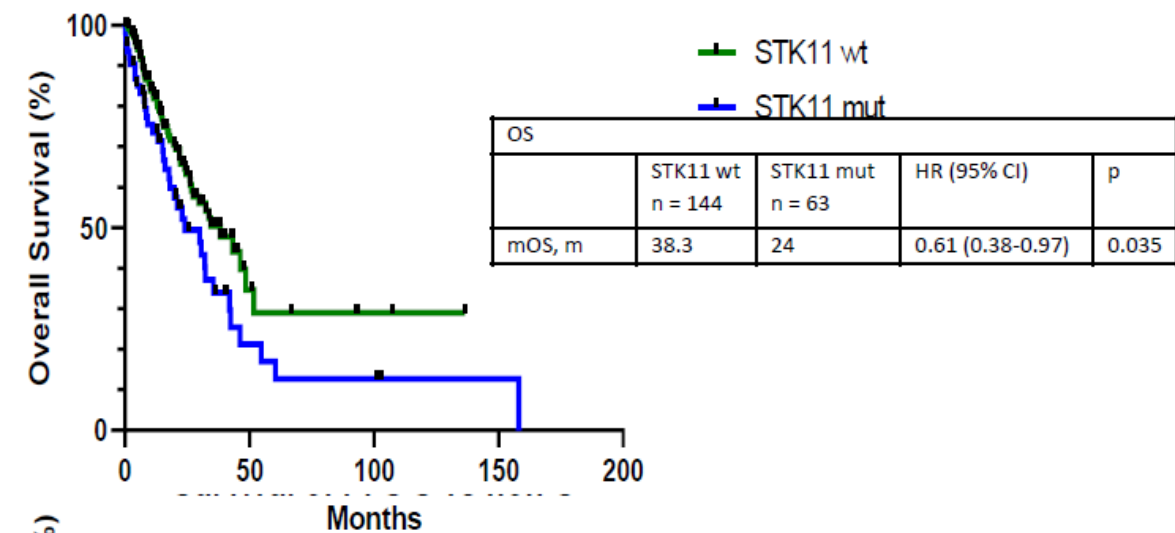
Results: PFS and OS by STK11 Status



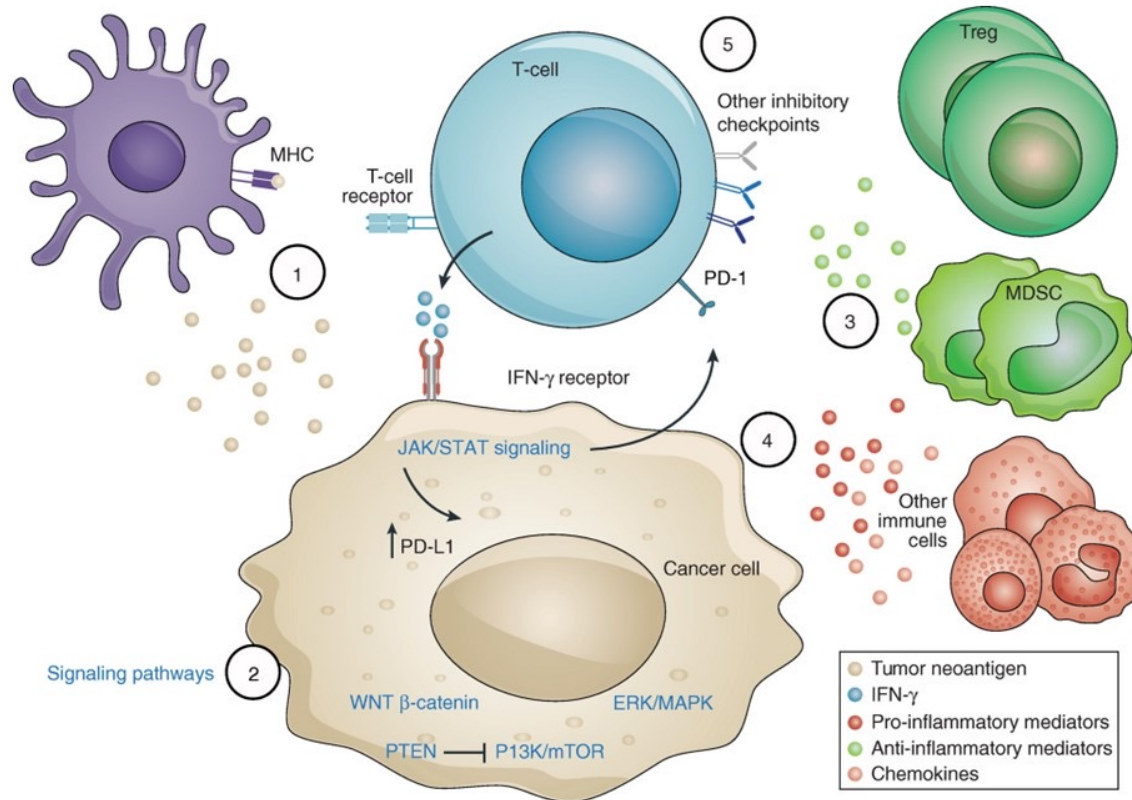
	STK11 wt n = 96	STK11 mut n = 31	HR (95% CI)	p
mPFS	6.3m	5.6m	1.35 (0.76-2.1)	0.35
12-m PFS	45%	43%	-	0.85

	STK11 wt n = 96	STK11 mut n = 31	HR (95% CI)	p
mOS	12.1m	8.6m	1.7 (1.0-3.6)	0.03
12-m OS	73%	55%	-	0.03

Favorable survival with co-mutation of STK11 and KRAS



Mechanisms of resistance to checkpoint inhibitors



Ricciuti et al.

Paulus et al.
Zhao et al.

Hu-Lieskovan et al., Future Oncol 2021

Immunotherapy resistance in NSCLC

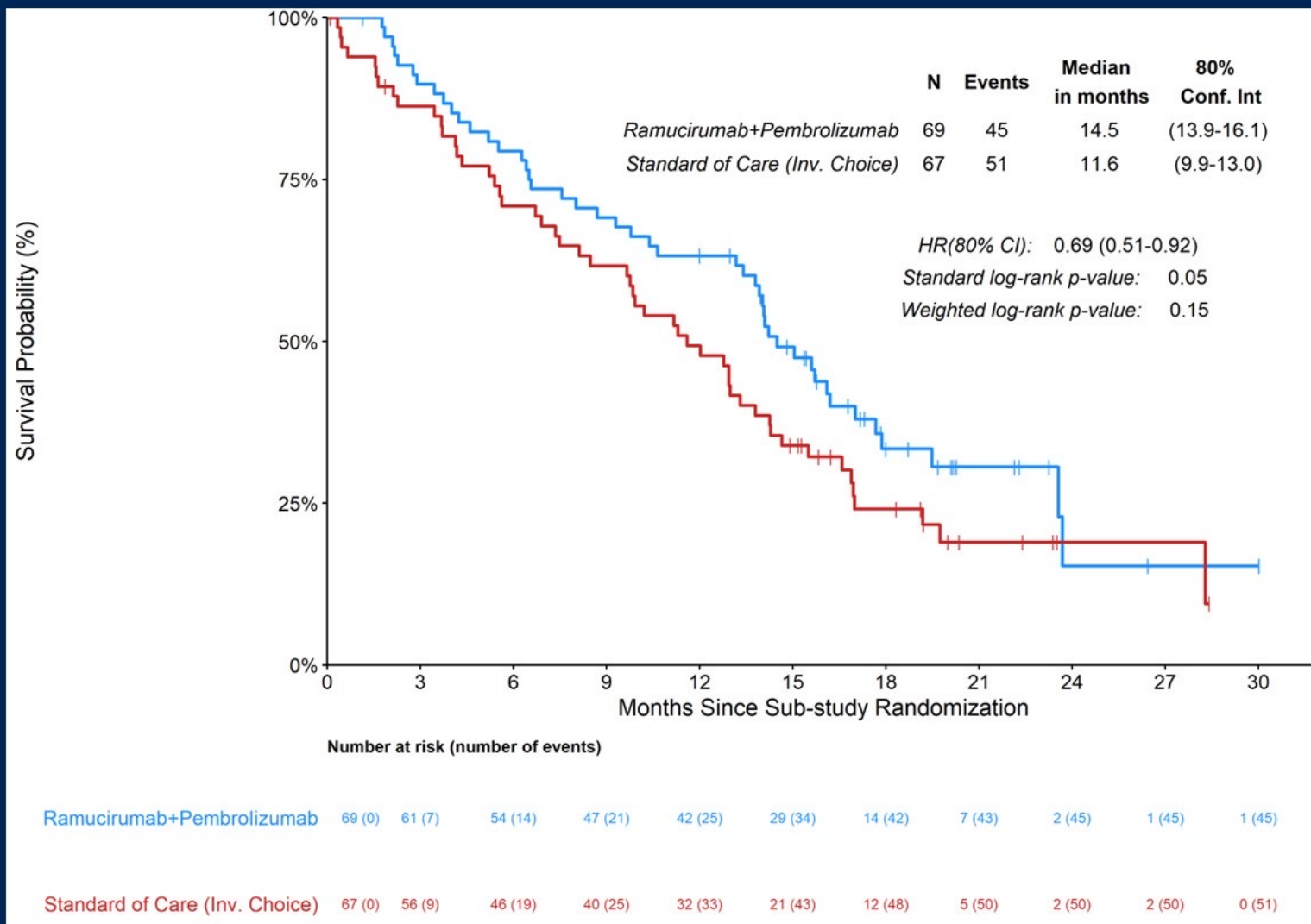
- Deacetylase Inhibitors (etinostat, vorinostat)
- Vaccines (Heat Shock Protein gp96)
- STK11/LKB1 and KEAP
- Cytokines (IL-10, IL-15)
- Adenosine pathway
- Combination checkpoints (IDO, TIM, LAG3)
- Adoptive T cell therapies (TILs, TILs + anti PD(L)-1, TCRs)
- B-catenin pathway

Overall survival from a phase II randomized study of ramucirumab plus pembrolizumab versus standard of care for advanced non-small cell lung cancer previously treated with immunotherapy—Lung-MAP non-matched sub-study S1800A

Karen L. Reckamp, M.D.¹, Mary W. Redman, PhD², Konstantin H. Dragnev, M.D.³, Liza Villaruz, M.D.⁴, Bryan Faller, MD⁵; Tareq Al Baghdadi, MD⁶, Susan Hines, MD⁷, Lu Qian, M.S.², Katherine Minichiello, M.S.², David R. Gandara, M.D.⁸, Karen Kelly, MD⁸, Roy S. Herbst, M.D., Ph.D.⁹

¹Cedars-Sinai Medical Center, Los Angeles, CA; ²SWOG Statistics and Data Management Center & Fred Hutchinson Cancer Research Center, Seattle, WA; ³Dartmouth-Hitchcock Norris Cotton Cancer Center, Lebanon, NH/Alliance for Clinical Trials in Cancer; ⁴University of Pittsburgh Medical Center (UPMC) Hillman Cancer Center; ⁵Missouri Baptist Medical Center, St. Louis, MO/Heartland NCORP; ⁶IHA Hematology Oncology Consultants-Ann Arbor/Michigan CRC NCORP; ⁷Novant Health Cancer Institute - Mount Airy/Southeast Clinical Oncology Research Consortium NCORP); ⁸UC Davis Comprehensive Cancer Center, Sacramento, CA; ⁹Yale University, New Haven, CT

Overall survival

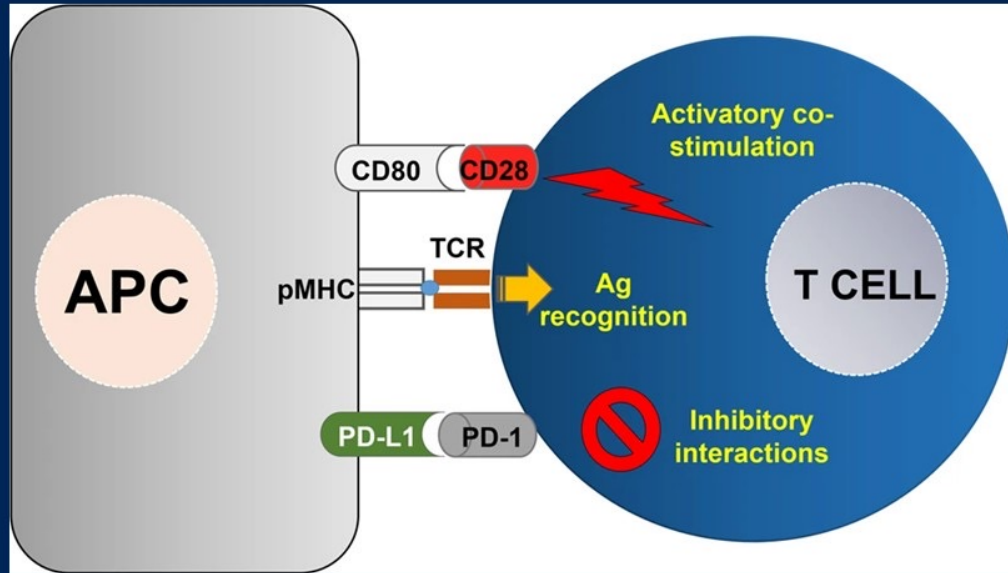


- Median OS for RP 14.5 months v. SOC 11.6 months
- HR= 0.69; SLR p-value 0.05

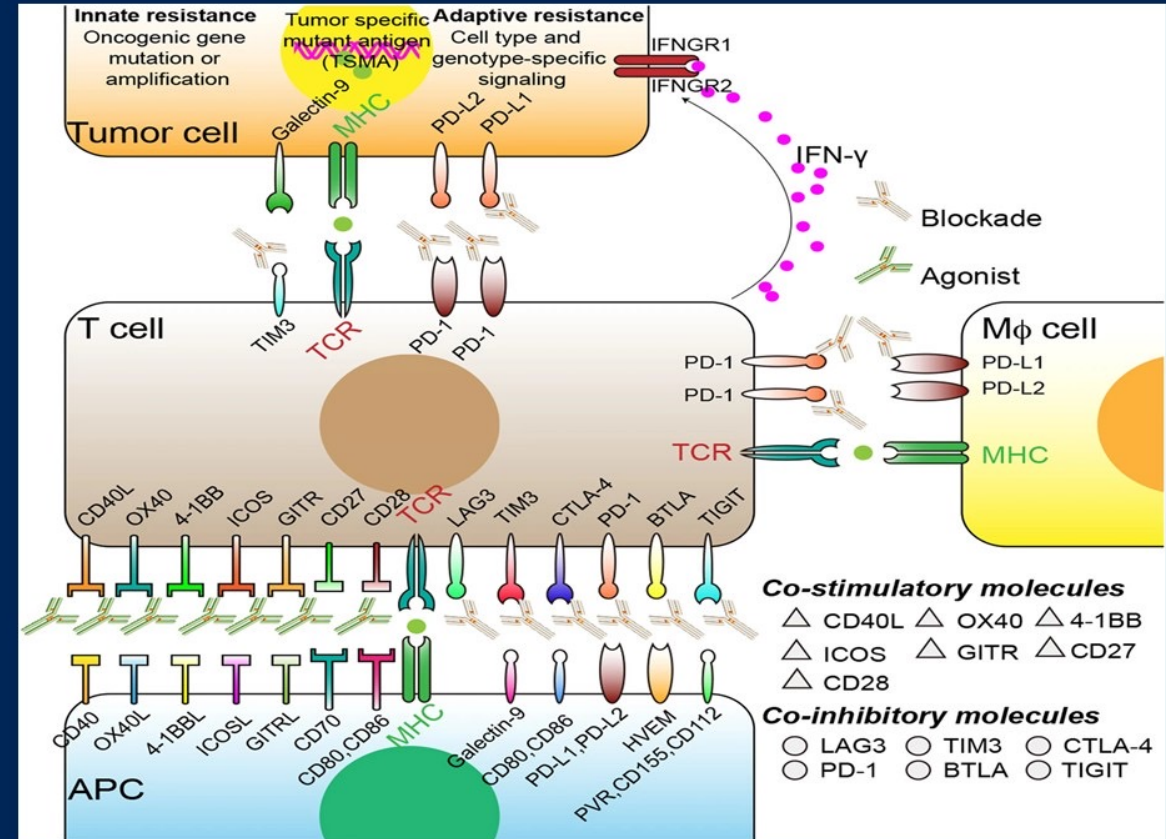
Standard of care therapy received:

- Docetaxel + Ramucirumab (n = 45)
- Docetaxel (n = 3)
- Gemcitabine (n = 12)
- Pemetrexed (n = 1)
- No treatment (n = 6)

Co-Stimulatory and Co-Inhibitory Interactions



Escors, et al Signal Transduct Target Ther 2018



Li Cellular and Molecular Immunology 2018



Thanks

