III JORNADA TRASLACIONAL
DE ONCOLOGÍA DE PRECISIÓN:
A TRAVÉS DE LAS VÍAS DE SEÑALIZACIÓN
SEVILLA, 12 Y 13 DE FEBRERO DE 2026

NUEVAS ESTRATEGIAS DE INMUNOTERAPIA EN EL CÁNCER DE PULMÓN

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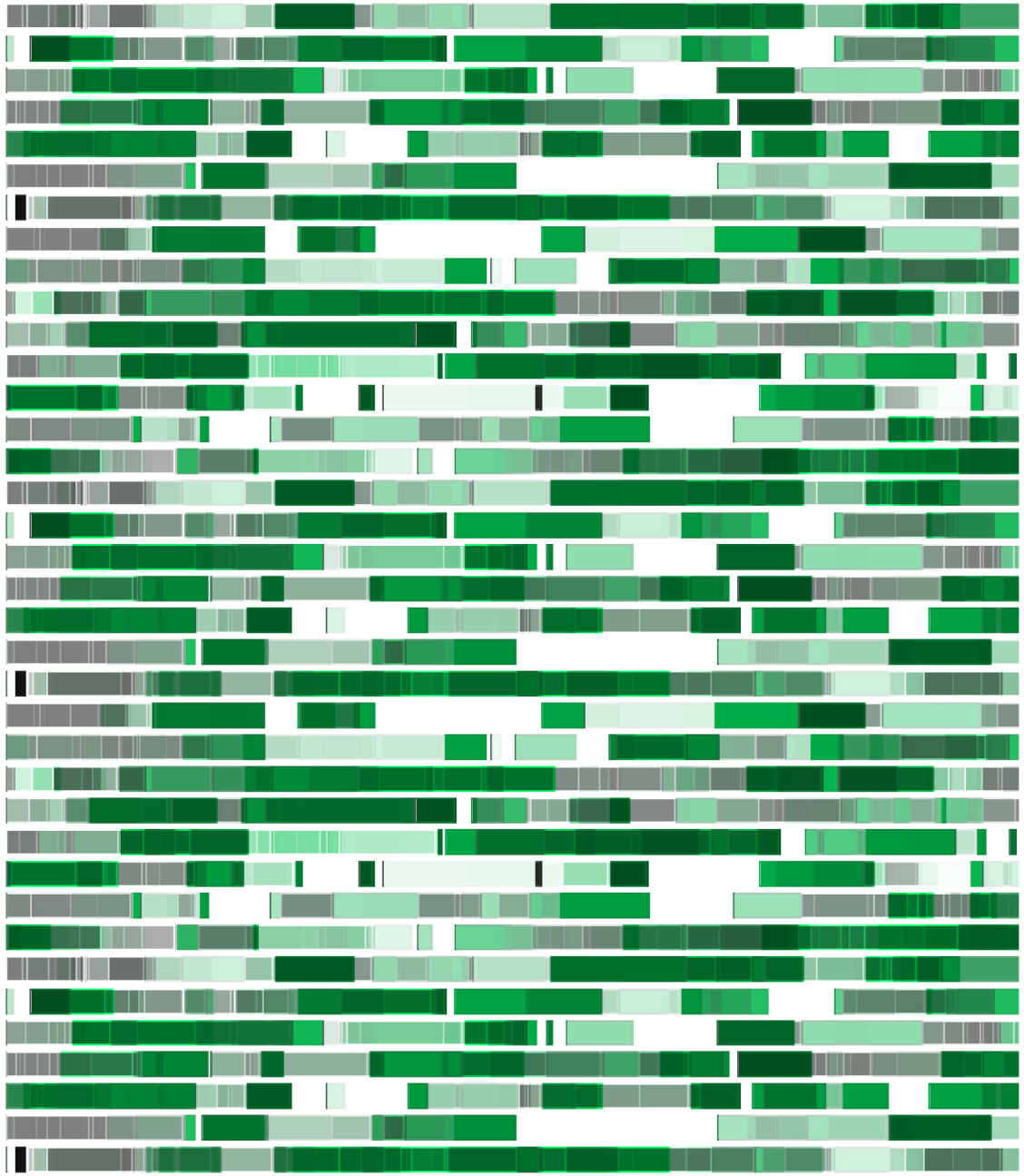
Organizador por:
HENDERE HEALTHCARE



DISCLOSURES

- Honoraria: Takeda, Roche, Sanofi, AstraZeneca, BMS, J&J, Regeneron, Pfizer, Bione, Amgen.
- Consulting or advisory role: Elipse, Sanofi, Takeda, BMS, Astrazeneca, Roche, Beone, J&J.
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- Stock Ownership: None

BIOLOGICAL FRAMEWORK FOR CORRELATES OF ICB RESPONSE

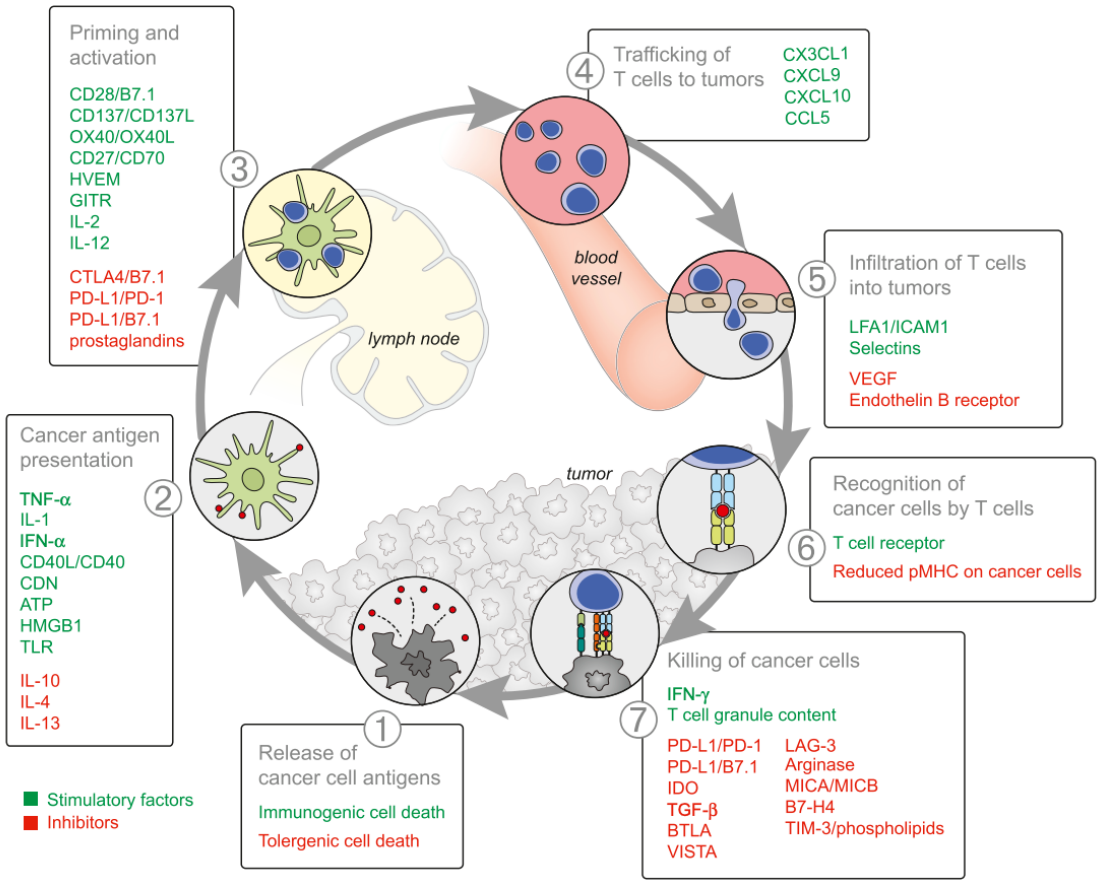
Tumor Intrinsic Predictors

Mutation burden/neoantigen load
- Clonality/heterogeneity
- Indel load
- Mutation signatures (smoking, APOBEC)

Genomic loss of neoantigens

Loss of antigen presentation
- B2M loss
- HLA loss/phenotypes

Single gene associations/ Oncogenic immune exclusion
- Oncogenic drivers (*EGFR*, *ALK*)
- *STK11/KEAP1*
- Cell cycle
- *JAK1/2* mutations
- Impaired STING activation



Tumor Extrinsic Predictors

T cell activation
- IFN-gamma/T cell inflamed signatures
- PD-L1 expression

T cell infiltrate/inflamed tumor

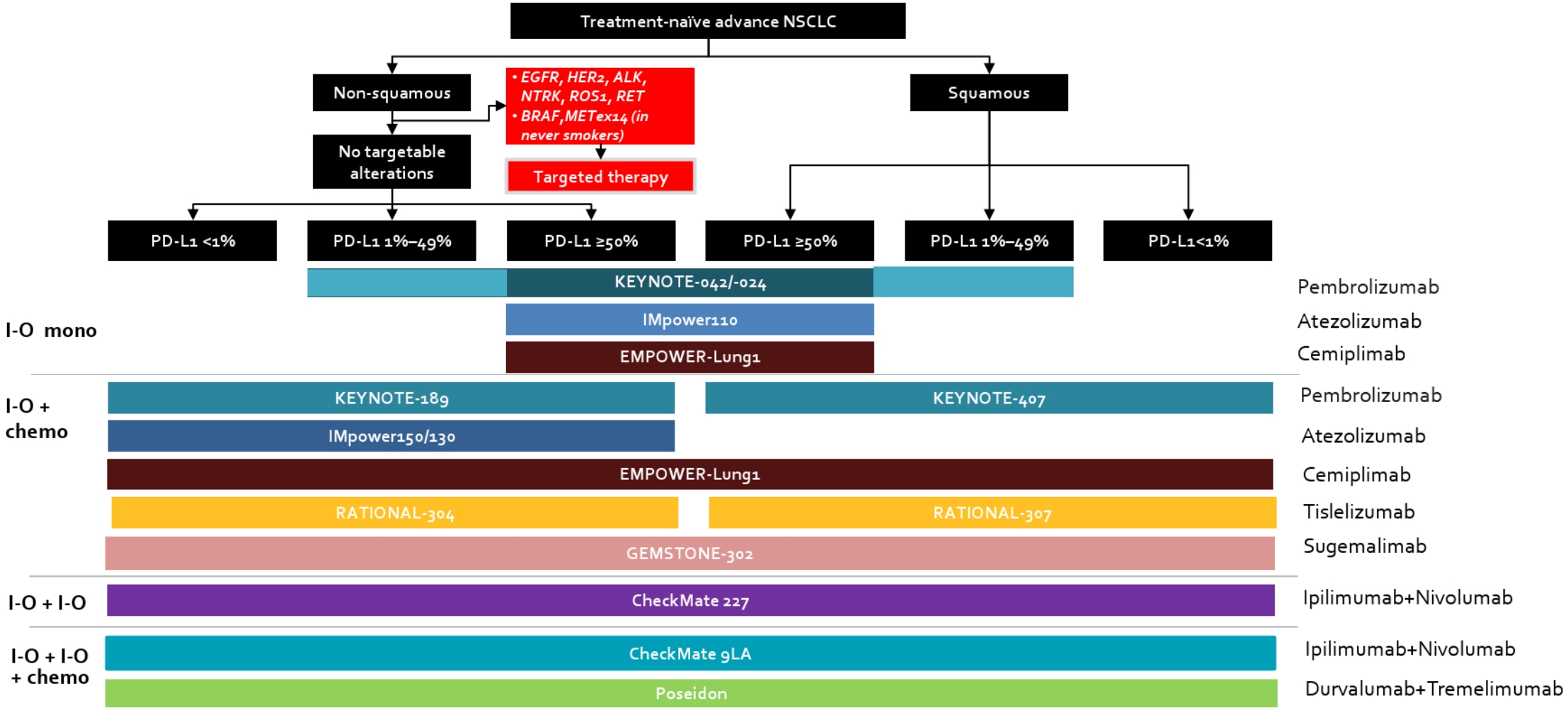
TCR diversity

Immune excluded/cold tumors

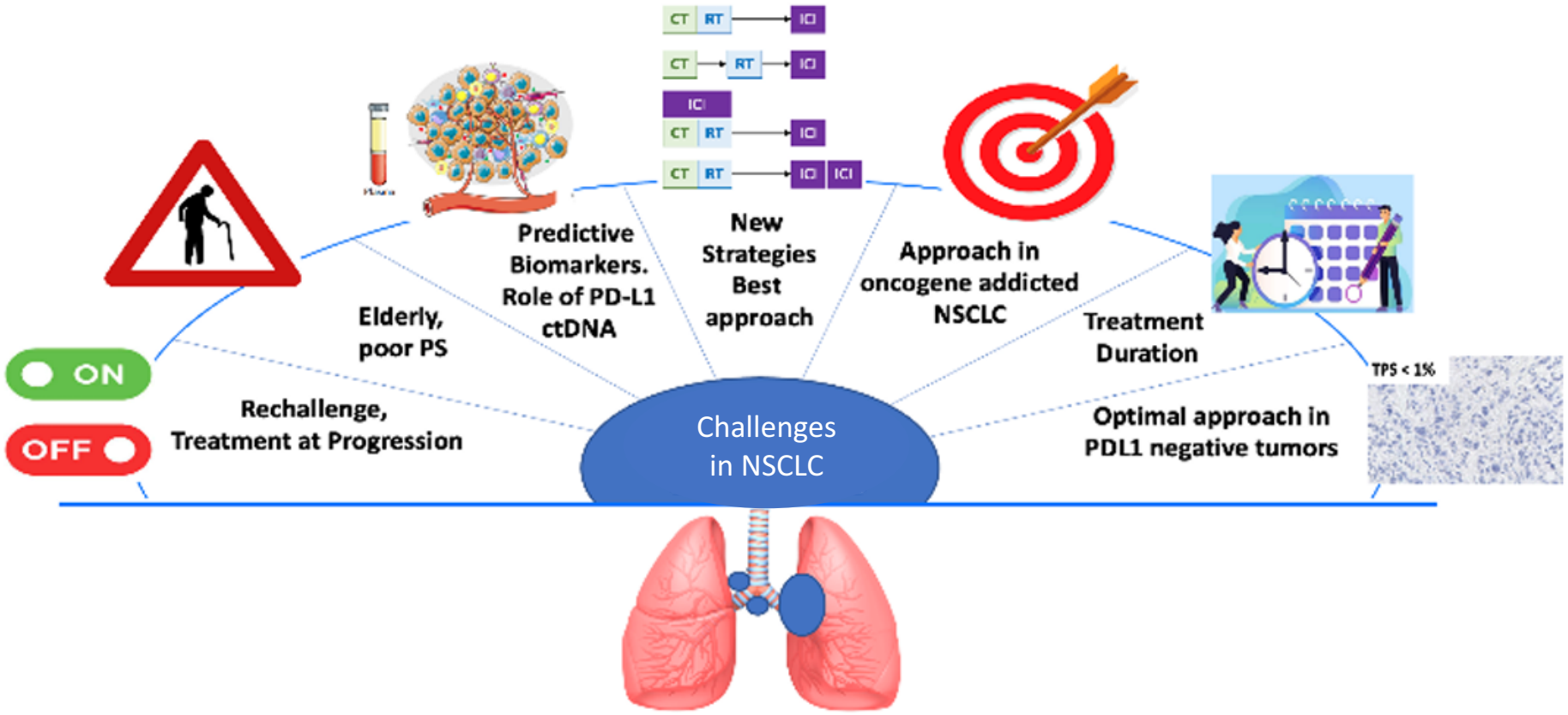
Immune suppressive populations
- Suppressive myeloid cells
- Fibroblasts/TGF-beta

Cheng DS, et al. Immunity, 2013.

CURRENT TREATMENT ALGORITHM IN ADVANCED NSCLC



CHALLENGES IN THE ICB SETTING FOR NSCLC



Remon & Hendriks Ther Adv Med Onc 2022; Remon NRCO 2025

DECISION-MAKING FACTORS IN CLINICAL PRACTICE

Disease

- PD-L1 expression
- Histology
- Metastatic sites (brain)
- Tumor kinetic
- Genomic (addictions, *KRAS*, *TP53*, *STK11*, *KEAP1*, *SMARCA4* ...)

Patient

- PS
- Sex, age
- Comorbidities
- CI immunotherapy
- Smoking habits
- Neutro./lympho. Ratio
- CRP, LDH

Co-medications

- Corticosteroids
- Antibiotics
- PPI

PRECISION IMMUNE-ONCOLOGY FOR THE TREATMENT OF MNSCLC

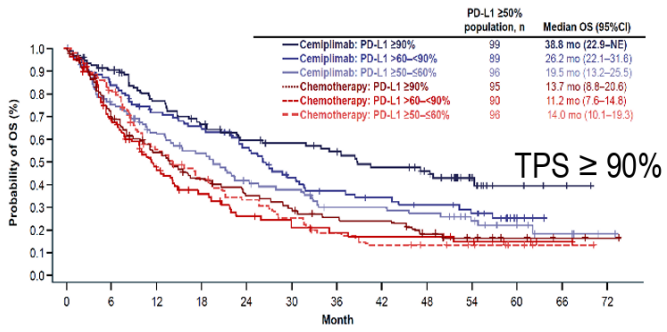
CT-ICB | ICB | 1-49% | <1%

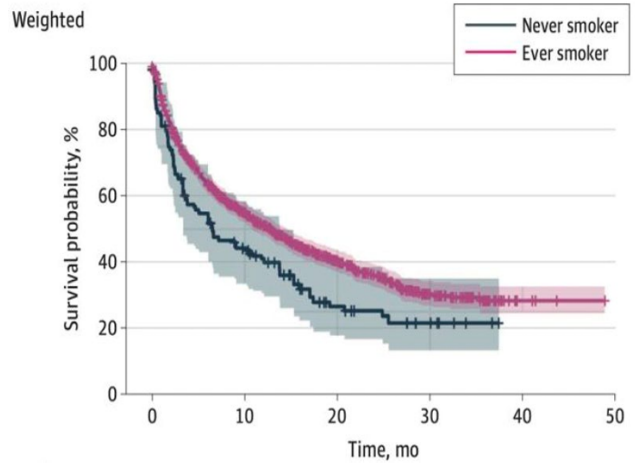
Hendriks Ann Oncol 2025

PRECISION IMMUNE-ONCOLOGY FOR THE TREATMENT OF MNSCLC

- PS 0-2 and PD-L1 ≥50%
- PS 0-1 and any PD-L1 level
- PS 2 and PD-L1 <50%
- PS 3-4 and any PD-L1 level

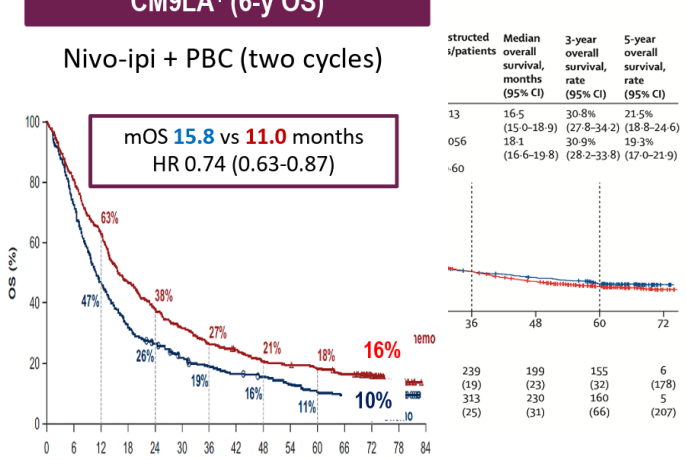
EMPOWER-LUNG1[1]

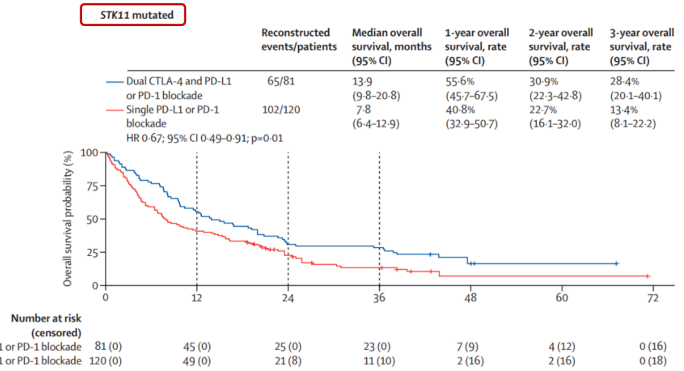


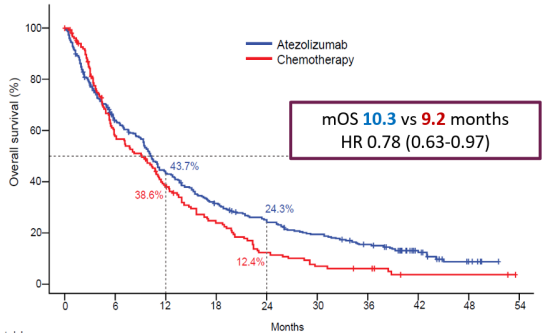


CM9LA[1] (6-y OS)

Nivo-ipi + PBC (two cycles)



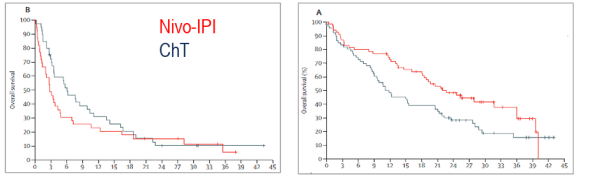




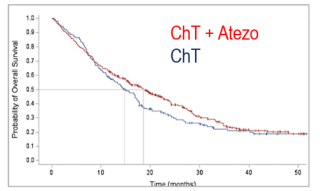
Benefit regardless of PD-L1 level
PS 0-1 > benefit (HR 0.64) vs PS 2/3 (HR 0.86-0.74)

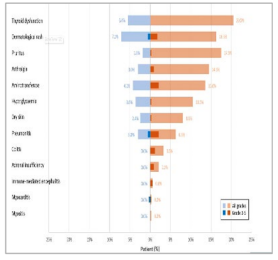
≥70 & PS PS2
mOS 2.9 vs 6.1 m (HR 1.31)

≥70 & PS 0-1
mOS 22.6 vs 11.8 m (HR 0.64)



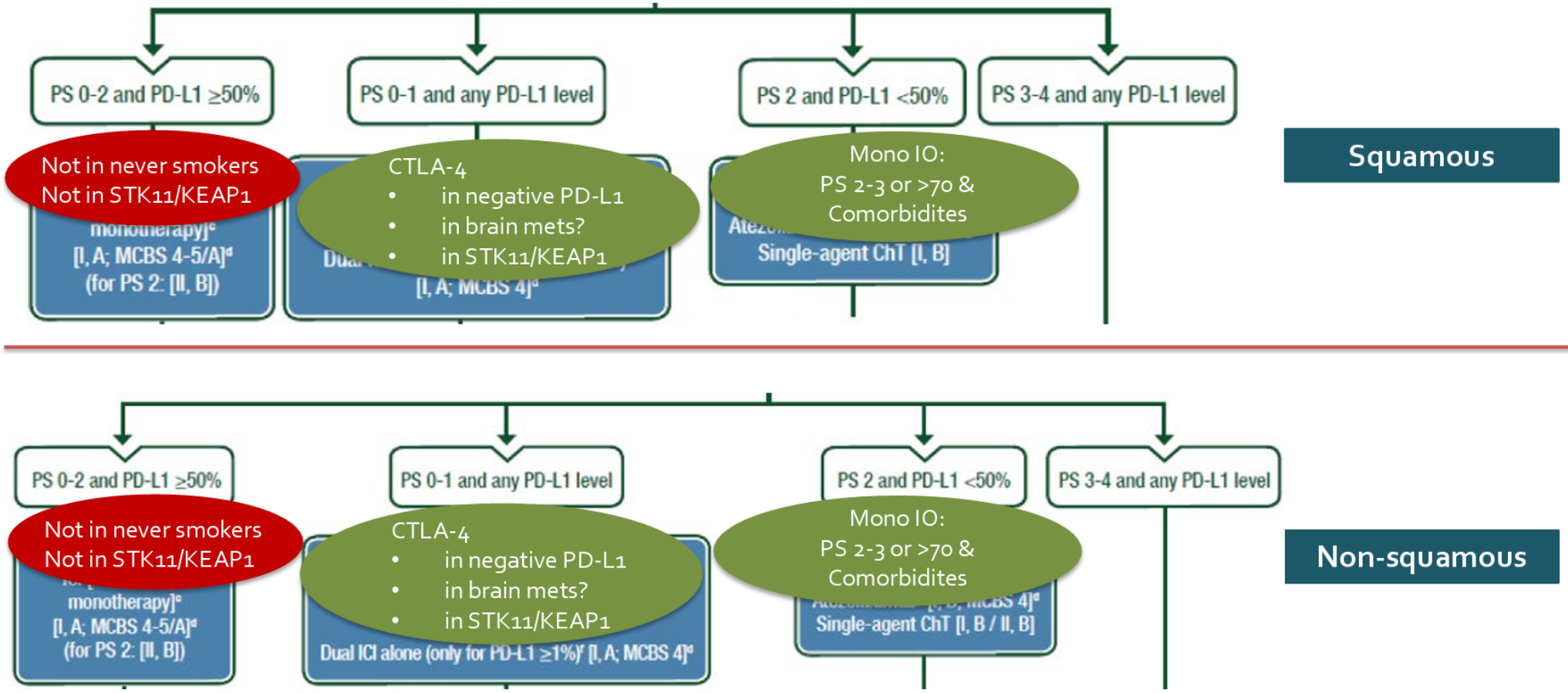
≥70 & PS 0-1
mOS 18.6 vs 15 mo (HR 0.87)





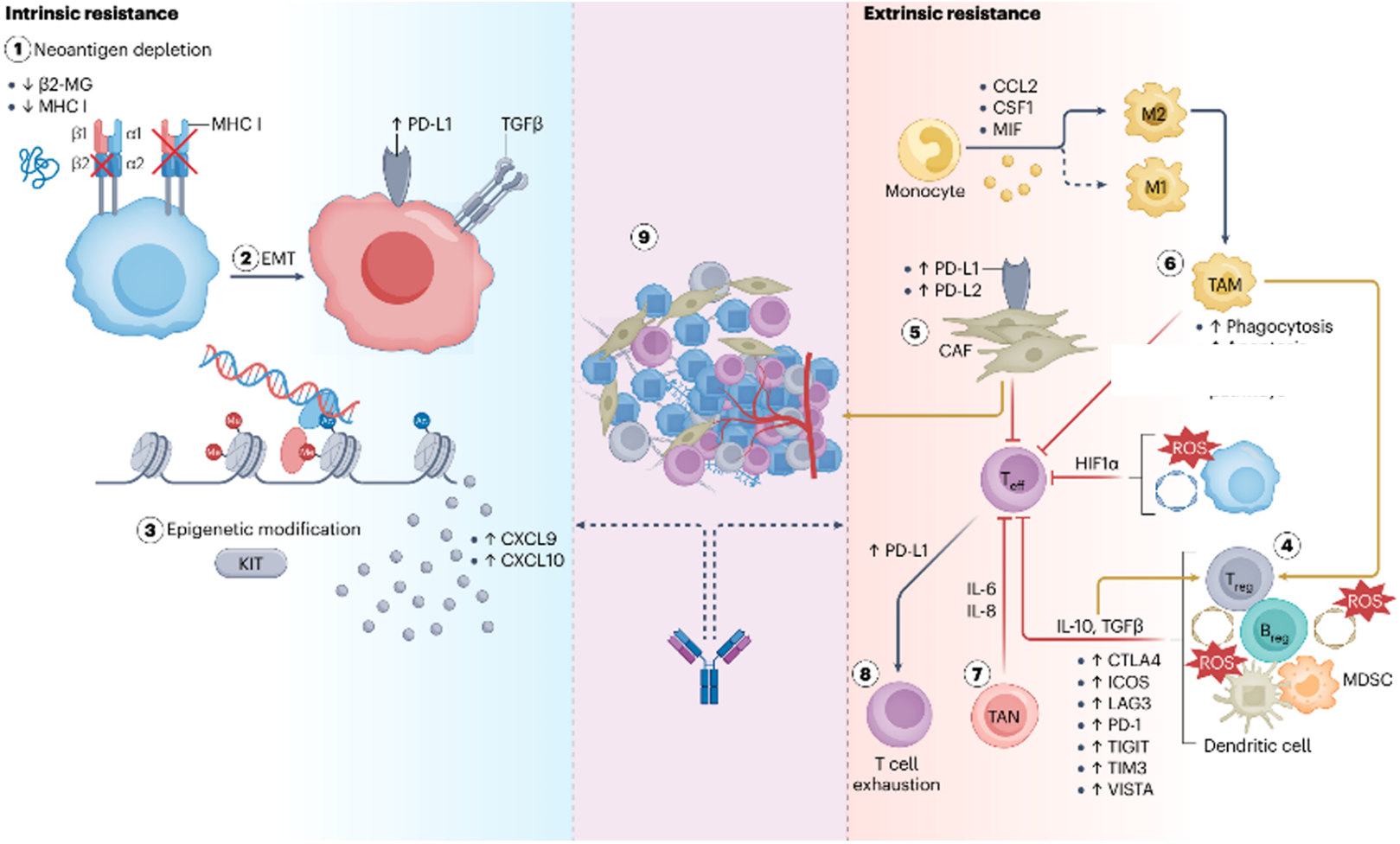
Hendriks Ann Oncol 2025; Di Federico A et al., Lancet Oncol 2025; Kilickap et al. JTO 2025; Aguilar et al. Ann Oncol 2019; Vallejo J e
Network 2022; CorkeLK, CurrOncology 2022; Ramalingam SS WCLC 2023; Lee Lancet 2023; Lena Lancet Resp Med 2024; Mascaux (

PRECISION IMMUNE-ONCOLOGY FOR THE TREATMENT OF MNSCLC



Hendriks Ann Oncol 2025

RESISTANCE MECHANISMS ? A SUMMARY OF THE UNKNOWN

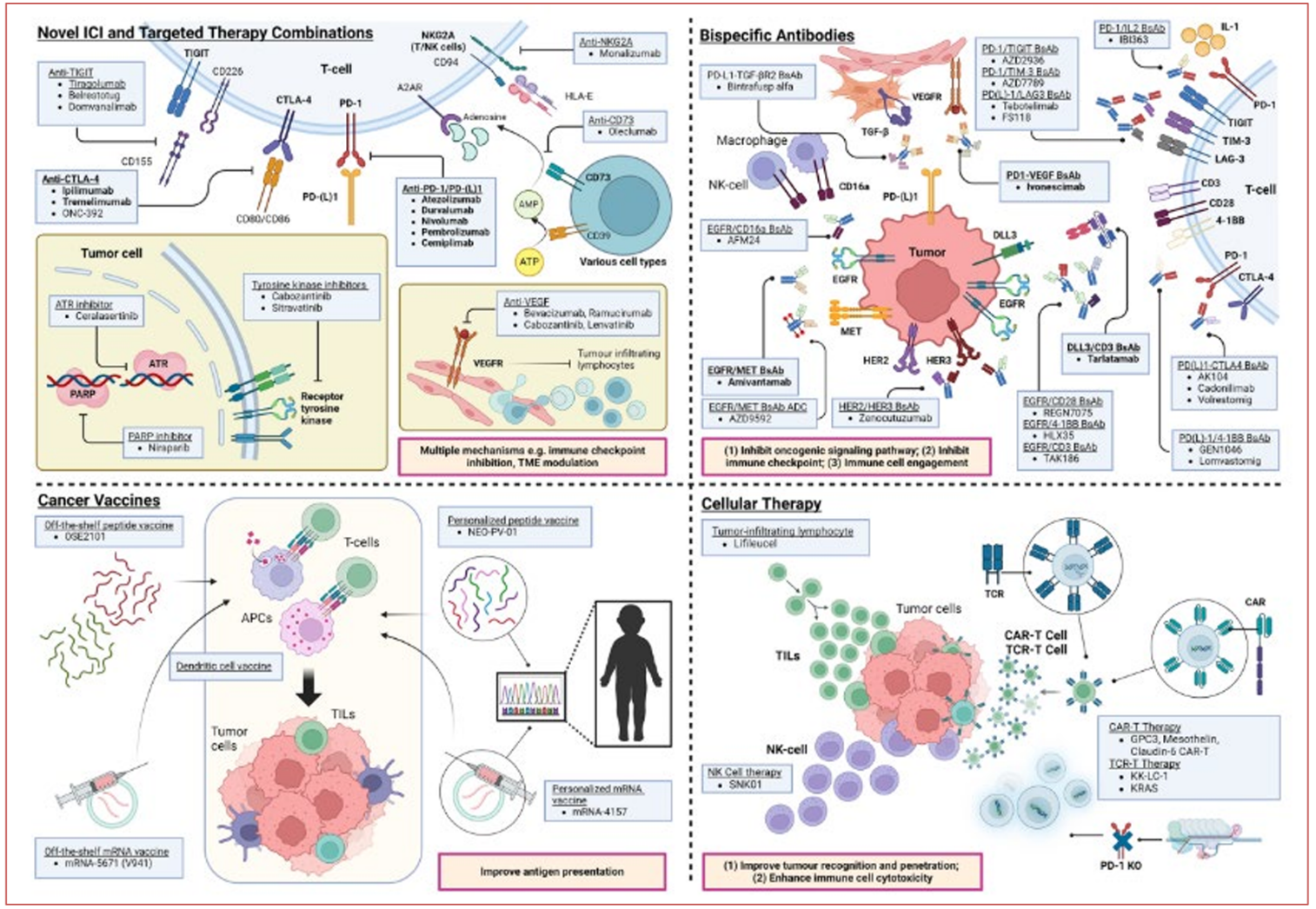


Reck, Nat RevClin Onco2025

MULTIPLE WAYS TO IMPROVE IMMUNOTHERAPY

Increase T cell function and improve TME

Increase tumor immunogenicity

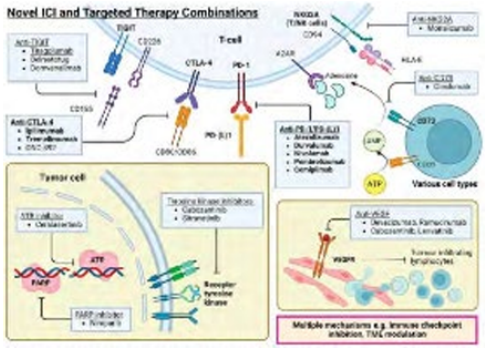


Imrpove T cell function and synergize with TME

Increase effector T cells number

Li MSC et al., Ther Adv Med Oncol 2024

TREATMENT STRATEGIES BEYOND PD-(L)1

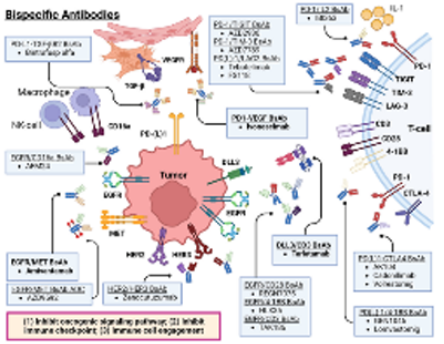


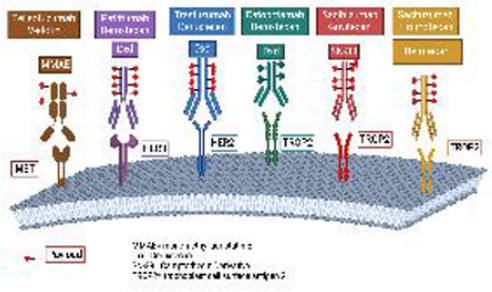
- TIGIT
- LAG3
- TIM3
- CD73
- NKG2A
- CCR8

Other Immune checkpoints

Bi-specifics

- Dual immune checkpoints
- Immune checkpoints and angiogenesis
- Other molecular pathways
- BiTEs



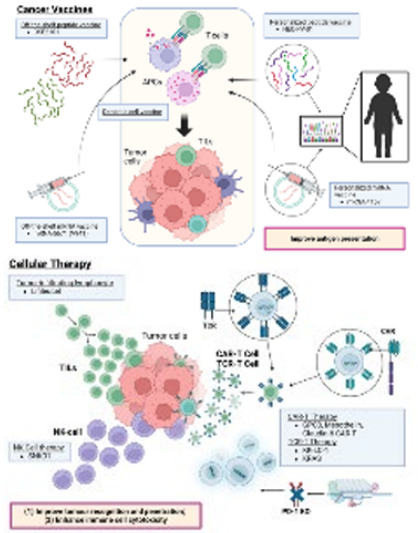


ADCs

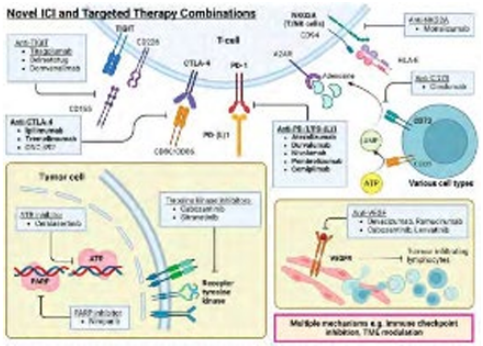
- TROP2
- HER2
- HER3
- MET
- B7-H3

Novel Molecules

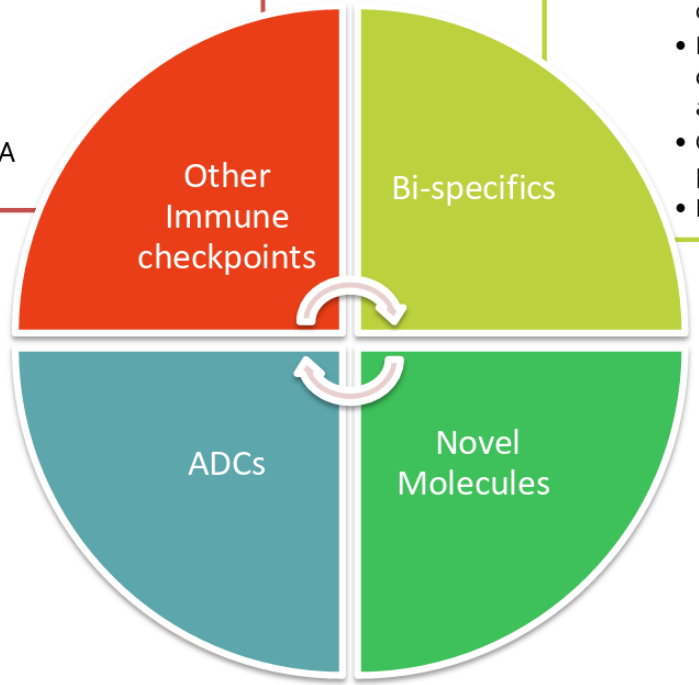
- mRNA vaccines
- Peptide vaccines
- Adoptive T-cell Therapies
- Intratumoral



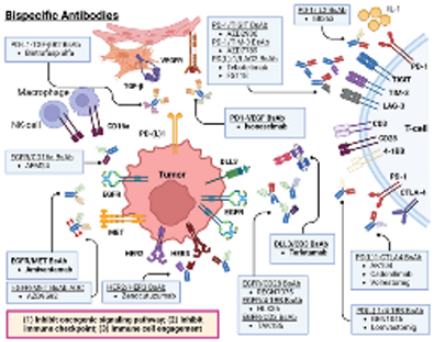
TREATMENT STRATEGIES BEYOND PD-(L)1



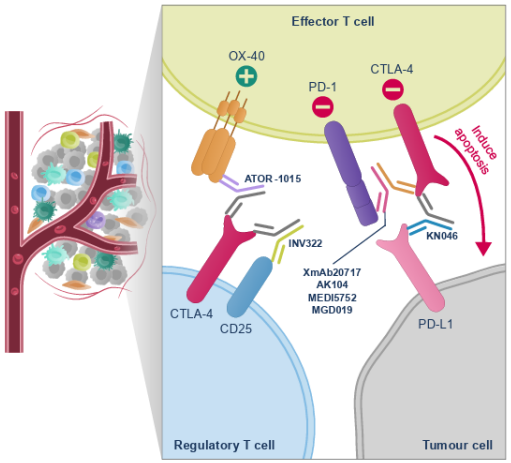
- TIGIT
- LAG3
- TIM3
- CD73
- NKG2A
- CCR8



- Dual immune checkpoints
- Immune checkpoints and angiogenesis
- Other molecular pathways
- BiTEs

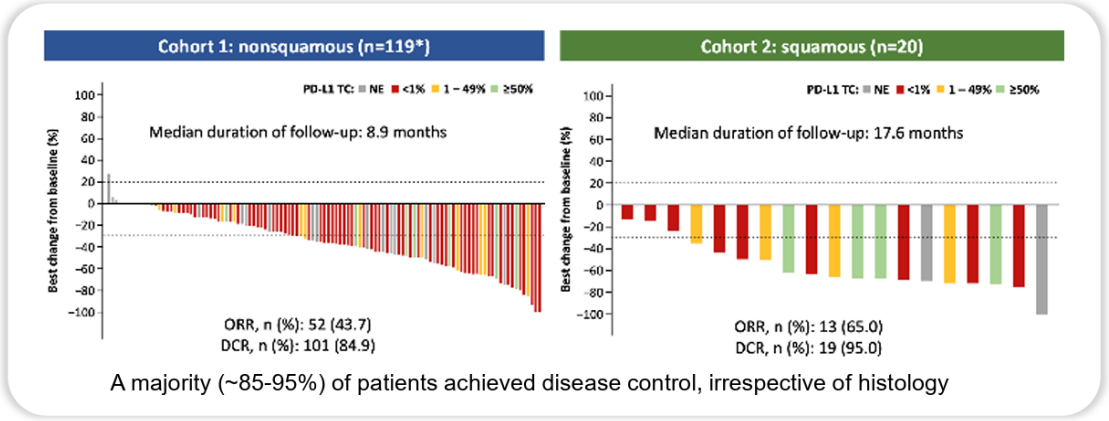


BISPECIFIC ANTI-PD1 AND CTLA-4 VOLRUSTOMIG + CHEMO: PHASE 1B/2 TRIAL

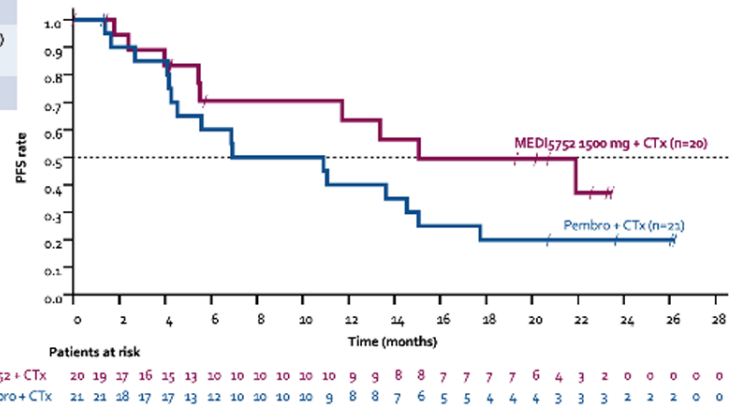


1L Non-squamous NSCLC	Randomised cohort (N=41)	
	MEDI5752 1500 mg + CTx (n=20)	Pembrolizumab + CTx (n=21)
Median follow-up, months (range)	22.8 (0.8–26.9)	14.5 (1.6–27.9)
ORR, n (%)	10 (50.0)	10 (47.6)
Disease control rate, n (%)	17 (85.0)	20 (95.2)
Median DOR, months (95% CI)	20.5 (4.1–NE)	9.9 (2.8–NE)
Median PFS, months	15.1	8.9
Median OS, months	NR	16.5
ORR, PD-L1 <1%, n/N (%) (95% CI)	5/9 (55.6) (21.2–86.3)	3/10 (30.0) (6.7–65.2)
Median PFS, PD-L1 <1%, months	13.4	9

Volrustomig 1500 mg + CTx



A majority (~85-95%) of patients achieved disease control, irrespective of histology



Volrustomig 750 mg + CTx leads to higher T cell proliferation and T cell clonal expansion when compared with pembro + CTx

Spigel DR, et al. WCLC 2024; Abstract #OA11.04; Spigel DR, et al. JTO 2024.

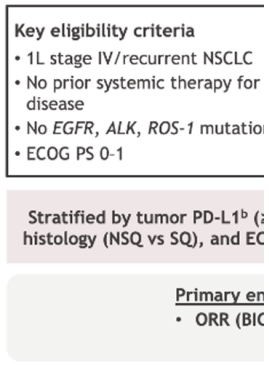
STATUS OF PD-(L)1XCTLA4 DEVELOPMENT IN NSCLC

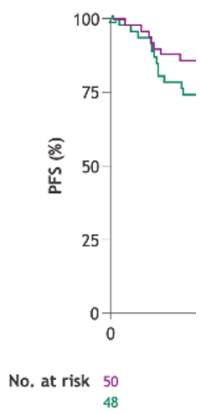
BsAb	Phase	Population	N	Treatment	PEP	NCT
Erfonrilimab	III	Advanced Sq-NSCLC, 1L	482	carboplatin and paclitaxel +/- KN046	PFS, OS	NCT04474119
Erfonrilimab	II	Advanced NSCLC, 1L	54	KN046+ Axitinib	ORR	NCT05420220
Cadonilimab	III	Advanced NSCLC, 1L, PD-L1 < 1%	642	Cadonilimab + chemo v Tislelizumab+ chemo	OS, PFS	NCT05990127
Cadonilimab	II	Resectable NSCLC	43	Periop Cadonilimab+ chemo	pCR	NCT05377658
Cadonilimab	III	Unresectable stage III NSCLC	560	Consolidation Cadonilimab Versus Sugemalimab	PFS	NCT06617416
Volrustomig	III	Advanced NSCLC, 1L, PD-L1 < 50%	900	MEDI5752+ chemo v pembro+ chemo	PFS, OS	NCT05984277
Volrustomig	II	Resectable II to IIIB	490	Neoadj Volrustomig+ chemo, adjuvant Volrustomig	pCR	NCT05061550
Volrustomig	Ib	Metastatic HER2+, NSCLC	244	Volrustomig+ T-DXd +/- carboplatin	Safety	NCT04686305
Vudalimab	Ib/rII	Advanced non-Sq NSCLC, 1L	168	Vudalimab+ chemo v pembro+ chemo	RP2D, PFS	NCT06173505

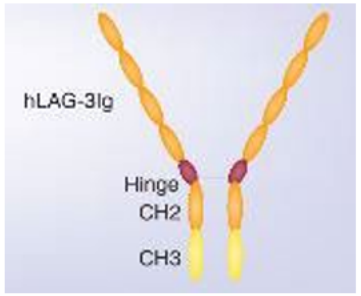
Clinicaltrial.org

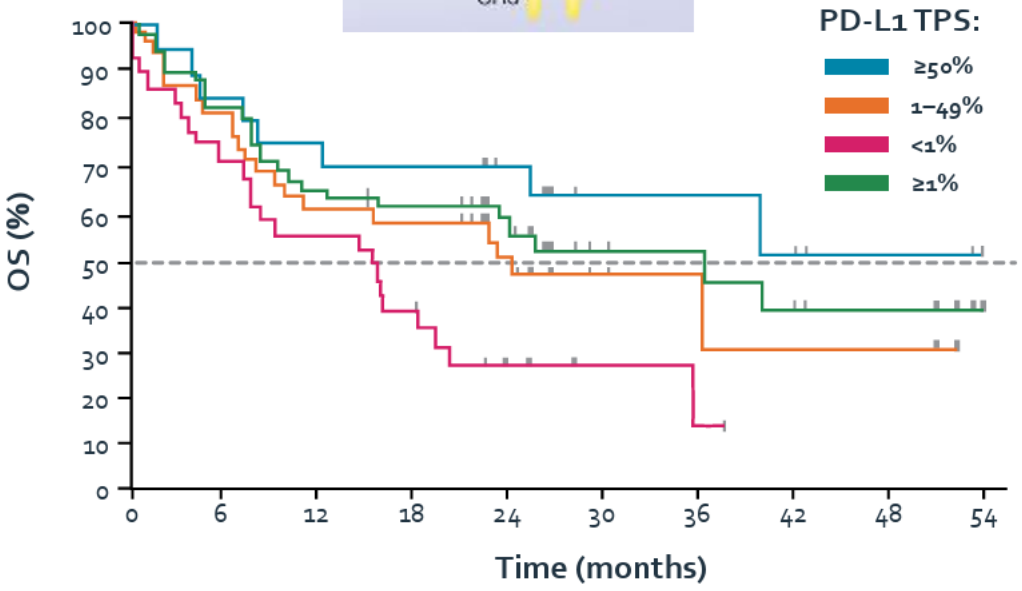
ADVANCES IN LAG3 CANCER IMMUNOTHERAPEUTICS

	Phase	Line	Primary endpoint	Sample size
Relatlimab: A Phase 3, Randomized, Open-label Study of Nivolumab + Relatlimab Fixed-dose Combination With Chemotherapy Versus Pembrolizumab With Chemotherapy as First-line Treatment for Participants With Non-squamous (NSQ), Stage IV or Recurrent NSCLC and With Tumor Cell PD-L1 Expression ≥ 1% **(RELATIVITY 1093)**				
Fianlimab: A Randomized, Double-Blind Phase 2/3 Study of Fianlimab, Cemiplimab, and Chemotherapy Versus Cemiplimab and Chemotherapy in First-Line Treatment of Patients With Advanced NSCLCI irrespective of PD-L1 Expression Levels				
Fianlimab A Randomized, Double-Blind Phase 2/3 Study of Fianlimab in Combination With Cemiplimab Versus Cemiplimab Monotherapy in First-Line Treatment of Patients With Advanced NSCLC With Tumors Expressing PD-L1 ≥50%				
Eftilagimod alpha: Study of Eftilagimod Alfa in Combination With Pembrolizumab and Chemotherapy Versus Placebo in Combination With Pembrolizumab and Chemotherapy in Participants With Metastatic NSCLC (**TACTI-004**)				



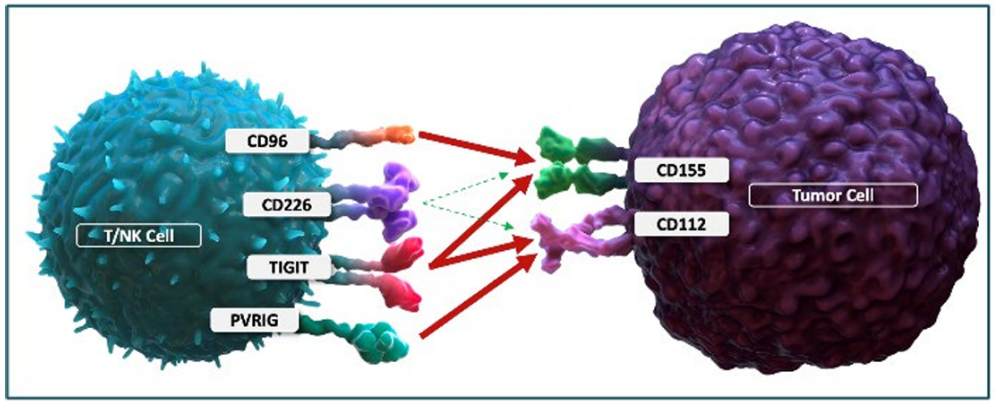


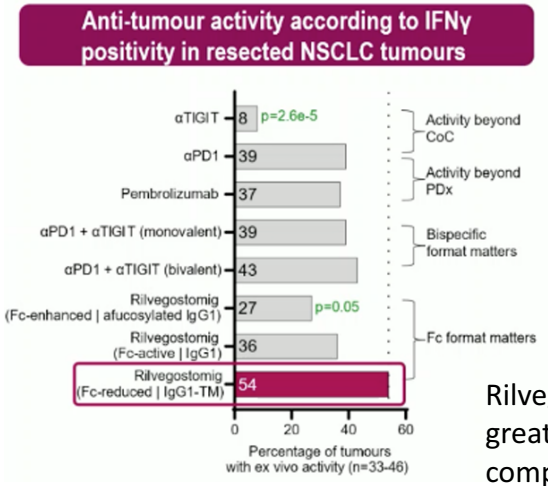




Spigel DR, et al. WCLC 2024; Abstract #OA11.04; Spigel DR, et al. JTO 2024; Girard, ESMO 2024; Carcereny E, et al. ESMO 2023; Nadal, ELCC 2025

ANTI-PD-1/TIGIT BISPECIFIC ANTIBODY





Rilvegostomig induced greater ex-vivo activity compared to other anti-PD-1/anti-TIGIT

Remon & Hendriks Ther Adv Med Onc 2022; Remon NRCO 2025

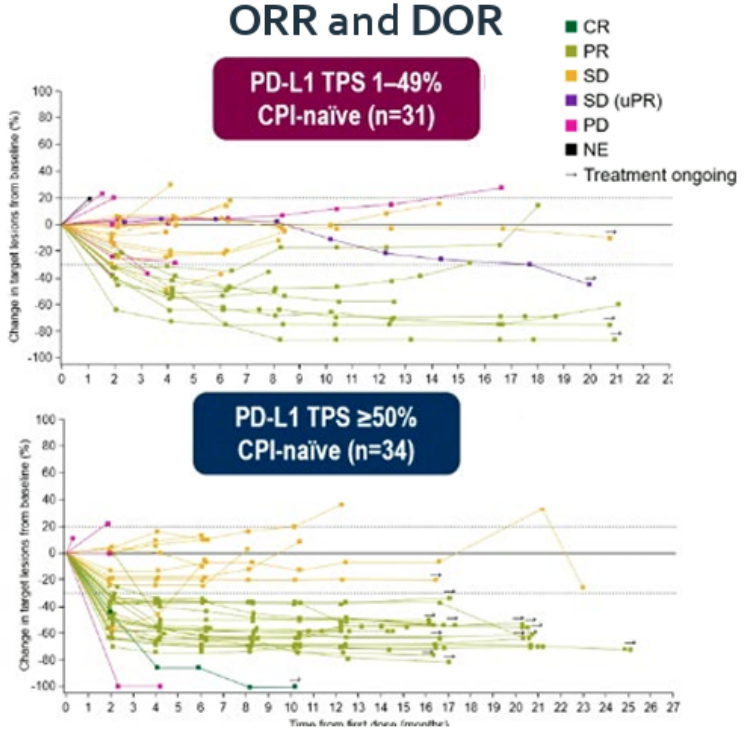
WHERE DO WE STAND WITH TIGIT IN MNSCLC?

COMPANY	AGENT	STUDY	SETTING	DESIGN	RESULTS/STATUS	REFERENCE
Roche	Tiragolumab	SKYSCRAPER-01 ph3	1st Line PDL1>50%	Atezo+Tira Vs Atezo	PFS 7 vs 6.6 m (HR=0.78) OS 23.1 vs 16.9m (HR=0.87) **NS**	Peters et al. AACR 2025
Roche	Tiragolumab	SKYSCRAPER-06 ph2/3	1st Line Non-squamous	PBC+Atezo+Tira Vs PBC+Pembro	DISCONTINUED Futility by IDMC	Press release 04JUL2024
MSD	Vibostolimab	KEYVIBE-003 ph3	1st Line PDL1>50%	Pembro+Vibo Vs Pembro	DISCONTINUED Futility by IDMC	Press release 16DEC2024
MSD	Vibostolimab	KEYVIBE-007 ph3	1st Line PDL1+	PBC+ MK7684A Vs PBC +Pembro	DISCONTINUED Futility by IDMC	Press release 16DEC2024
ARCUS GILEAD	Domvanalimab	ARC-10 Ph2/3	1st Line PDL1>50%	Zimbe+Domva Vs Zimbe vs PBC (modified to Pembro as control)	Part-1 Random Ph2 Significant improvement in PFS/OS over zimbe or chemo. Ph3 ongoing	Naidoo et al. JITC 2024
NOVARTIS BEIGENE	Ociperlimab	AdvanTIG-302 ph3	1st-Line PDL1>50%	Ociperlimab+Tisle Vs Tislelizumab	DISCONTINUED Futility by IDMC	Press release 03APR2025
ITEOS GSK	Belrestotug	GALAXIES-LUNG-301	1st Line PDL1>50%	Dostarlimab+ Belrestotug Vs Pembro	DISCONTINUED ph2 GALAXIES-LUNG 201 met Futility criteria	Press release 13MAY 2025

Clinicaltrial.org

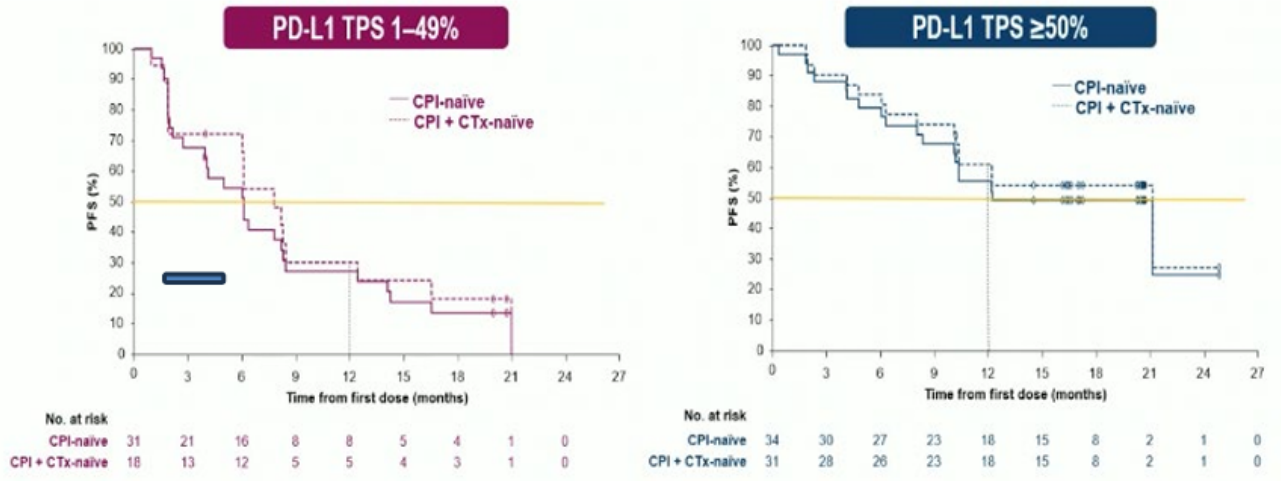
ARTEMIDE-01 (PHASE 1/2): RILVEGOSTOMIG, AN ANTI-PD-1/TIGIT BISPECIFIC ANTIBODY, AMONG CHECKPOINT INHIBITOR-NAÏVE METASTATIC NSCLC

ORR and DOR



	PD-L1 TPS 1–49%		PD-L1 TPS ≥50%	
	CPI-naïve (n=31)	CPI + CTx-naïve (n=18)	CPI-naïve (n=34)	CPI + CTx-naïve (n=31)
ORR, % (95% CI)	29.0 (14.2–48.0)	44.4 (21.5–69.2)	61.8 (43.6–77.8)	67.7 (48.6–83.3)
Median DoR, months (range)	9.9 (4.1–NC)	8.5 (4.1–NC)	NR (10.3–NC)	NR (10.3–NC)

PFS in CPI-naïve and CPI+CTx-naïve patients



	PD-L1 TPS 1–49%		PD-L1 TPS ≥50%	
	CPI-naïve (n=31)	CPI + CTx-naïve (n=18)	CPI-naïve (n=34)	CPI + CTx-naïve (n=31)
Median PFS, months (95% CI)	6.1 (2.7–8.3)	7.8 (1.9–12.5)	12.3 (8.4–NC)	21.2 (10.2–NC)
12-month PFS, % (95% CI)	27.2 (12.9–43.6)	30.1 (11.1–52.0)	55.5 (37.3–70.3)	60.8 (41.4–75.6)

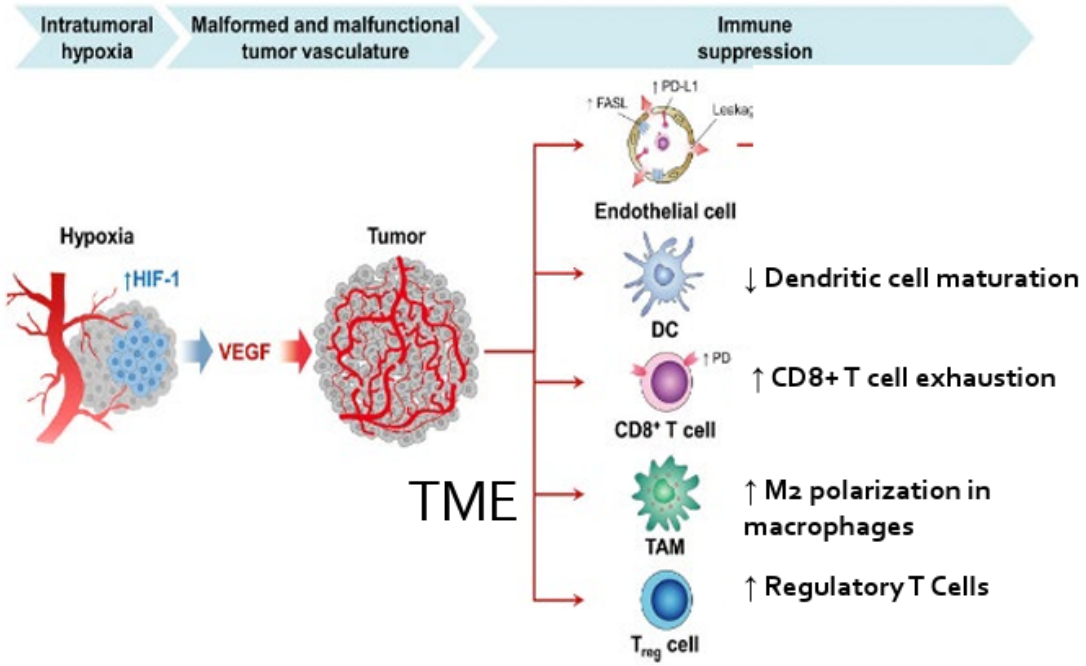
No notable activity at anti-PD-1/PD-L1 resistance

Brandao M., et al., ESMO 2023; Hiltermann J., eyt al., WCLC 2024

REVISITINGVEGF BLOCKADE AND IMMUNOTHERAPY IN NSCLC

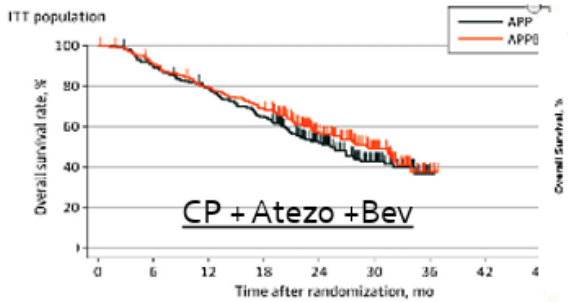
A Promising Concept…

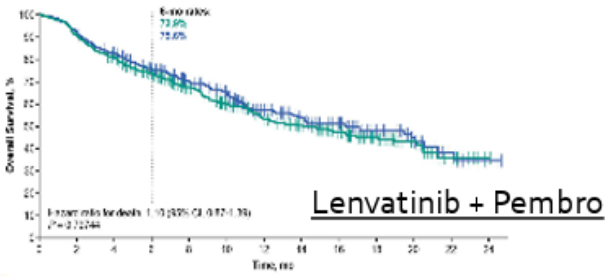
VEGF Supresses Antitumor Immunity

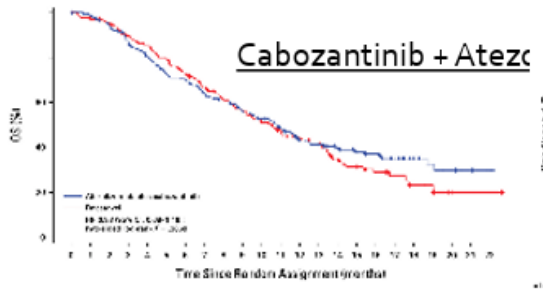


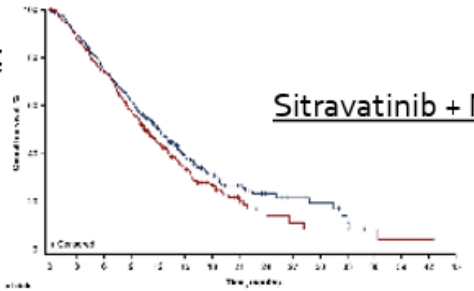
When Hopes Fall Short: Several Failed Attemps Combining CPIs + Anti-Antiangiogenics[2-5]

APPLE (WJOG11218L), LEAP-007, CONTACT-01, SAPPHIRE, Lung-MAP S1800A,, …









Adapted from Lee WS et al. Exp & Molecular Medicine 2020; Shiraishi Y, et al. JAMA Oncol 2023; Yang JC et al, JTO 2024; Neal J et al. JCO 2024

BI-ABS TARGETING PD – (L)1 AND VEGF IN NSCLC: SELECTED PHASE II/III

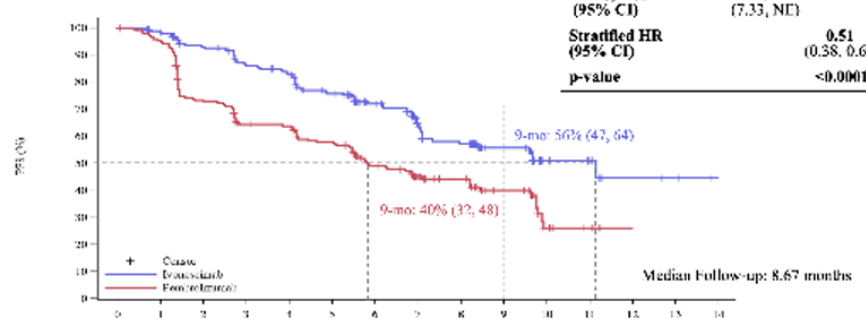
AGENT	Manufacturer	TARGET	SETTING	Phase	Intervention (for phase III)	Trial
Ivonescimab	Summit (Akeso)	PD-1X **VEGF**	1L metastatic NSCLC	III	PBC + Ivonescimab vs PBC + Pembrolizumab	HARMONi-3
Ivonescimab	Summit (Akeso)	PD-1X **VEGF**	1L mNSCLC with PD-L1>50%	III	Ivonescimab vs Pembrolizumab	HARMONi-7
Ivonescimab	Summit (Akeso)	PD-1X**VEGF**	1L Squamous mNSCLC	III	PBC + Ivonescimab vs PBC+ Tislelizumab	HARMONi-6
Pumitamig	Biontech (BMS)	PD-L1X**VEGF**	1L metastatic NSCLC	II/III	PBC + Pumitamig vs PBC+ Pembrolizumab	ROSETTA– LUNG 01
SSGJ-707	Shenyang Sunshine	PD-1X**VEGF**	1L advanced NSCLC PDL1>1%	III China	SSGJ-707 vs pembrolizumab	NCT06980272
LM-299	Merck (LaNova)	PD-1X**VEGF**	Solid tumors	I China		NCT06650566
JS207	Junshi Biosciences	PD-1X**VEGF**	1L advanced NSCLC with chemotherapy	II China		NCT06969027
SCTB-014	Sinoceltech	PD-1X**VEGF**	Solid tumors	I-II		Trial registered in China

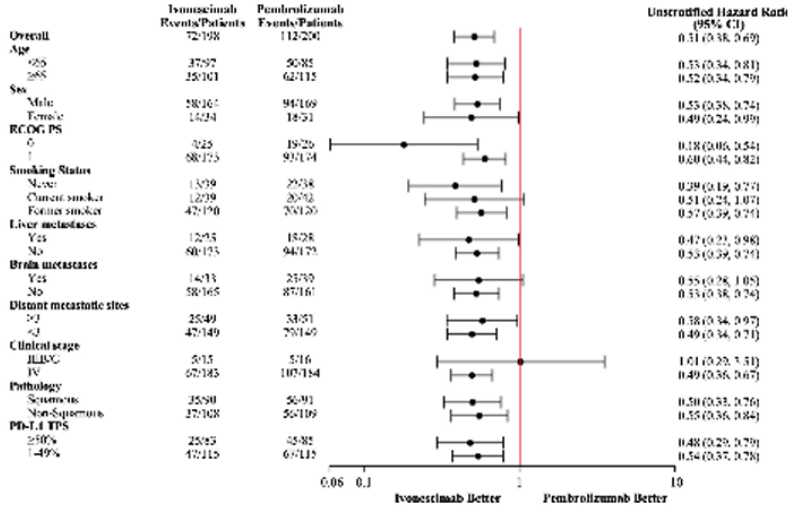
Adapted from Lee WS et al. Exp & Molecular Medicine 2020; Shiraishi Y, et al. JAMA Oncol 2023; Yang JC et al, JTO 2024; Neal J et al. JCO 2024

HARMONi-2

Primary endpoint: PFS per IRRC

	Ivonescimab (n = 198)	Pembrolizumab (n = 200)
mPFS, mos (95% CI)	11.14 (7.33, NE)	5.82 (5.03, 8.21)
Stratified HR (95% CI)	0.51 (0.38, 0.69)	
p-value	<0.0001	





Interim analysis of overall survival (OS) at 39% maturity (with α set at 0.0001) reported HR=0.777, corresponding to a 22.3% reduction in death risk. PFS 4.99% of α, OS 0.01%10

HARMONi-6

A multicenter, randomized, double-blind, parallel-controlled phase III study

Key Eligibility Criteria

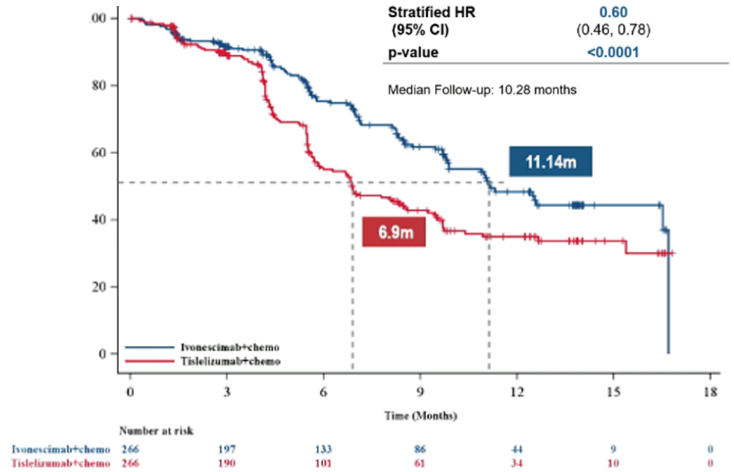
- Pathologically confirmed sq-NSCLC
- Stage IIIB-IV
- No prior systemic therapy
- No EGFR mutations or ALK rearrangements
- ECOG PS 0 or 1

R 1:1 N=532

- Ivonescimab (20 mg/kg, Q3W) + Carboplatin (AUC 5, Q3W) + Paclitaxel (175 mg/m², Q3W) up to 4 cycles → Ivonescimab (20 mg/kg, Q3W) up to 24 months or unacceptable toxicity
- Tislelizumab (200 mg, Q3W) + Carboplatin (AUC 5, Q3W) + Paclitaxel (175 mg/m², Q3W) up to 4 cycles → Tislelizumab (200 mg, Q3W) up to 24 months or unacceptable toxicity

	Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=266)
mPFS, months (95% CI)	11.14 (9.86, NE)	6.90 (5.82, 8.57)
Stratified HR (95% CI)	0.60 (0.46, 0.78)	
p-value	<0.0001	

Median Follow-up: 10.28 months

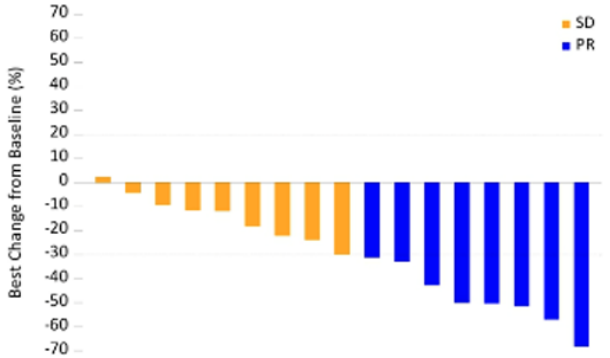


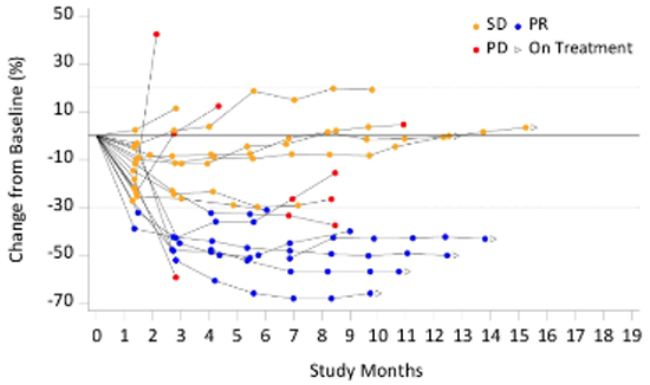
Possibly VEGF-Related AEs#	Ivonescimab + chemo (N=266)		Tislelizumab + chemo (N=265)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any	123 (46.2)	20 (7.5)	60 (22.6)	6 (2.3)
Proteinuria	72 (27.1)	6 (2.3)	29 (10.9)	0
Haemorrhage	57 (21.4)	5 (1.9)	25 (9.4)	2 (0.8)
Hypertension	27 (10.2)	8 (3.0)	12 (4.5)	3 (1.1)

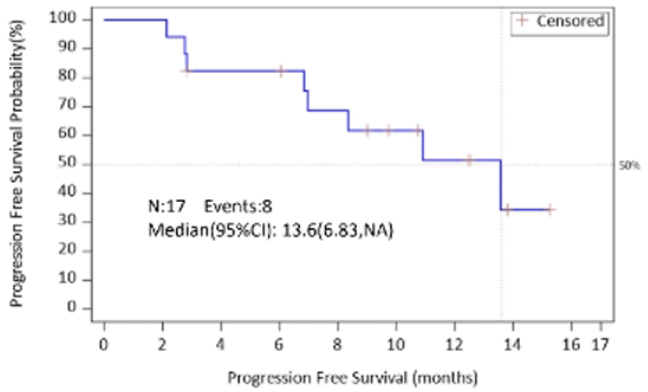
Challenging the dogma of SCC Lung treatment: VEGF inhibition is (relatively) safe and efficacious Await global confirmatory phase 3: HARMONI-3

Zhou, WCLC 2024; Lu, presented at ESMO 2025

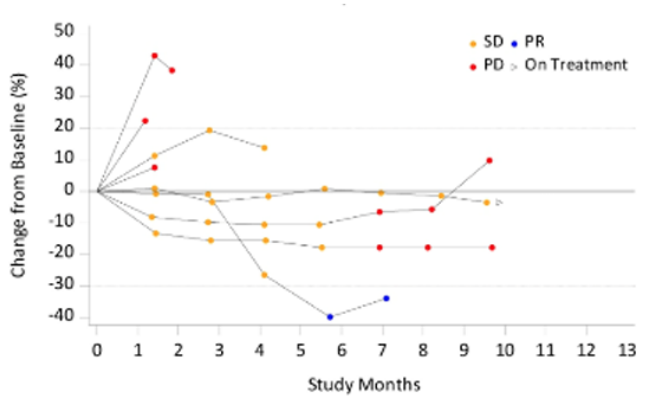
BNT327/PM8002 PUMITAMIG PHASE 1/2 IN NSCLC

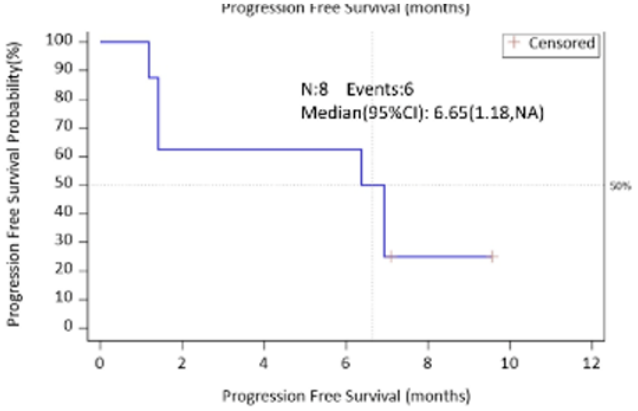






PD-L1 positive treatment naive



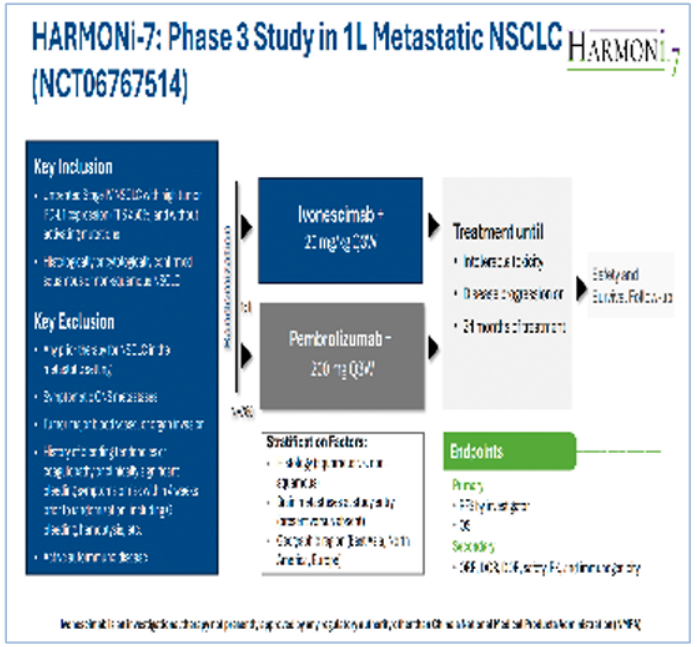


After chemo/IO failure

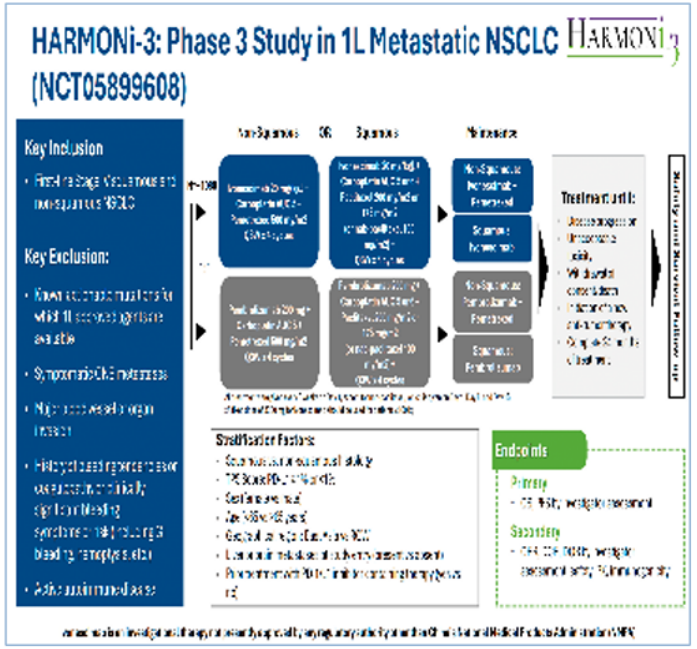
Wu, ASCO 2024

ONGOING FRONTLINE GLOBAL PHASE 3 HEAD-TO-HEAD TRIALS

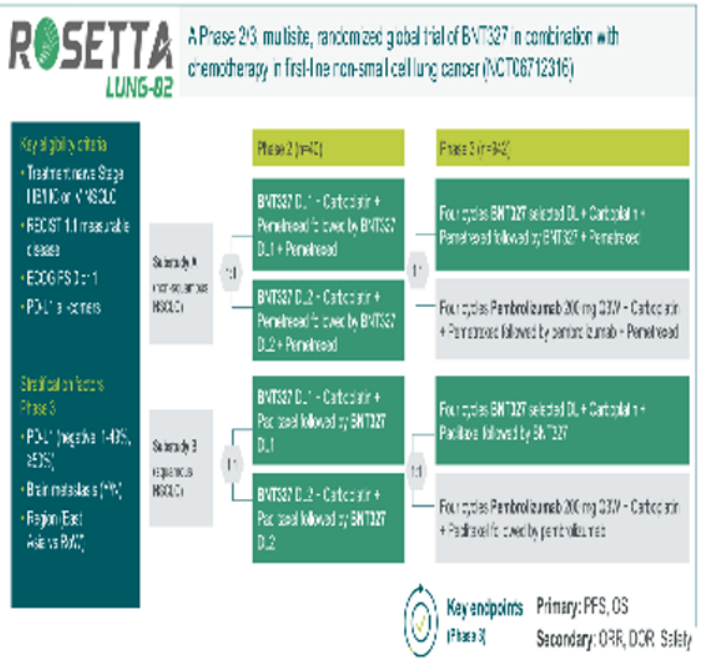
IVO Monotherapy
1L SQ + NSQ, TPS ≥ 50%



IVO + ChT Combo
1L SQ + NSQ , TPS all comers

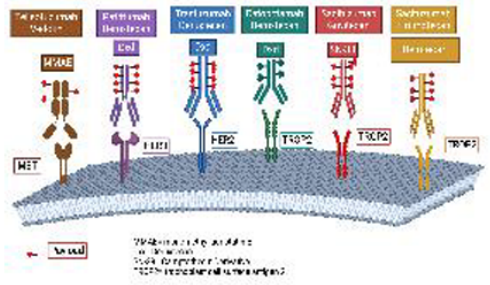


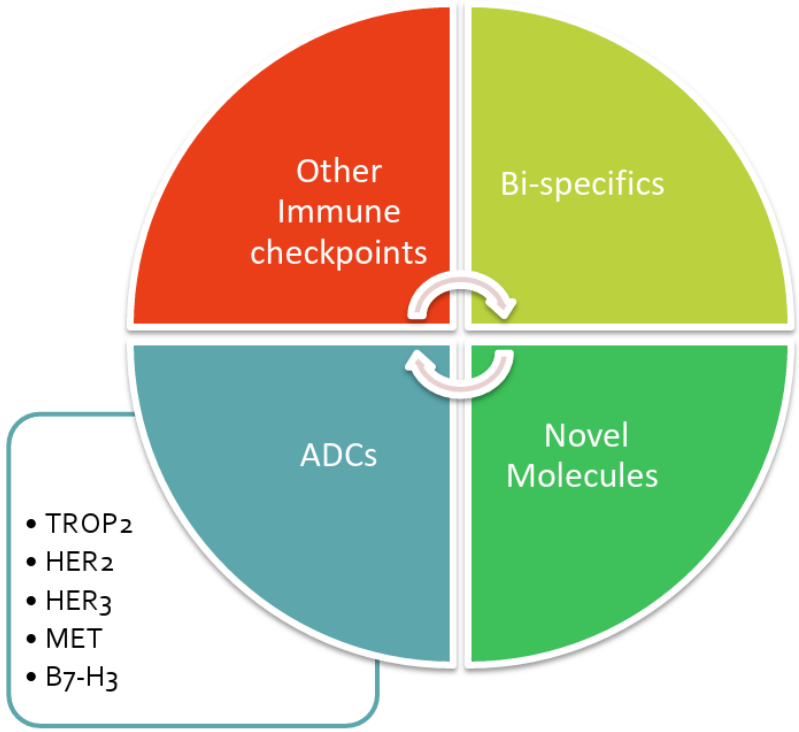
BNT327 + ChT Combo
1L SQ + NSQ, TPS all comers



NCT06767514, NCT05899608, NCT06712316

TREATMENT STRATEGIES BEYOND PD-(L)1





III JORI DE ON

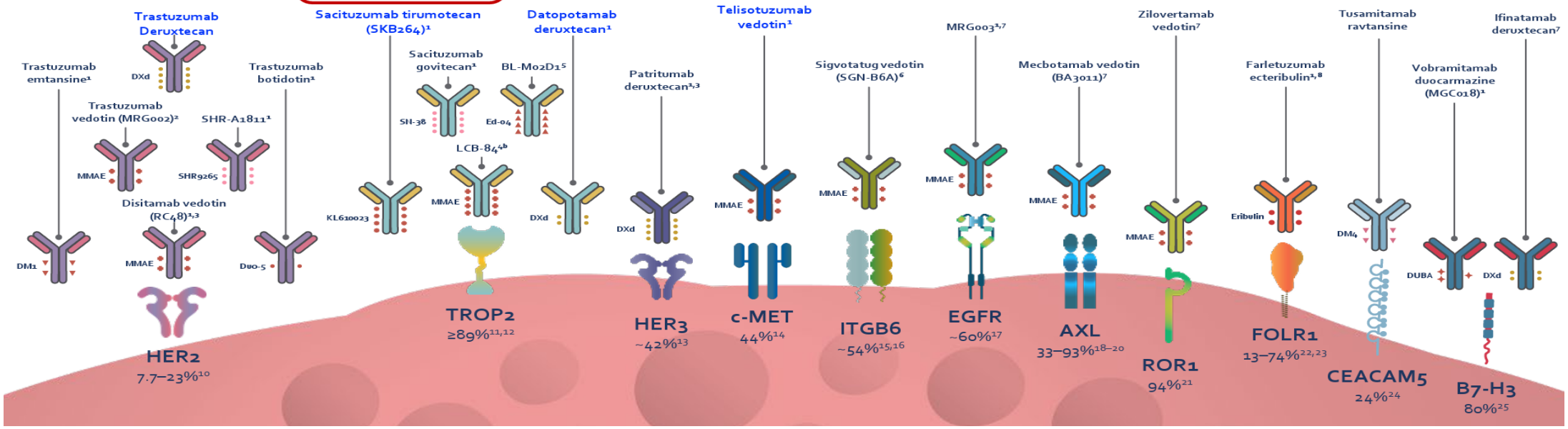
2022: FDA and EMA APPROVED **trastuzumab deruxtecan** (HER2mut)
FDA (HER2 3+)
2025: NMPA approval **trastuzumab rezetecan** (HER2m)

2024: FDA Breakthrough designation for pretreated EGFR+
2025: NMPA approval of **sacituzumab tirumotecan** for EGFR+ NSCLC

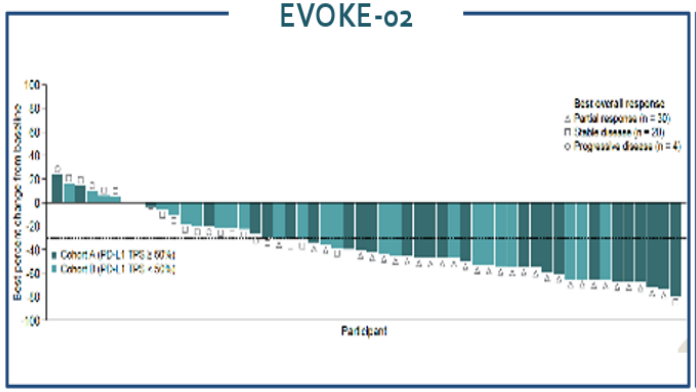
2025: FDA approves **datopotamab deruxtecan** for pretreated EGFR-mutated advanced NSCLC

2025: FDA accelerated approval for **telisotuzumab vedotin** in MET3+

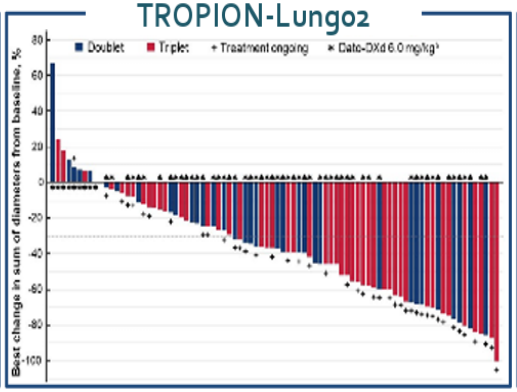
DISCONTINUED **tusamitamab ravtansine**



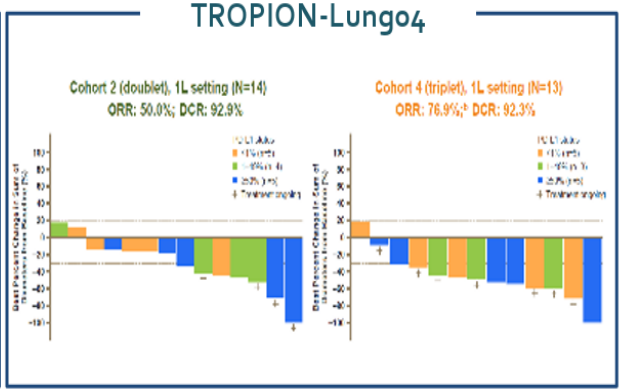
EVOKE-02



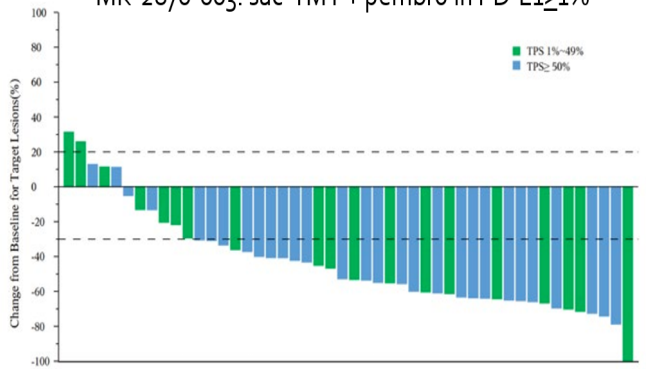
TROPION-Lung02



TROPION-Lung04



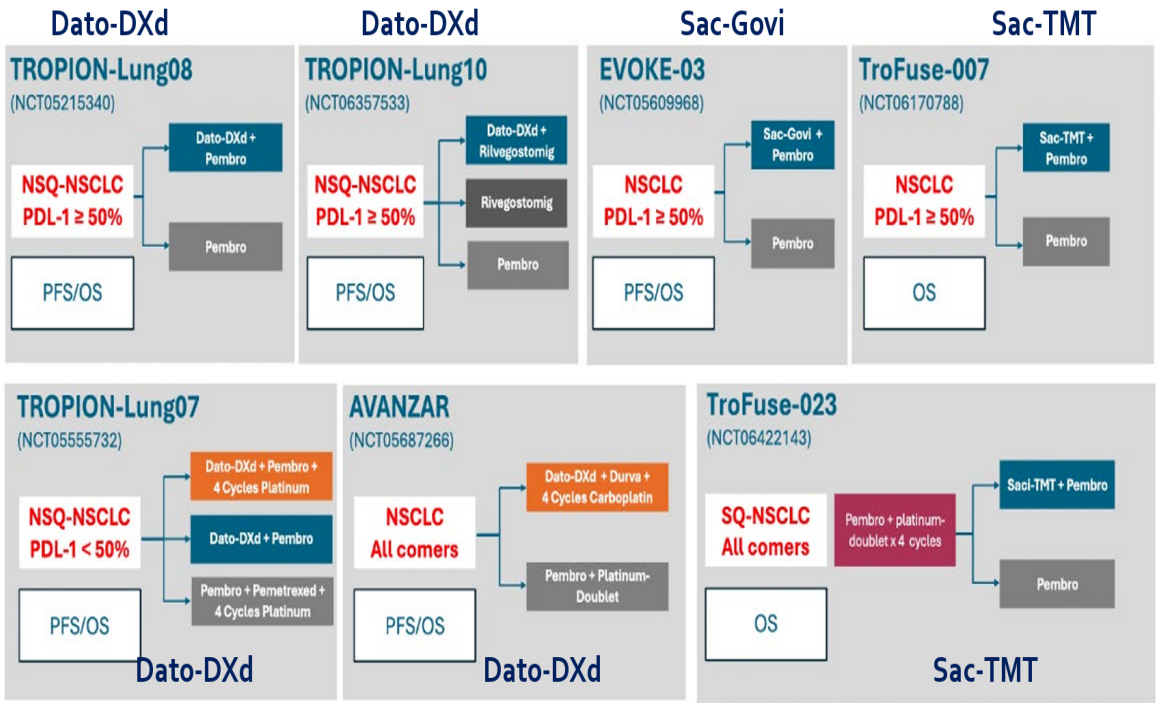
MK-2870-003: sac-TMT + pembro in PD-L1≥1%



Cho B, et al. WCLC 2023; Oral presentation OA05.04; 2. Goto Y, et al. ASCO 2023; Oral presentation 9004; 3. Papadopoulos KP, et al. WCLC 2023; Oral presentation OA05.06. 4. Fang W et al. ESMO 2025, Abstract 1949P

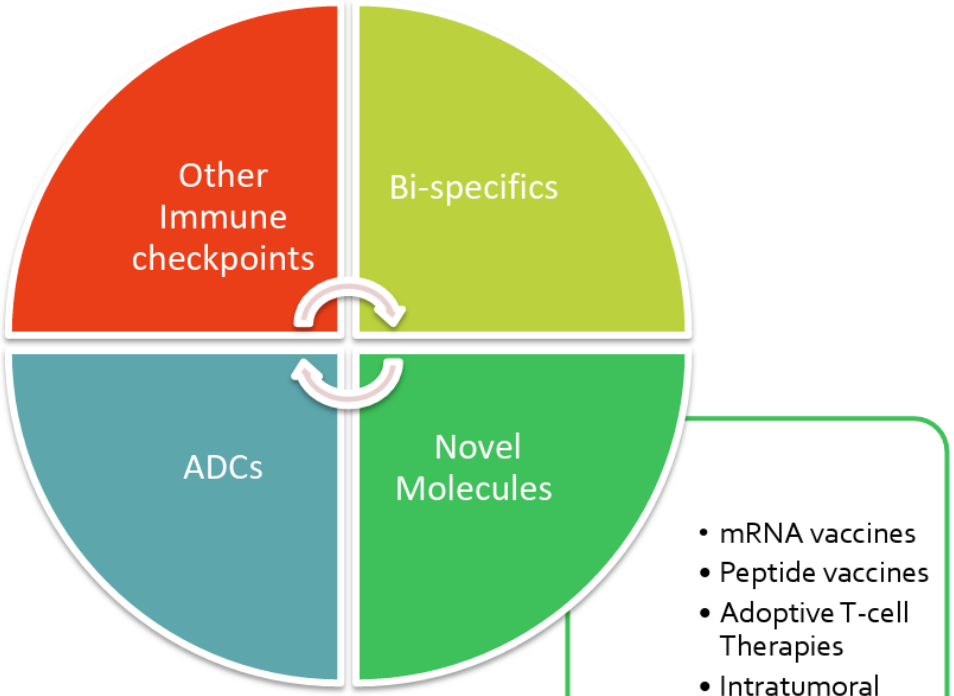
TROP2-DIRECTED ADCS+ ANTI-PD(L)-1 +/-CARBO(CIS)PLATININ 1L

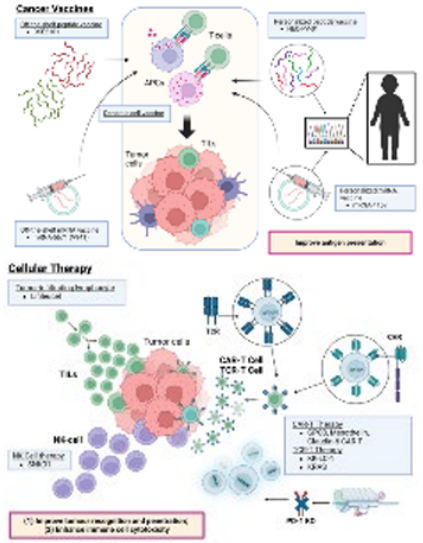
Trial	Combination	Patients	N	ORR
Evoke-02	Saci-Govitecan + Pembro	PD-L1≥50%	30	**69%**
Evoke-02	Saci-Govitecan + Pembro	PD-L1<50%	33	**44%**
TL-04	Dato-DXd + durvalumab	All PD-L1	19	**50%**
TL-04	Dato-DXd + durvalumab + carboplatin	All PD-L1	14	**76.9%**
TL-02	Dato-DXd + pembrolizumab	All PD-L1	42	**54.8%**
TL-02	Dato-DXd + pembro + carbo(cis)platin	All PD-L1	54	**55.6%**
OptiTROP-Lung01	Saci-tirumotecan + tagitanlimab q2w	All PD-L1	63	**77.6%**
2870-003	Saci-tirumotecan + pembrolizumab q6w	PD-L1≥1%	50	**68%**
Keynote 024	Pembrolizumab	PD-L1≥50%	154	**46.1%**
Keynote 189	Carbo(cis)-pemetrexed-pembrolizumab	N-Sq, PD-L1≥50%	132	**62.1%**
Keynote 407	Carbo-(nab)paclitaxel-pembrolizumab	Sq, PD-L1≥50%	73	**64.4%**
Keynote 189	Carbo(cis)-pemetrexed-pembrolizumab	N-Sq, all PD-L1	410	**48.3%**
Keynote 407	Carbo-(nab)paclitaxel-pembrolizumab	Sq, all PD-L1	278	**62.2%**



Levy B, ASCO 2025; Reck M, JCO 2021; Garassino M, JCO 2023; Novello S, JCO 2023; Papadopoulos et al., WCLC 2023; Cho B, WCLC 2023; Fang, ASCO 2024; Zhang, ASCO 2025

TREATMENT STRATEGIES BEYOND PD-(L)1





Peptide-based vaccines

Drug (trial)	TAA	Disease setting
MAGE-A3 (MAGRIT trial)	MAGE-A3	Adjuvant (MAGE-A3+ tumors)
Tecemotide (START trial)	MUC1	Locally advanced (maintenance after chemo-RT)
CIMAvax-EGF	Epidermal Growth Factor	Advanced (maintenance after 1L platinum)

ARTEMIA (NCT06472245)

KEY ELIGIBILITY CRITERIA
- Metastatic squamous and non-squamous NSCLC without known actionable genomic alterations.
- HLA-A2 positive in blood by central laboratory.
- In 2nd line treatment after 1st - line CT-immune checkpoint inhibitor (ICI) with secondary resistance to ICI
- ECOG PS 0 to 1
- No treated or untreated brain metastases

Stratification criteria
- Histology: squamous vs non-squamous
- ECOG performance status: 0 vs 1

R 2:1

N=363

ARM A: OSE2101 5 mg (1 mL) Q3W for 6 sc. inj., then Q8W until end year 1, then Q12W until PD, toxicity or withdrawal of consent & up to 24 months

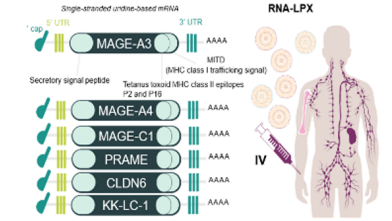
ARM B: DOCETAXEL 75 mg/m² Q3W iv infusion until PD, toxicity or withdrawal of consent

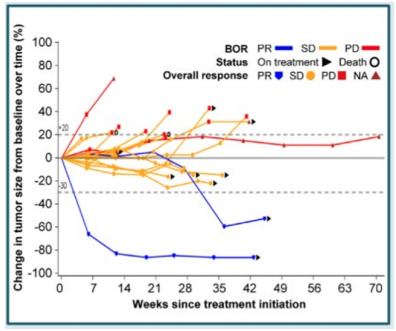
PRIMARY ENDPOINT: Overall Survival

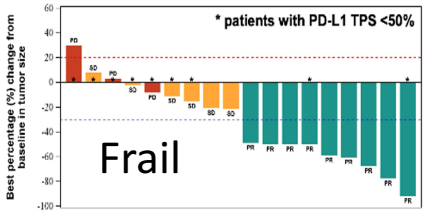
SECONDARY ENDPOINTS:
- Patient Reported Outcomes: QLQ-C30 Physical functioning, Role functioning & Global Health Score
- Time to ECOG PS >1 deterioration

DNA vs RNA vaccines

Preliminary results from LuCa-MERIT-1, a Phase I trial evaluating BNT116, a fixed antigen mRNA vaccine, plus cemiplimab in advanced non-small cell lung cancer after progression on PD-1 inhibition



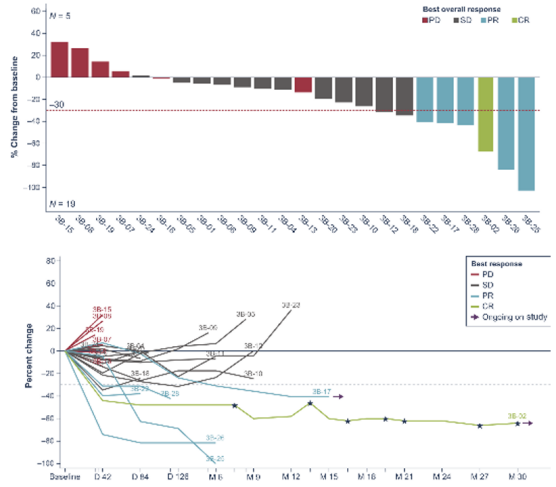




RECIST 1.1, investigator	LuCa-MERIT-1 frail NSCLC patients (N=20)
Best overall response, n (%)	
PR	9 (45.0%)
SD	6 (30.0%)
PD	3 (15.0%)
Missing	2 (10.0%)
ORR (%)	45.0%
DCR (%)	75.0%

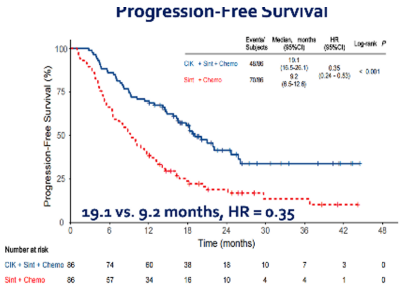
Data cut-off date: March 1, 2025

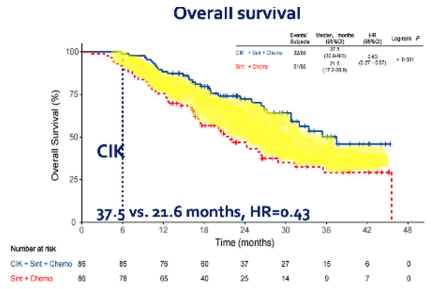
Adoptive Cell Therapies: TILs, CARs, TCRs



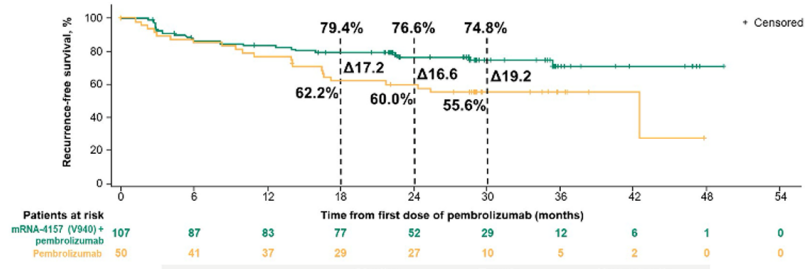
Lifileucel, an autologous TILs monotherapy in resistance to ICIs

Chemo/ICI vs chemo/ICI + CIK Administration





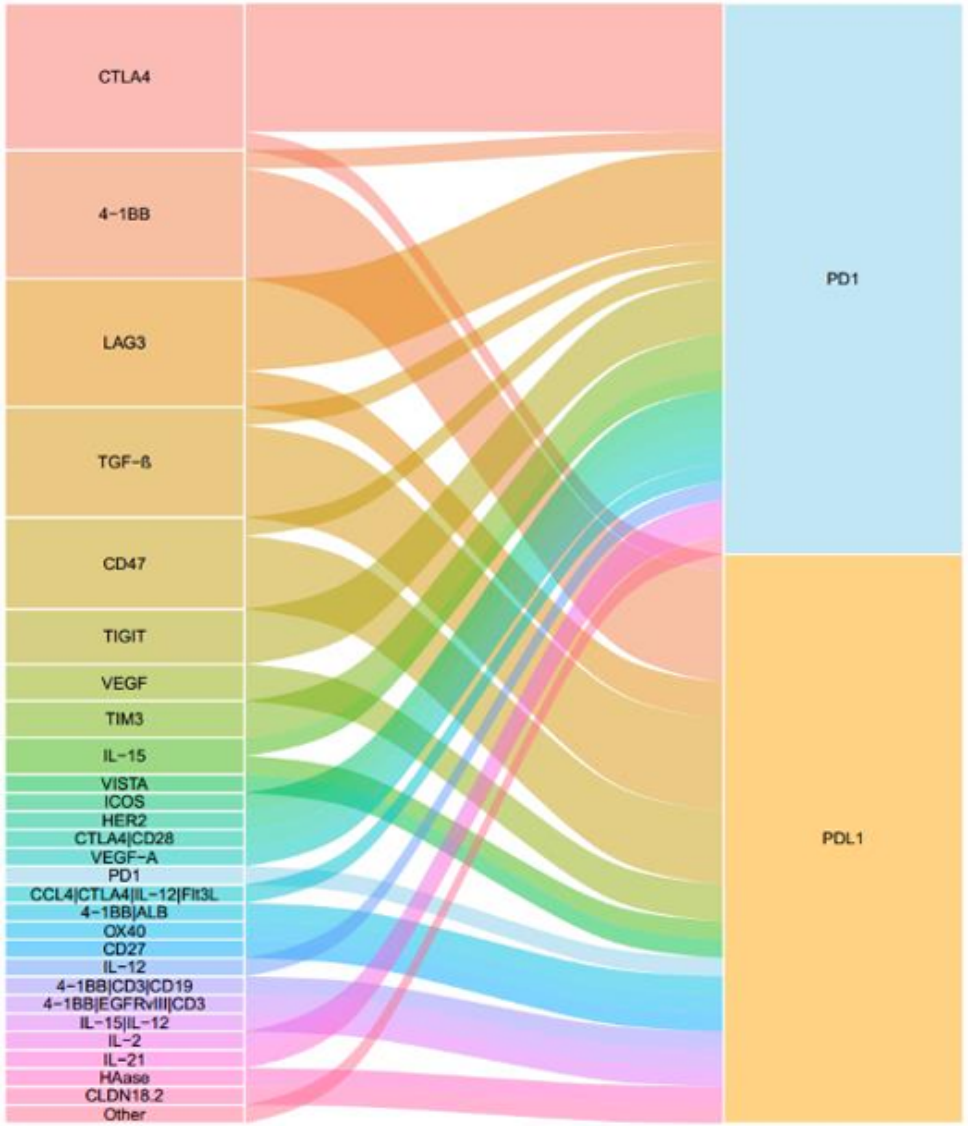
mRNA-4157 (V940) in early melanoma

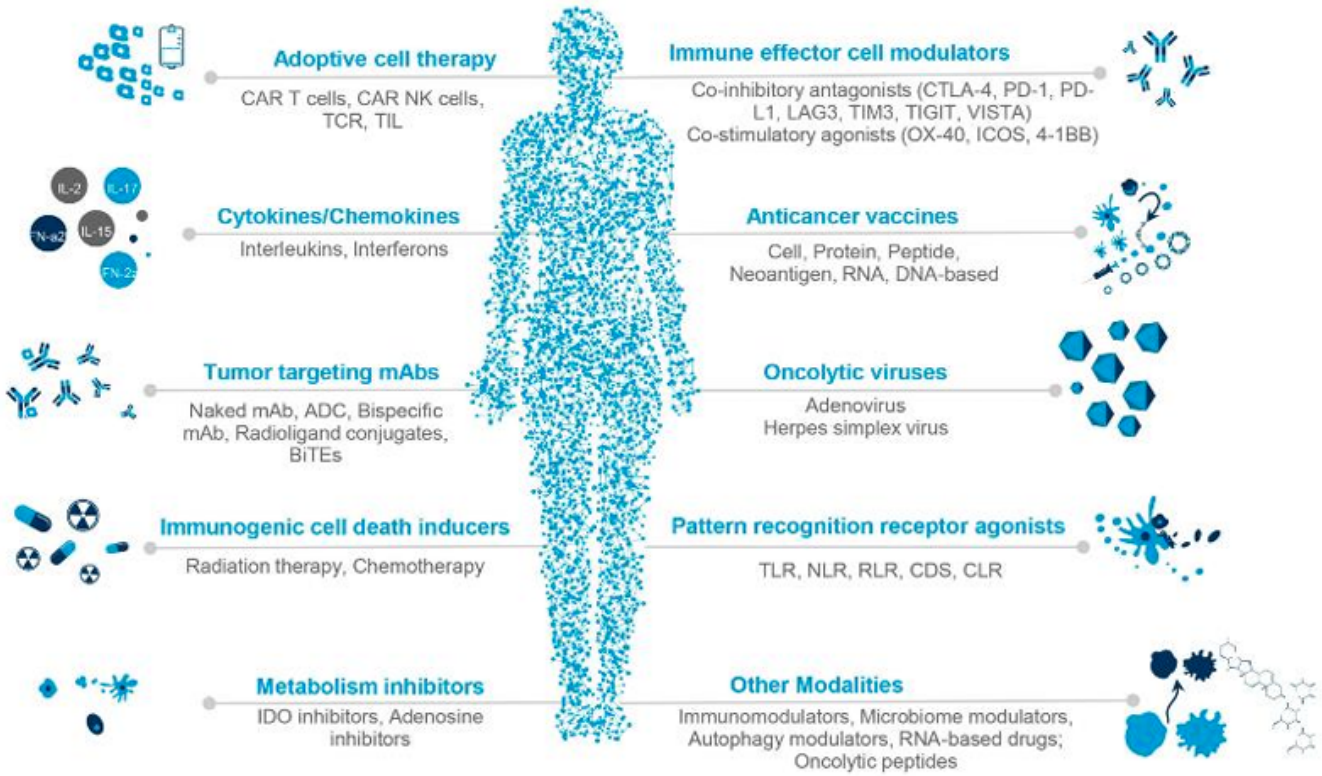


	Median (95% CI), months	Events, % (n/N)	Hazard ratio (95% CI)[a]
mRNA-4157 (V940) + pembrolizumab	NE	23.4 (25/107)	0.510 (0.288–0.906) P = 0.019[b]
pembrolizumab	42.51 (16.59–NE)	44.0 (22/50)	

V940 (mRNA-4157) is a novel individualized neoantigen therapy (INT) that encodes up to 34 personalizedneoantigens

Dingzhi Huang et al. ESMO-ASIA 2025; Schoenfeld, Cancer Discovery, 2024; Khattak A et al. Presented at AACR 2023 ; Weber, The Lancet, 2024; Dziadzuisko, AACR 2025; Atmaca, SITC 2024; Atmaca, SITC 2024; Atmaca, SITC 2024

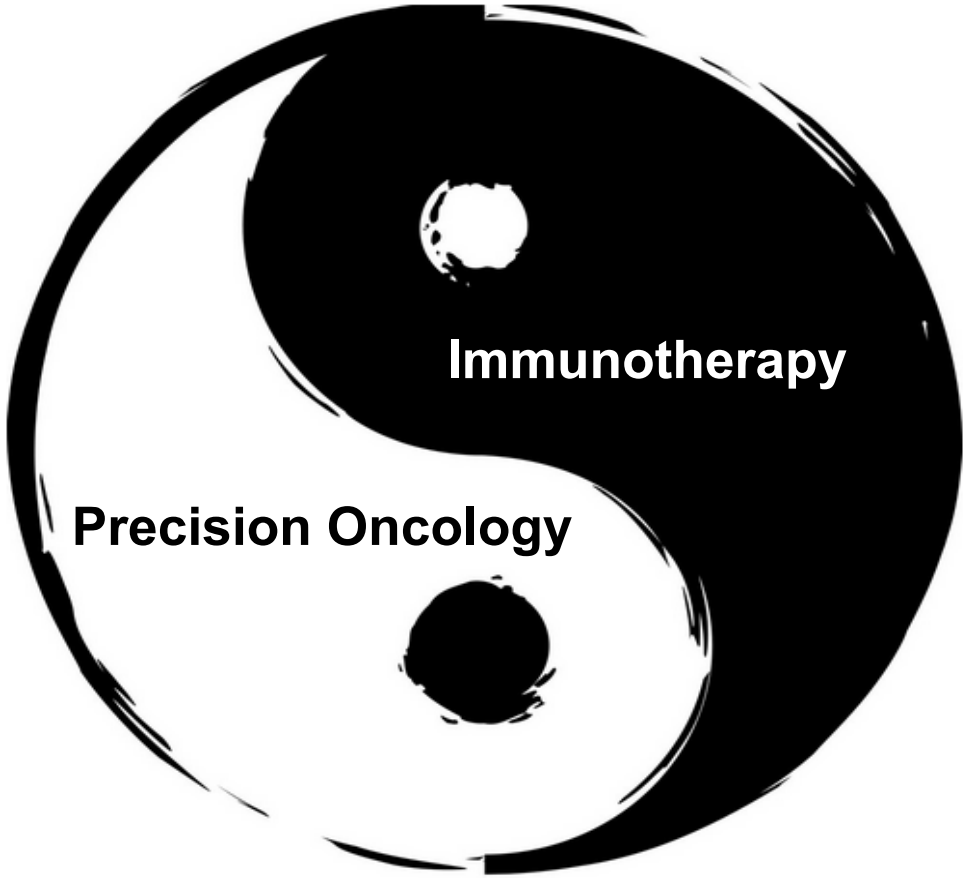




Franklin, JITC 2022

ONGOING FRONTLINE IO-BASED PHASE III TRIALS IN NON-AGA

Trial name	Experimental arm	Comparator am	Setting	Biomarker	Primary End-Point
ZEAL-1	Pembrolizumab + P-chemo + Niraparib	Pembrolizumab + P-chemo	1L NSq & Sq	PD-L1 all comers	PFS, OS
HARMONi-3	Ivonescimab+ P-chemo	Pembrolizumab+ P-chemo	1L NSq & Sq	PD-L1 all comers	PFS, OS
HARMONI-7	Ivonescimab	Pembrolizumab	1L NSq & Sq	PD-L1 ≥ 50%	PFS, OS
BNT327 NSCLC	BNT327+ P-chemo	Pembrolizumab+ P-chemo	1L NSq & Sq	PD-L1 all comers	PFS, OS
TROPION-Lung07	Dato-Dxd + Pembrolizumab +/- P-chemo	Pembrolizumab +/- P-chemo	1L NSq	PD-L1 < 50% with or without AGA	PFS, OS
TROPION-Lung08	Dato-DXd + Pembrolizumab	Pembrolizumab	1L NSq & Sq	PD-L1 ≥50%	PFS, OS
AVANZAR	Dato-DXd + Durva + Carbo	Pembrolizumab + P-chemo	1L NSq & Sq	PD-L1 all comers	PFS, OS
EVOKE-03	Sacituzumab govitecan + Pembrolizumab	Pembrolizumab	1L Nsq & Sq	PD-L1 ≥50%	PFS, OS
TROPION-Lung010	Dato-DXd + Rilvegostomig	Pembrolizumab	1L Nsq	PD-L1 ≥50%	PFS, OS
MK-2870-007	Sacituzumab Tirumotecan + Pembrolizumab	Pembrolizumab	1L Nsq	PD-L1 ≥50%	OS
SKB264	Sacituzumab Tirumotecan + Pembrolizumab	Pembrolizumab	1L NSq & Sq	PD-L1 ≥1%	PFS
eVOLVE-Lung02	Volrustomig + P-chemo	Pembrolizumab + P-chemo	1L NSQ & Sq	PD-L1 < 50%	PFS, OS
ARTEMIDE-Lung03	Rilvegostomig + P-chemo	Pembrolizumab + P-chemo	1L NSQ & Sq	1L NSQ	PFS, OS
RELATIVITY-1093	Nivolumab + Relatlimab + P-chemo	Pembrolizumab + P-chemo	1L NSQ	PD-L1 ≥1%	OS PD-L1 1-49%



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