Immunotherapy for Metastatic NSCLC and What after IO Failure?

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First Line Lung Cancer Therapy with no actionable genes

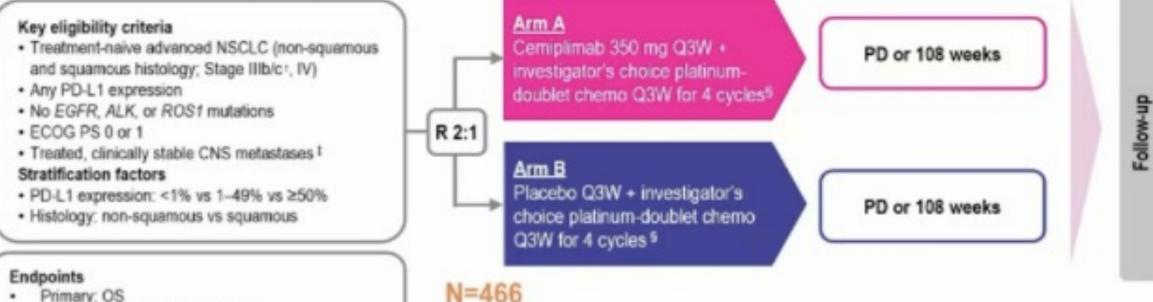
NSQCC:

 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]
 Durvalumab +Tremelimumab/Chemotherapy 	[Poseidon 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]



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 ≥50% (EMPOWER-Lung 1 Study1)



- Key secondary: PFS and ORR .
- Additional secondary: DOR, BOR, safety, and PRO ٠

N=466

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



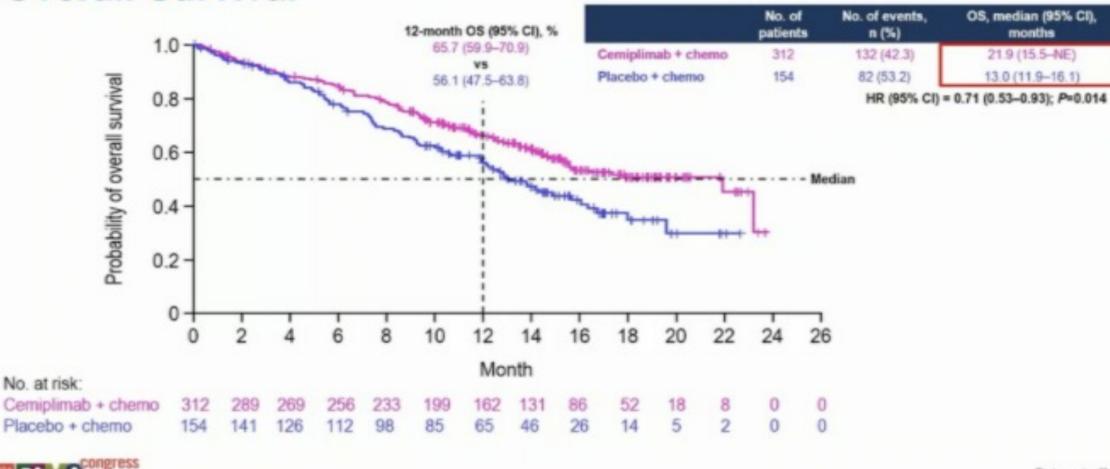
"Patient not a candidate for definitive chemoradiation. I Patient must have neurologically returned to baseline (except for residual signs or symptoms related to the CNS treatment). IFor patients with nonsquamous NSCLC, pemetrexed is mandatory as maintenance therapy for those patients initially assigned to receive a pemetrexed-containing regimen. ALK anaplastic lymphoma kinase gene; BOR, best overall response: chemo, chemotherapy; CNS, central nervous system; DCR, duration of response; ECCG 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.

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



Overall Survival

ESVO

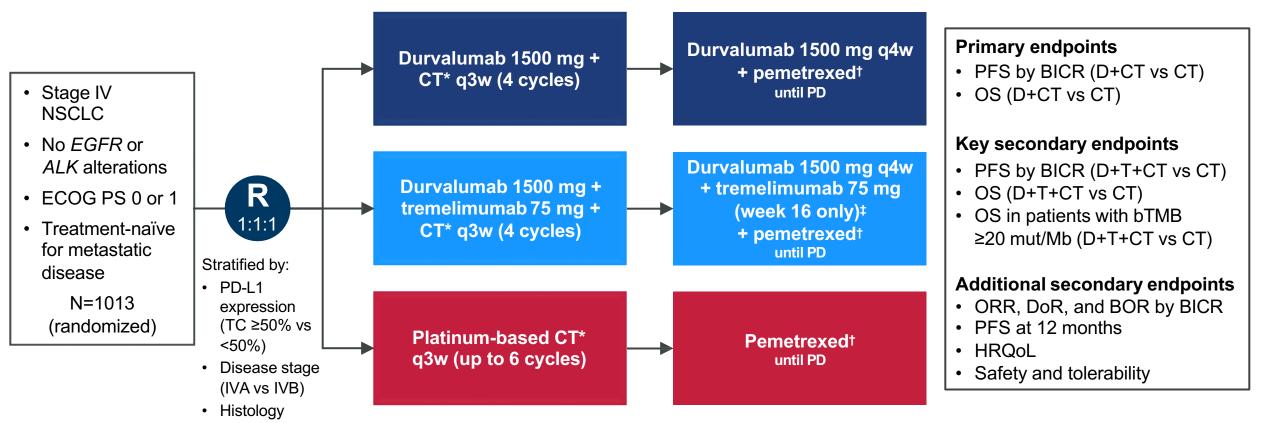


Chemo, chemotherapy; CI, confidence interval; HR, hazard ratio; OS, overall survival.

Data cut-off date: 14 June 2021

POSEIDON Study Design

Phase 3, global, randomized, open-label, multicenter study



*CT options: gemcitabine + carboplatin/cisplatin (squamous), pemetrexed + carboplatin/cisplatin (non-squamous), or nab-paclitaxel + carboplatin (either histology); *Patients with non-squamous histology who initially received pemetrexed during first-line treatment only (if eligible); *Patients received an additional dose of tremelimumab post CT (5th dose)

 IASLC
 2021 World Conference on Lung Cancer

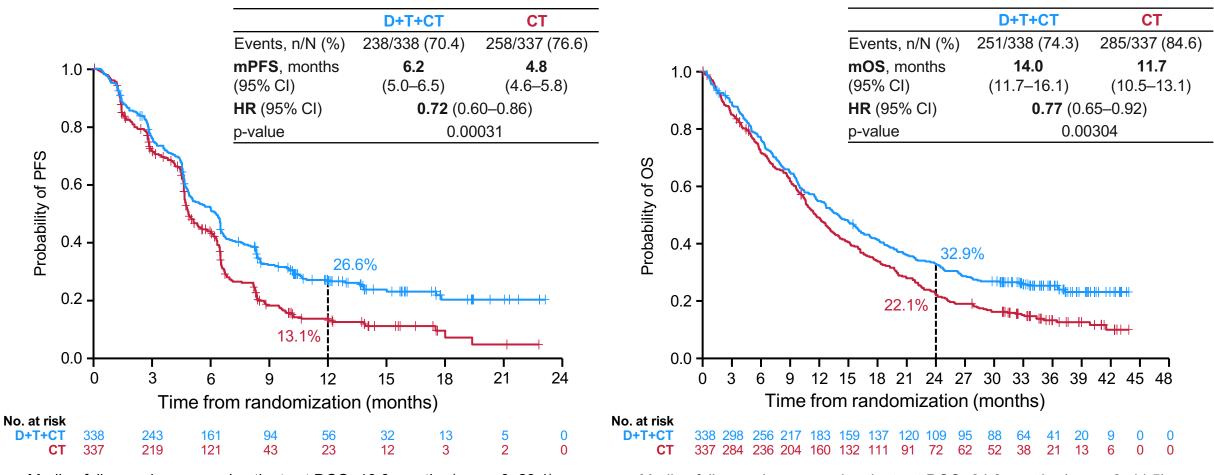
 SEPTEMBER 8 - 14, 2021 I WORLDWIDE VIRTUAL EVENT

BICR, blinded independent central review; BOR, best objective response; bTMB, blood tumor mutational burden; D, durvalumab; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; HRQoL, health-related quality of life; Mb, megabase; mut, mutations; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PS, performance status; q3w, every 3 weeks; q4w, every 4 weeks; T, tremelimumab; TC, tumor cell

Durvalumab + Tremelimumab + CT vs CT: PFS and OS

PFS

OS



• Median follow-up in censored patients at DCO: 10.3 months (range 0–23.1)

• Median follow-up in censored patients at DCO: 34.9 months (range 0–44.5)

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DCO PFS FA: Jul 24, 2019; DCO OS FA: Mar 12, 2021

Conclusions

- In POSEIDON, PFS was significantly improved with first-line durvalumab + CT vs CT in patients with mNSCLC, with a positive trend for OS that did not reach statistical significance
 - PFS HR 0.74 (95% CI 0.62–0.89; p=0.00093)
 - OS HR 0.86 (95% CI 0.72–1.02; p=0.07581)
- First-line durvalumab + tremelimumab + CT demonstrated statistically significant and clinically meaningful improvements in both PFS and OS vs CT in patients with mNSCLC
 - PFS HR 0.72 (95% CI 0.60–0.86; p=0.00031)
 - OS HR 0.77 (95% CI 0.65–0.92; p=0.00304)
 - OS and PFS benefit were more prominent among patients with non-squamous (than squamous) histology
- Overall, the safety profile was similar across all three arms, with no new safety signals identified. Adding tremelimumab to durvalumab + CT did not lead to a meaningful increase in treatment discontinuation
 - TRAE discontinuation rate 15.5% and 14.1% with D+T+CT and D+CT, respectively
- Durvalumab + tremelimumab + CT represents a potential new first-line treatment option for mNSCLC

First Line Lung Cancer Therapy with no actionable genes

Chemotherapy/IO Combinations

- Carboplatin/Pemetrexed/Pembrolizumab
- Carboplatin/Paclitaxel/Bevacizumab/Atezolizumab
- Carboplatin/Paclitaxel or nab-paclitaxel/Pembrolizumab
- Cemiplimab/Chemotherapy
- Durvalumab + Tremelimumab/Chemotherapy

IO single Agent (PDL1>50%)

- Pembrolizumab
- Atezolizumab
- Cemiplimab

Immunotherapy combinations:

- Ipilimumab and Nivolumab
- Ipilimumab and Nivolumab plus 2 cycles of chemotherapy

[Keynote 189] [IMPOWER 150] [Keynote 407] [Empower Lung-3] [Poseidon 3]

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

[Checkmate 227] [Checkmate 9LA]



ORR slightly in favor of combination chemo+IO

	KN 24 (TPS > 50%)	KN 42 (TPS > 50%)	IMPW 10 TC3/IC3 (>50% and	KN 407 (TPS > 50%)	KN 189 (TPS > 50%)
ORR	45%	39.5%	>10%) 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 more prevalent with Chemo/IO

	KN-42		KN-24		KN-189		KN-407	
	Pembro	СТ	Pembro	СТ	Pembro + CT	СТ	Pembro + CT	СТ
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%

Reck M, NEJM 2016, Mok T et al, Lancet 2019, Paz Ares, NEJM 2018, Ghandi, NEJM 2018



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2022 ASCO

ANNLIAI MEETIN



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 ≥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

PRESENTED BY: Oladimeji Akinboro, MD, MPH

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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

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*** Control arm in IMpower150: Bevacizumab plus platinum-based doublet chemotherapy



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Exploratory OS, PFS, and ORR: NSCLC PD-L1 ≥50%

	Chemo-IO (<i>N</i> =455)		IO-alone (<i>N</i> =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 p cancer; NE=not estimable; ORR=objective response rate; OS=over					



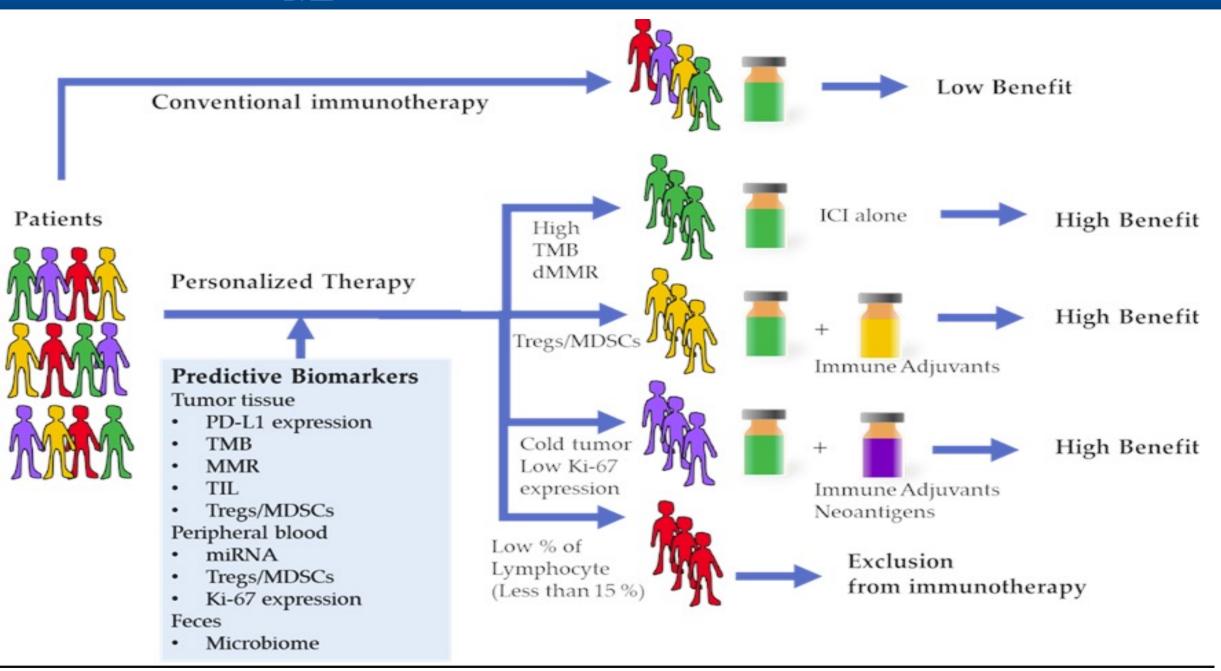


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FDA

MEMORIAL HEALTHCARE SYSTEM





Co-mutational status (STK11, KEAP, TP53) and PD-L1 expression in *KRAS* mutant non-small cell lung cancer (NSCLC)

- Molecular profiles of 27748 NSCLC tumors were tested with nextgeneration sequencing (Caris Life Sciences, Phoenix, AZ) and classified by KRAS mt.
- PD-L1 IHC (22C3) was reported as TPS.
- Co-occurring genomic alterations, tumor mutational burden (TMB) and PD-L1 IHC (22C3, TPS score) were analyzed by KRAS mt type.
- Real-world post-immunotherapy (IO) overall survival (OS) was obtained from insurance claims and calculated from start of an immune check-point inhibitor (with or without chemotherapy) to the last day of follow-up.
- Prognosis was evaluated by rwOS calculated from tissue collection to last contact
- Molecular groups including K-only, KP, KL, KK and KKL were defined based on distinct mutational status of four genes as described below.

	Gene mutations						
Molecular Groups	KRAS	KRAS STK11		KEAP1			
K-only	MT	WT	WT	WT			
КР	MT	WT	MT	WT			
KL	MT	MT	WT	WT			
КК	MT	WT	WT	MT			
KKL	MT	MT	WT	MT			

Table 1: Molecular sub-groups

End point: Median rwOS (Tissue collection to Last Contact)						
	mrwOS (m) 95% CI					
K-only 23.1 20.9-25.3						
KP	KP 17.7 16.2-19.35					
KL	KL 19.1 16.6-21.2					
КК	9.7	7.4-14.2				
KKL	8.0	6.6-9.0				

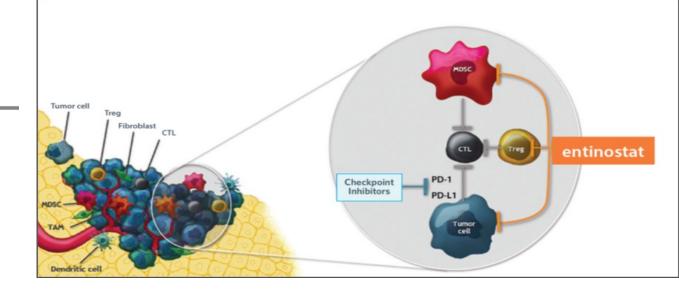
We report a large real-world dataset evaluating outcomes with checkpoint inhibitors in NSCLCs with *KRAS* and specific co-mts. Across the subgroups, KKL (KRAS mt/STK-11 mt/KEAP-1 mt) demonstrated universally poor outcomes in all *KRAS* subtypes; irrespective of PD-L1 expression.



CLINICAL CANCER RESEARCH | CLINICAL TRIALS: IMMUNOTHERAPY

Entinostat plus Pembrolizumab in Patients with Metastatic NSCLC Previously Treated with Anti-PD-(L)1 Therapy

Matthew D. Hellmann¹, Pasi A. Jänne², Mateusz Opyrchal³, Navid Hafez⁴, Luis E. Raez⁵, Dmitry I. Gabrilovich⁶, Fang Wang⁶, Jane B. Trepel⁷, Min-Jung Lee⁷, Akira Yuno⁷, Sunmin Lee⁷, Susan Brouwer⁸, Serap Sankoh⁸, Lei Wang⁸, David Tamang⁸, Emmett V. Schmidt⁹, Michael L. Meyers⁸, Suresh S. Ramalingam¹⁰, Elaine Shum¹¹, and Peter Ordentlich⁸

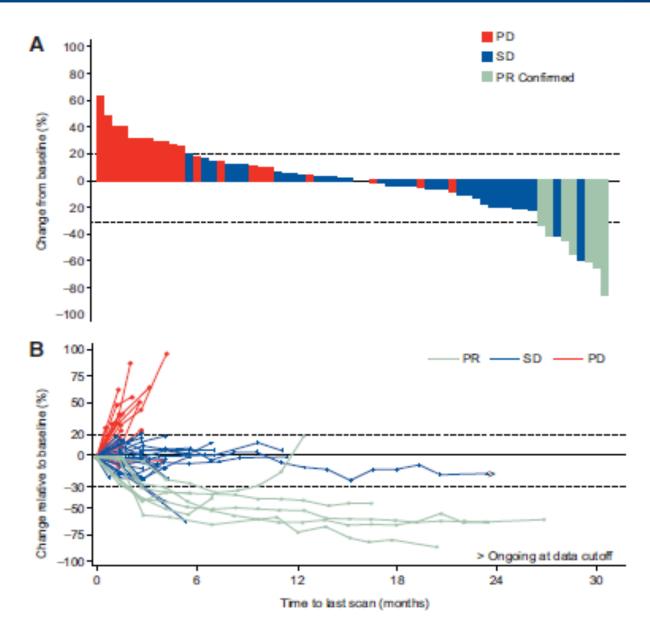


- Entinostat (ENT) is an oral class I-selective histone deacetylase inhibitor
- ENT leads to downregulation of immunosuppressive cell types in the tumor microenvironment
- Synergy with anti-PD1 inhibition in preclinical models
- Promising activity shown in combination with pembrolizumab in patients with melanoma and lung cancer

Hellmann M (Raez L) Clin Can Research 2021 Feb 15;27(4):1019-1028.

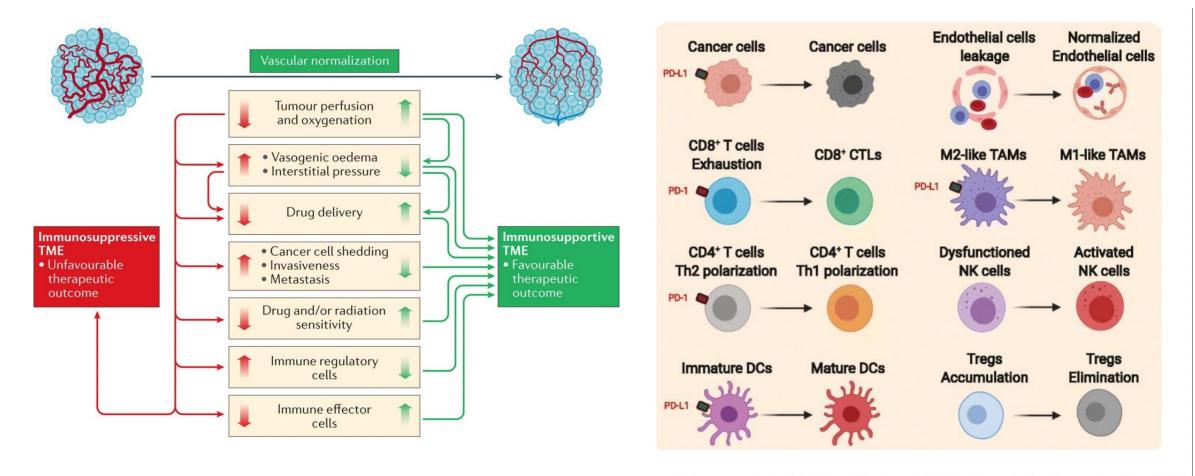


- Median duration of response was 5.3 months
- An additional 50% of patients achieved disease stabilization
- Median progression-free survival = 2.8 months (95% CI: 2.1-4.1)



Hellmann M (Raez L) Clin Can Research 2021 Feb 15;27(4):1019-1028.

Targeting angiogenesis to overcome ICI resistance



Fukumura et al., Nat Rev Clin Oncol 2018; Chen et al., Biomarker Res 2021



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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



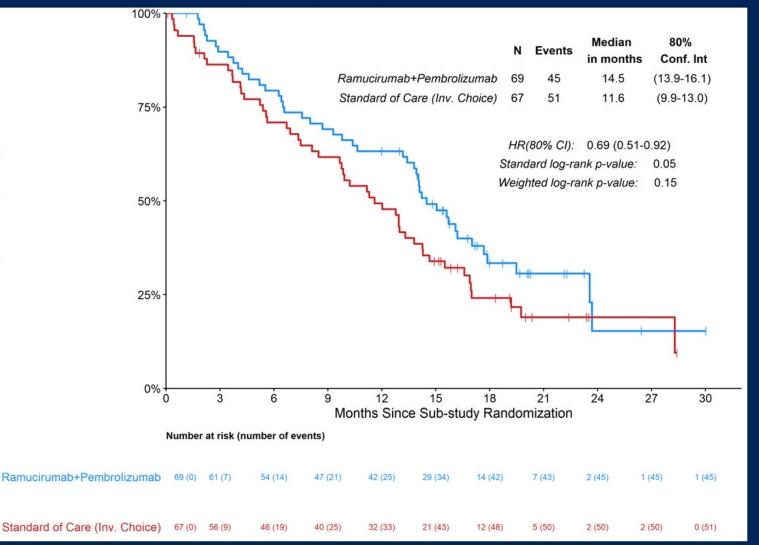
PRESENTED BY: Karen L. Reckamp, MD, MS







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)



PRESENTED BY: Karen L. R

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Karen L. Reckamp, MD, MS

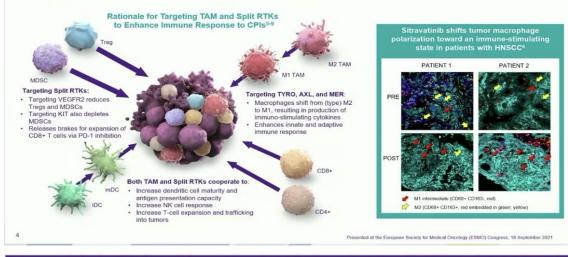
ALUNG-MAP





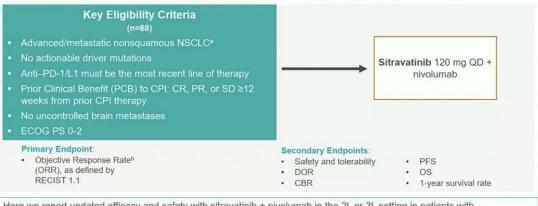
MRTX-500: Sitravatinib + Nivolumab in Nonsquamous NSCLC After CPI Therapy

Sitravatinib Is a TKI That Targets TAM Receptors (TYRO3, AXL, MERTK) and Split-Family Receptors (eg, VEGFR2)



MRTX-500: Sitravatinib + Nivolumab in Nonsquamous NSCLC After CPI Therapy

MRTX-500: Phase 2, Open-Label Study of Sitravatinib + Nivolumab in Patients With Nonsquamous NSCLC With Prior Clinical Benefit From Checkpoint Inhibitor Therapy

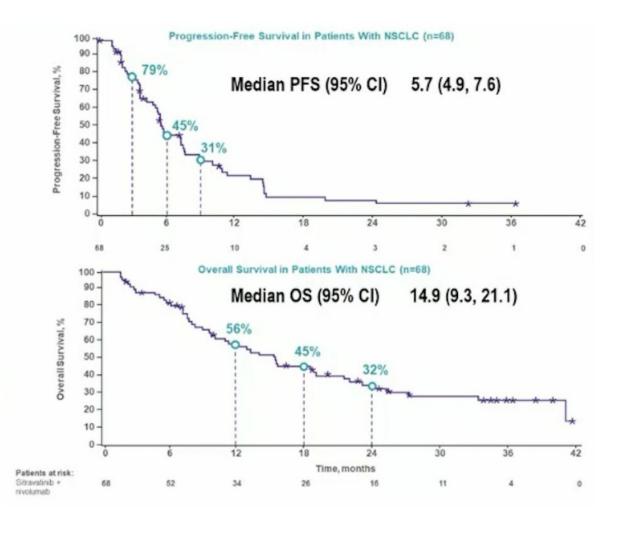


Here we report updated efficacy and safety with sitravatinib + nivolumab in the 2L or 3L setting in patients with nonsquamous NSCLC who have experienced clinical benefit on a prior CPI and subsequent disease progression

Data as of 1 June 2021

*Additional cohorts included a CPI-experienced cohort that did not receive prior clinical benefit from CPI therapy (radiographic progression of disease s12 weeks after initiation of treatment with CPI) and a CPI-naive cohort in patients that were previously treated with platinum-based charmotherapy. ¹Objective response rate based on investigator assessment. Costing: sitzavatinib the base formulation, involumab, 240 mg Q2W or 480 mg Q4W. Treatment discontinuation could be due to fut is not limited to j disease progressions, globah hadit heteroration, Exp. protocol violation, to to follow-up, refusai of thirther treatment, study fermatance or death.

Presented at the European Society for Medical Oncology (ESMO) Congress, 18 September 2021



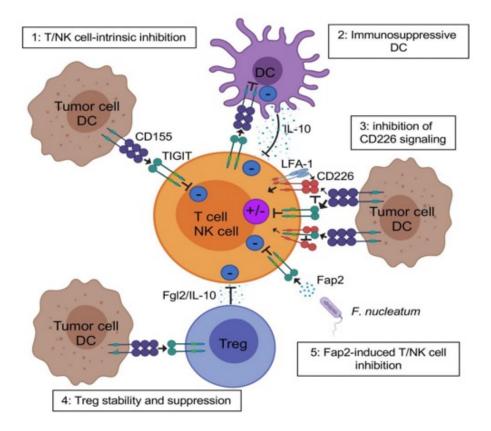
Ticiana Leal. ESMO 2021.



TIGIT

- TIGIT/CD155:
- Directly inhibits T cells
- Triggers IL-10 production, IL-12 decrease from APCs
 = Indirectly inhibits T cells
- Enhances immunosuppressive **Treg** function
- Interaction with **gut microbiome**: Binds with Fusobacterium nucleatum
 - = Inhibitory signaling

Mechanisms of TIGIT inhibition of T cells in TME

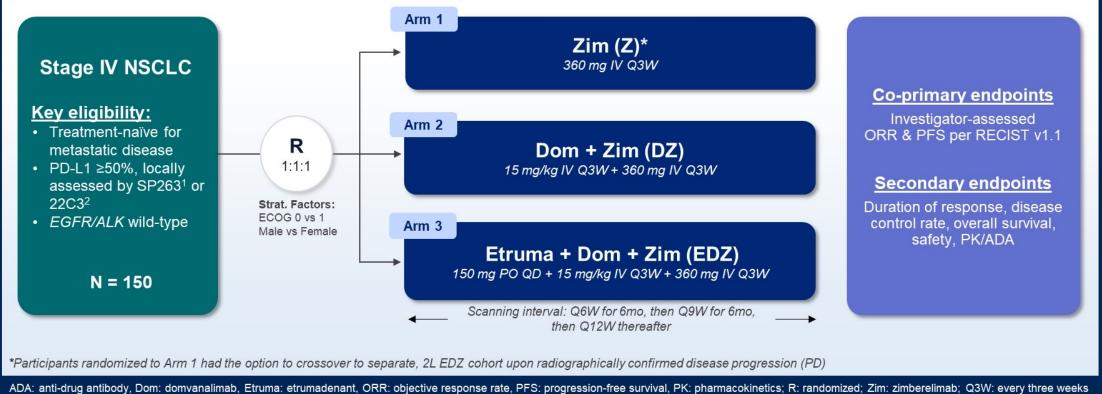


Joe-Marc Chauvin, and Hassane M Zarour J Immunother Cancer 2020;8:e000957

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ARC-7: Randomized, Open-label, Phase 2 Study in First-Line, Metastatic, PD-L1-High NSCLC

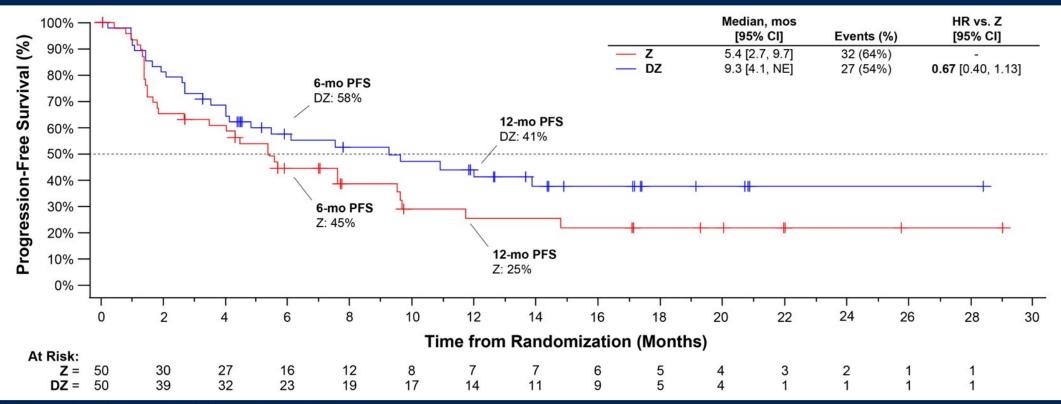


¹Ventana SP263 assay; ²PharmDx 22C3 assay

2023 ASCO ANNUAL MEETING #ASCO23 Melissa Johnson, MD, Director Lung Cancer Research PRESENTED BY: Sarah Cannon Research Institute at Tennessee Oncology Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org. @MLJohnsonMD2



Progression-Free Survival (mITT) Zim Monotherapy vs. Dom + Zim Doublet



CI: confidence interval; HR: hazard ratio; Mos: months; NE: not evaluable

Addition of dom to zim resulted in 33% reduction in risk of progression or death as compared to zim alone



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8

Conclusions

- In an updated analysis of ARC-7, with longer median follow-up of 18.5 months, domcontaining arms continued to demonstrate clinically meaningful improvement in ORR and PFS as compared to zim monotherapy. Specifically, TIGIT combinations resulted in:
 - Greater ORR, Δ: +10 to 14%, compared to zim alone
 - Approximately 30% reduction in risk of progression or death compared to zim alone
- Clinical activity and safety of zim performed as expected with agents in the anti-PD-1 class
- Dom + zim combinations with or without etruma were generally well-tolerated with similar, manageable safety profiles across all arms
 - Rates of infusion-related reactions were low across dom-containing arms (4 12%), as intended with the Fc-silent design of dom
- The data presented support the ongoing phase 3 studies with domvanalimab: ARC-10 (NCT04736173), STAR-121 (NCT05502237), STAR-221 (NCT05568095) and PACIFIC-8 (NCT05211895)



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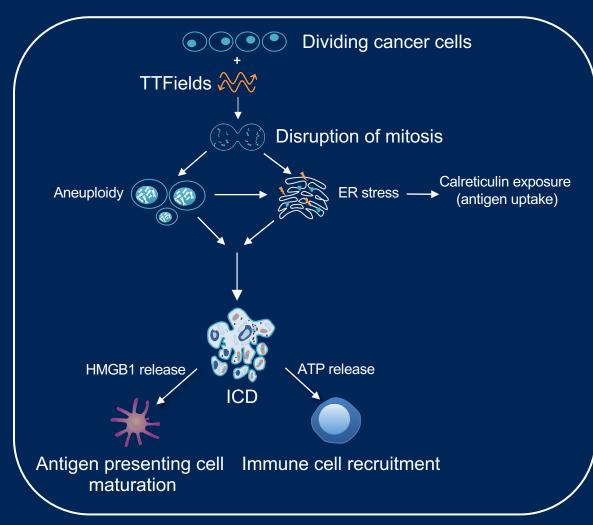
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Current trials in Stage IV NSCLC targeting TIGIT

	VELOCITY-Lung	STAR-121	ARC-7	KEYVIBE-007	KEYVIBE-003	SKYSCRAPER-01	CITYSCAPE
	NCT05633667	NCT05502237	NCT04262856	<u>NCT05226598</u>	<u>NCT04738487</u>	<u>NCT04294810</u>	NCT03563716
Anti-TIGIT	Domvanalimab (DOM)	Domvanalimab (DOM)	Domvanalimab	Vibostolimab*	Vibostolimab*	Tiragolumab	Tiragolumab
Immunotherapy	Zimberelimab (ZIM)	Zimberelimab (ZIM)	Zimberelimab (ZIM)	Pembrolizumab*	Pembrolizumab*	Atezolizumab	Atezolizumab
Additional Tx	Sacituzumab <u>govitecan</u> (SG)/ <u>Etrumadenant</u> (ETRUMA)	Chemotherapy	Etrumadenant (ETRUMA)	Chemotherapy	n/a	n/a	n/a
Control Arm	SOC	Pembrolizumab + CT	Zimberelimab	Pembrolizumab + CT	Pembrolizumab	Placebo + Atezolizumab	Placebo + Atezolizumab
Line of Therapy	1 L	1L	1L	1L	1L	1L	1L
Histology	NSQ	NSQ/SQ	NSQ/SQ	NSQ/SQ	NSQ/SQ	NSQ/SQ	NSQ/SQ
Patient Population	Non-AGA	No EGFR/ALK	PD-L1 >50% No EGFR/ALK	Non-AGA	No EGFR/ALK/ROS1 PD-L1 <u>></u> 1%	Non-AGA PD-L1 <u>></u> 50%	CT Naïve
Start Date	Not Yet Recruiting	October 2022	May 2020	March 2022	April 2021	March 2020	August 2018
Estimated Completion Date	January 2027	December 2027	February 2024	September 2025	April 2026	February 2025	June 2019
Primary Outcome	ORR	PFS/OS	ORR/PFS	PFS/OS	OS	PFS/OS	ORR: 31.3% PFS: 5.4 months
Trial Type	Phase II	Phase III	Phase II	Phase III	Phase III	Phase III	Phase II

*Coformulation (MK-7684A)

Tumor Treating Fields (TTFields) Mechanism of Action



- TTFields are electric fields that exert physical forces on electrically charged components in dividing cancer cells, leading to an antimitotic effect^{1,2}
- Downstream effects include cell stressinduced immunogenic cell death (ICD), triggering a systemic anti-tumor immune response^{3,4}

ATP, adenosine triphosphate; ER, endoplasmic reticulum; HMGB1, high mobility group box 1 protein; ICD, immunogenic cell death; TTFields, Tumor Treating Fields. 1. Mun EJ et al. Clin Cancer Res. 2018;24(2):266–275; 2. Giladi M et al. Sci Rep. 2015;5:18046; 3. Voloshin T et al. Cancer Immunol Immunother. 2020;69(7):1191–1204; 4. Barsheshet Y et al. Int J Mol Sci. 2022;23(22):14073. Figure adapted from: Shteingauz A et al. Cell Death Dis. 2018;9(11):1074.





PRESENTED BY: Ticiana Leal, MD, Winship Cancer Institute - Emory University

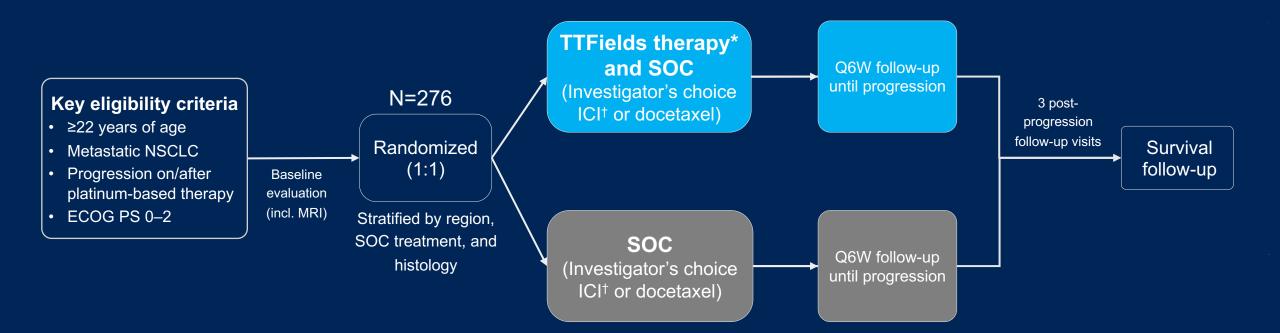
Scan for presentation slides



CLINICAL ONCOLOGY

LUNAR Phase 3 Study Design

Objective: To evaluate safety and efficacy of TTFields therapy with standard of care (SOC) compared to SOC alone in metastatic NSCLC progressing on or after platinum-based therapy



Data cut-off: November 26, 2022 **Study sites:** 124 in 17 countries (North America, Europe, Asia)

*150 kHz; ≥18 h/day; [†]pembrolizumab, nivolumab, or atezolizumab.

ECOG PS, Eastern Cooperative Oncology Group performance status; ICI, immune checkpoint inhibitor; MRI, magnetic resonance imaging; NSCLC, non-small cell lung cancer; Q6W, every 6 weeks; SOC, standard of care; TTFields, Tumor Treating Fields.





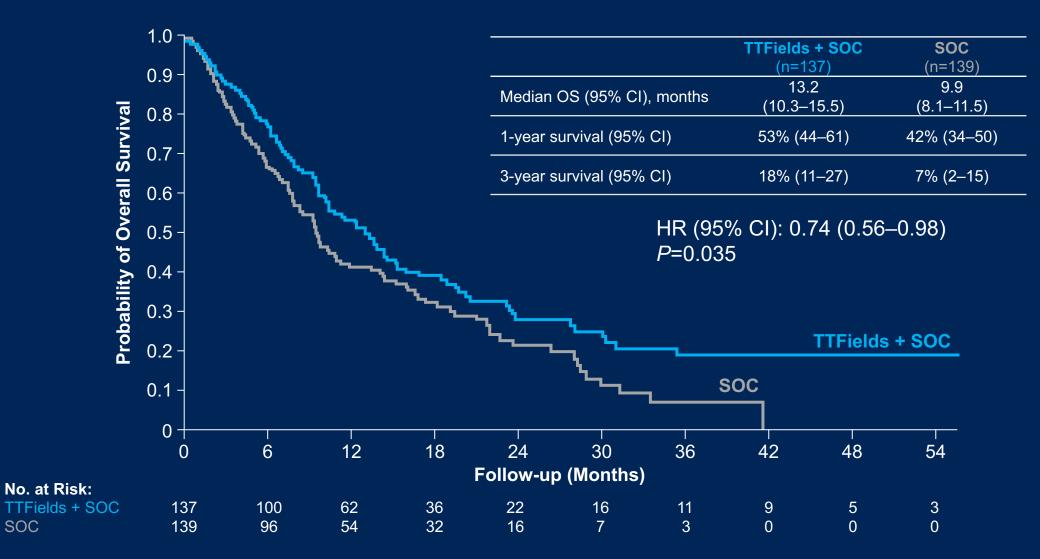
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Overall Survival in the ITT Population



CI, confidence interval; HR, hazard ratio; ITT, intent-to-treat; OS, overall survival; SOC, standard of care; TTFields, Tumor Treating Fields.

Median (range) follow-up: 10.0 (0.03–58.7) months

2023 ASCO ANNUAL MEETING

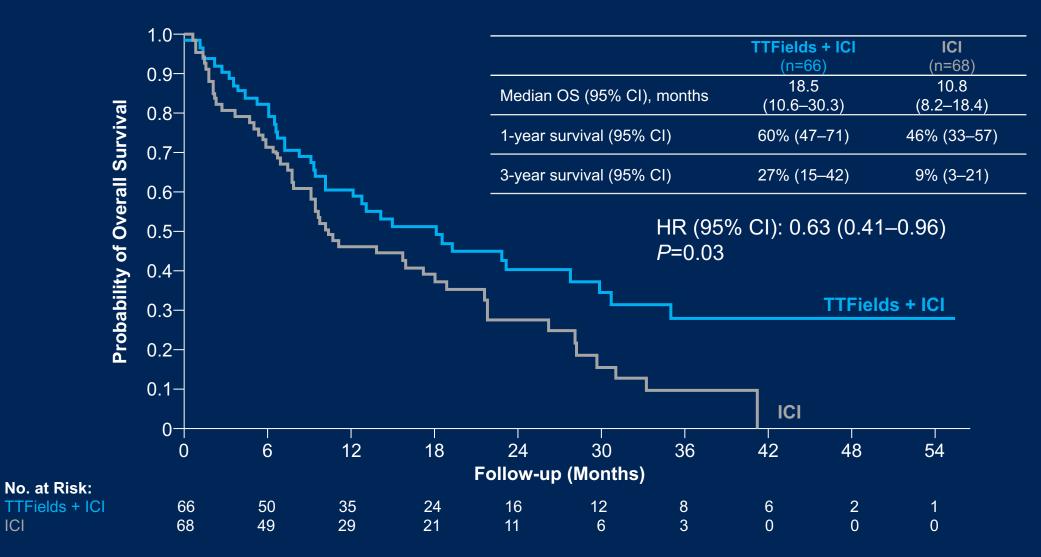
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Overall Survival in ICI-Treated Patients



CI, confidence interval; HR, hazard ratio; ICI, immune checkpoint inhibitor; OS, overall survival; TTFields, Tumor Treating Fields.



ICI

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Thanks



