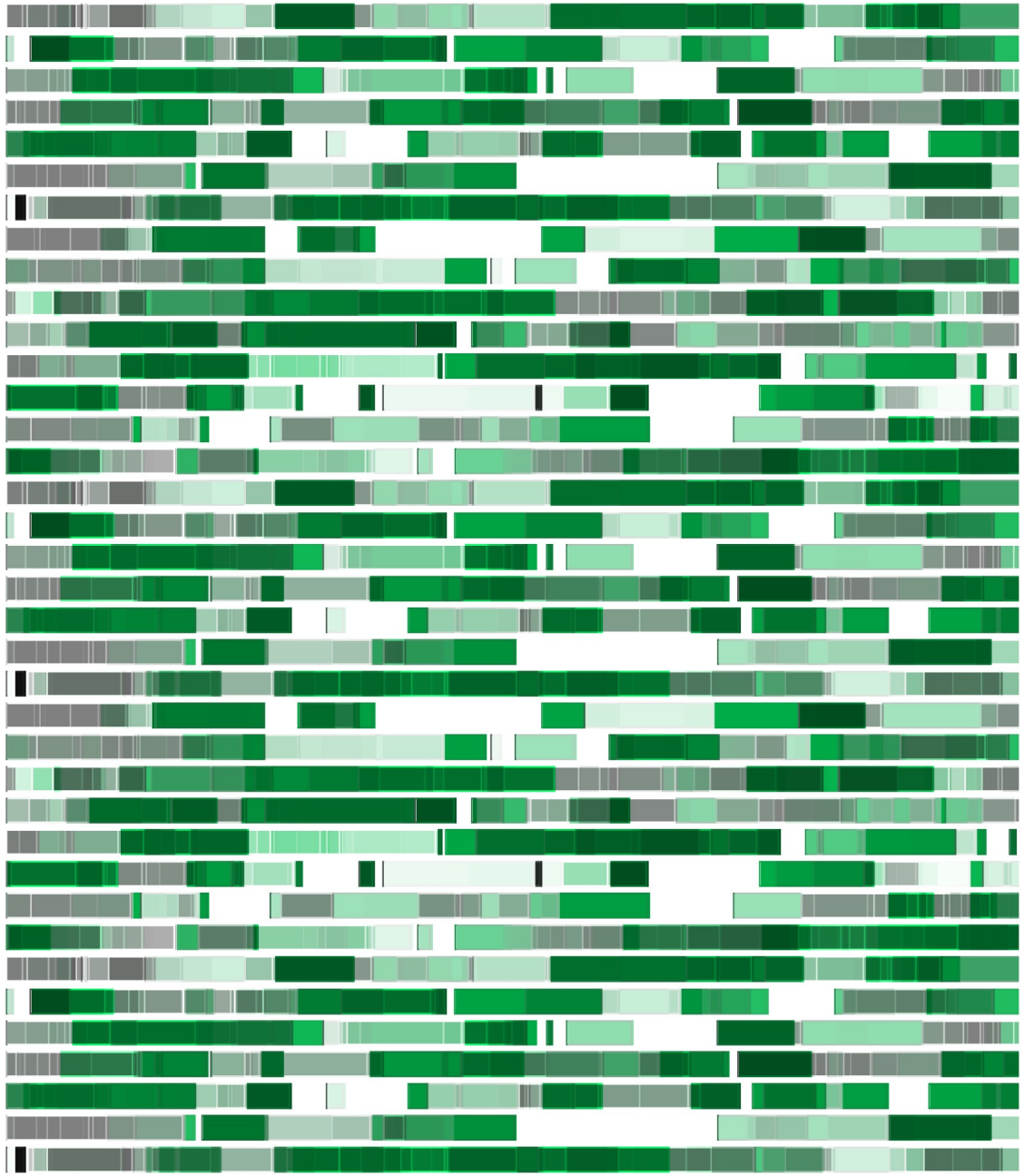
III JORNADA TRASLACIONAL DE ONCOLOGÍA DE PRECISIÓN:
A TRAVÉS DE LAS VÍAS DE SEÑALIZACIÓN
SEVILLA, 12 Y 13 DE FEBRERO DE 2026

Ventajas e inconvenientes de la neoadyuvancia frente a la adyuvancia en el CPNM (Cáncer de Pulmón No Microcítico) estadios iniciales

Enric Carcereny i Costa, MD, MS
Coordinator of Thoracic, Brain, and Sarcoma Tumors Group
Medical Oncology Department, Catalan Institute of Oncology (ICO Badalona); B-ARGO/CARE-IGTP

Organizador por:
HENDERE HEALTHCARE



Disclosures

- **Advisory / Consultancy :** AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, MSD, Novartis, Roche, Takeda, Pfizer, Johson&Johnson

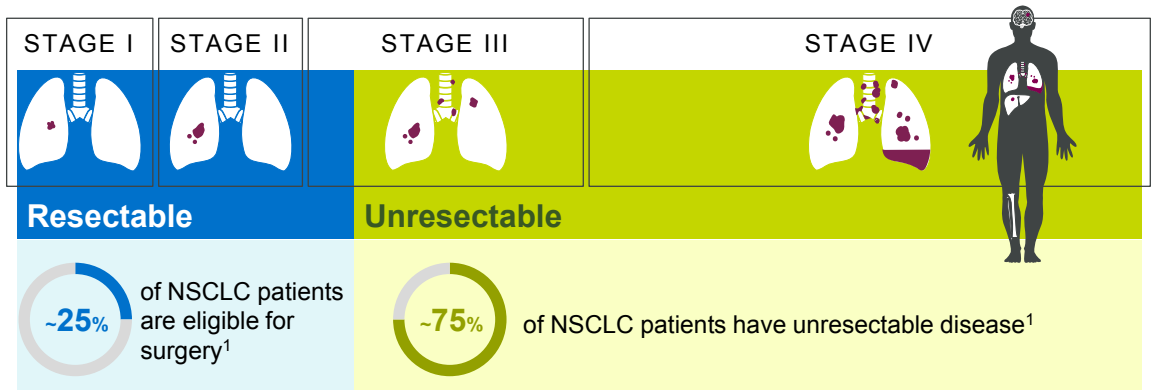
- **Speaker Bureau / Expert testimony:** AstraZeneca, Boehringer Ingelheim, Bristol-Myers Squibb, MSD, Novartis, Pfizer, Roche, Takeda, Pierre-Fabre, Regeneron

- **Travel / Accommodation / Expenses** :Bristol-Myers Squibb, Pfizer, Roche, Takeda, Astra Zeneca.

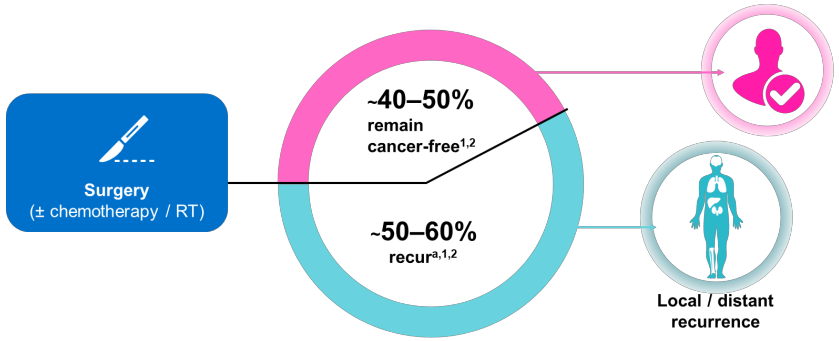
Introduction

Locally Advanced Lung Cancer: Where Surgery Alone Falls Short

NSCLC Staging and Surgical Eligibility

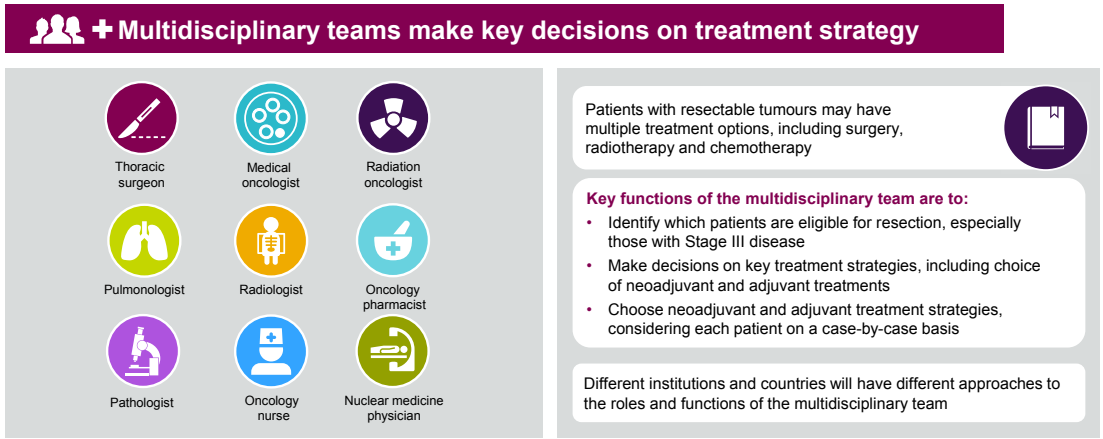


Recurrence Rates After Initial Treatment of Resectable NSCLC

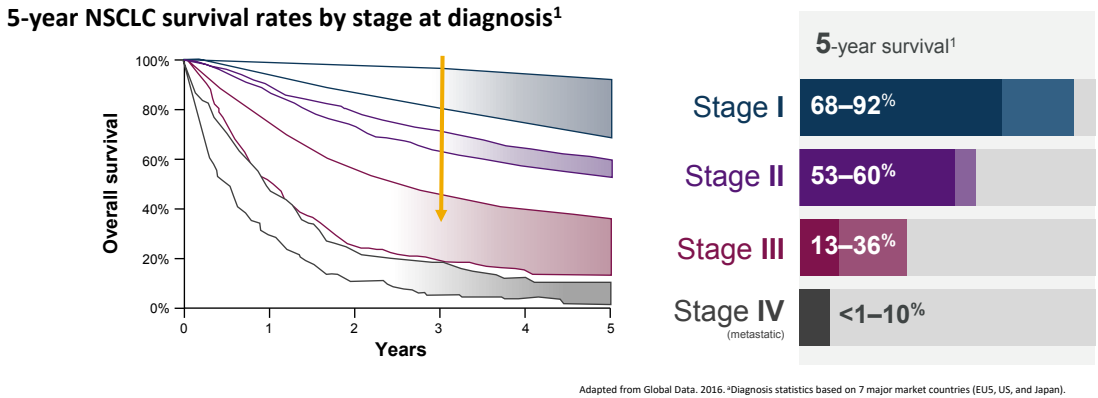


After initial treatment, more than half of patients with resectable NSCLC experience recurrence within 5 years

Role of the Multidisciplinary Team in Treatment Decisions



Five-Year Survival Rates by NSCLC Stage at Diagnosis



Adapted from Global Data. 2016. [a]Diagnosis statistics based on 7 major market countries (EU5, US, and Japan).

Deslypere G. Ther Adv Med Oncol. 2018 Postmus PE Ann Oncol. 2017 Goldstraw P J Thorac Oncol 2016 Boyd JA J Thorac Oncol 2010 McMurry TL Ann Surg 2018. Sekihara K Eur J Cardiothorac Surg 2017

Introduction

Neoadjuvant

Strengths

Activation of the immune system (immune priming) while the tumor is still present

Early control of micrometastatic disease

Assessment of pathological response (pCR/MPR) at surgery

Potential reduction in tumor stage (downstaging)

Efficacy ?

Weaknesses

Risk of preoperative attrition, with 16–22% of patients in clinical trials failing to reach surgery due to disease progression or treatment-related toxicity

Potential delays in surgical scheduling

Adjuvant

Strengths

Treatment is administered after confirming a complete R0 resection and is based on accurate pathological staging following surgery.

Weaknesses

Low treatment adherence (many patients do not initiate or complete all cycles due to postoperative recovery)

Delayed initiation of systemic therapy against residual disease.

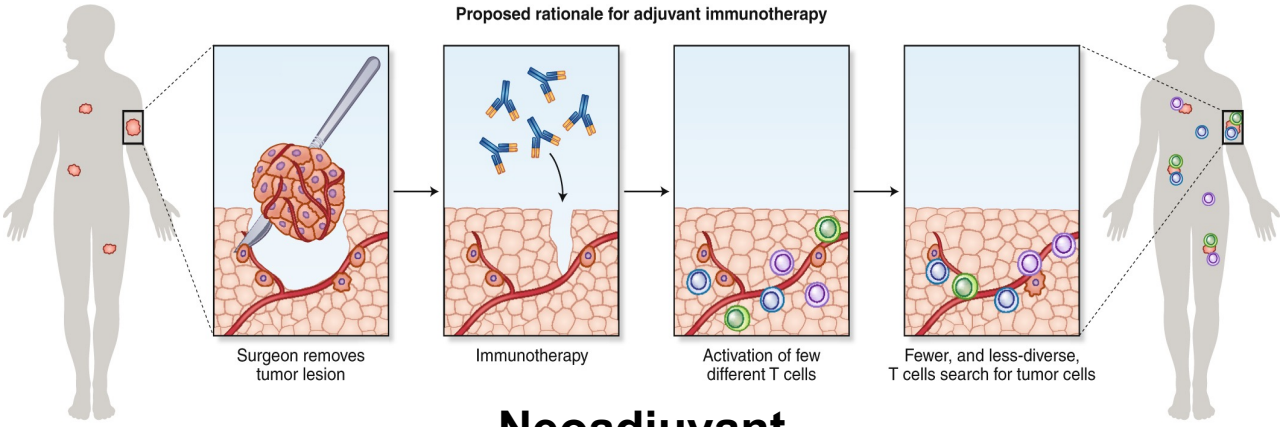
Cost

Outline

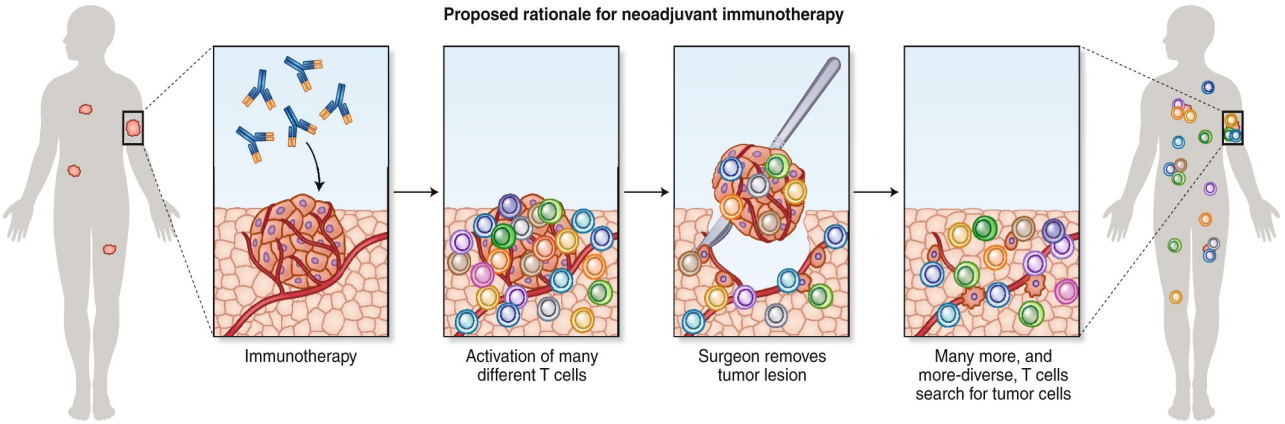
1. **Biological Advantages:** Immune activation and systemic control
2. **Clincal Efficacy Signal:** Efficacy and pCR/MPR as a surrogate of Benefit
3. **Risks and Attrition:** Progression or toxicity preventing surgery
4. **Treatment Delivery and Adherence:**Neoadjuvant feasibility/ Adjuvant non-compliance
5. **Clinical Trade-offs:**Timing of systemic therapy/ Cost and real-world implications

Biological Advantages: Immune activation and systemic control

Adjuvant



Neoadjuvant

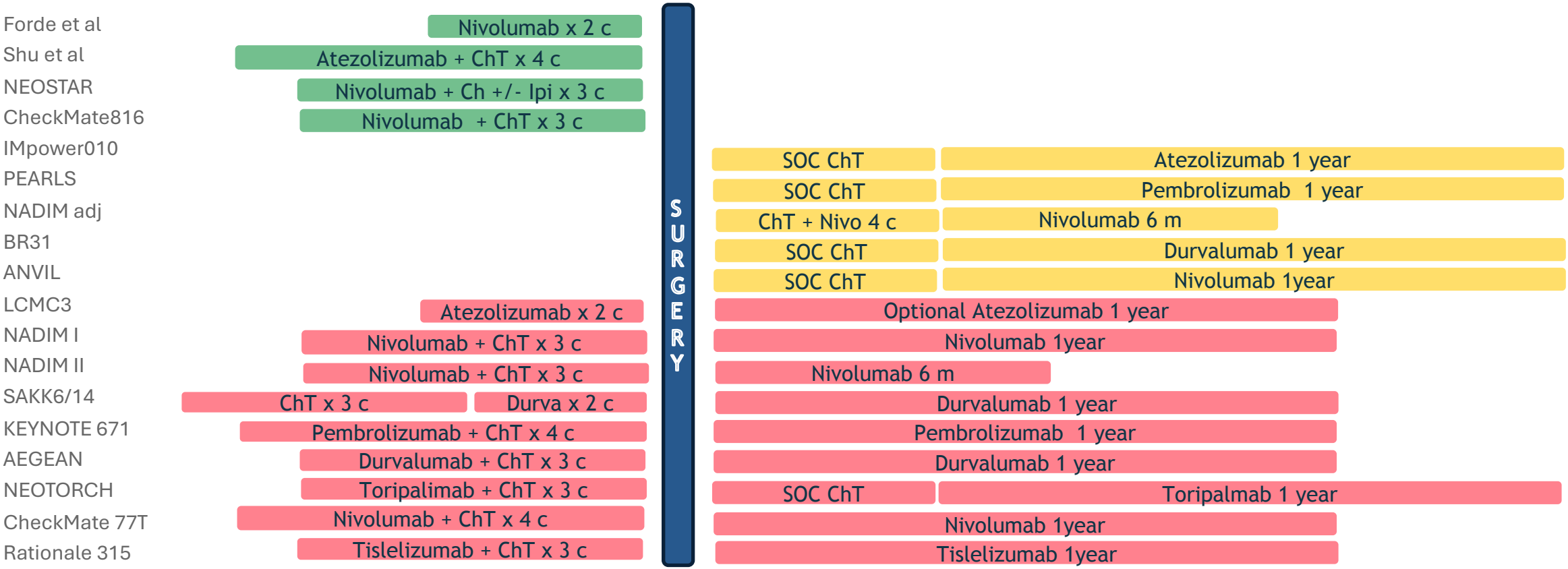


Versluis J et al, *Nat Med* 2020

- Robust activation of immune system prior to surgery (tumor neoantigen burden, low clonal resistance)[1,2]
- Neoadjuvant CT plus ICIs: Possible maximal response upfront and assessment of pathologic response to guide adjuvant therapy[1,2]
- Rapid readout of activity based on surrogate endpoints (MPR, pCR)[3]; translational analyses on pre- and post-therapy samples
- Perioperative ICIs: Treatment throughout the surgical setting → potential enhanced micrometastatic disease killing and antitumor immunity

Clincal Efficacy Signal: Efficacy and pCR/MPR as a surrogate of Benefit

Summary of Key Neoadjuvant, Perioperative, and Adjuvant Studies in Operable NSCLC



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Clincal Efficacy Signal: Efficacy and pCR/MPR as a surrogate of Benefit

What Works: Efficacy Data from Modern Resectable NSCLC Trials

Trial	Setting	Drug	n	Primary endpoint	STAGES	HR (EFS/DFS)	Median EFS/DFS (ICI vs placebo)	pCR	OS
CM-816	Neoadj	Nivolumab	358	EFS /pCR	IB-IIIA	0.63 (0.43-0.91) p=0.005	43.8 vs 18,4 m	24% vs 2.2%	65.4% vs 55% (5 y)
KN-671	Periop	Pembrolizumab	797	EFS/OS	II-IIIB	0.58 (0.46-0.72) p < 0.00001	47.2 vs 18.3 m	18,1% vs 4%	67.1% vs 51.5% (4 y)
AEGEAN	Periop	Durvalumab	802	EFS/pCR	II-III	0.68 (0.53-0.88) p= 0.004	NR vs 30 m	17,2% vs 4.3%	Not reported
CM-77T	Periop	Nivolumab	735	EFS	IIA-IIIB	0.58 (0.42-0.81) p=0.00025	NR vs 18.4 m	25,3% VS 4.7%	Not reported
NEOTORCH	Periop	Toripalimab	501	EFS/MPR	II-IIIB	0.40 (0.28–0.57) p < 0.001	NR vs 15.1 m	24,8% vs 1%	81% 2 y
RATIONALE 315	Periop	Tislelizumab	453	MPR	II-IIIA	0.56 (0.40–0.79) p=0.0003		41% vs 6%	89% 2 y
IMpower010	Adj	Atezolizumab	1269	DFS	IB-IIIA	(Stage IB–IIIA): 0.81(0.67, 0.99)p=040	65,6 vs 47,8 m	NA	ITT 79% 3 y
PEARLS	Adj	Pembrolizumab	1177	DFS	II-IIIA	0.76 (0.63–0.91) p= 0.0014	53.6 VS 42 m	NA	2% (1.5 y)
BR31	Adj	Durvalumab	1360	DFS PDL1 >25%	IB-IIIA	PD-L1 25%: 0.935 (0.70-1.247)	-	NA	Not reported

Wakelee N Engl J Med, 2023 Cascone N Engl J Med, 2024 Lu JAMA, 2024 Yue Ann Oncol, 2023 Yue Ann Oncol, 2024 Felip Lancet, 2021 O'Brien Lancet Oncol, 2022 Goss Ann Oncol, 2024 Awad MM Ann Oncol. 2025 Heymach JV N Engl J Med. 2023 Forde PM N Engl J Med. 2022

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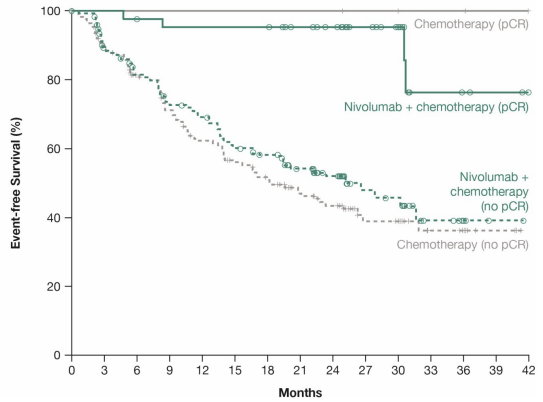
Clincal Efficacy Signal: Efficacy and pCR/MPR as a surrogate of Benefit

Subgroup Analyses by pCR: EFS by pCR status

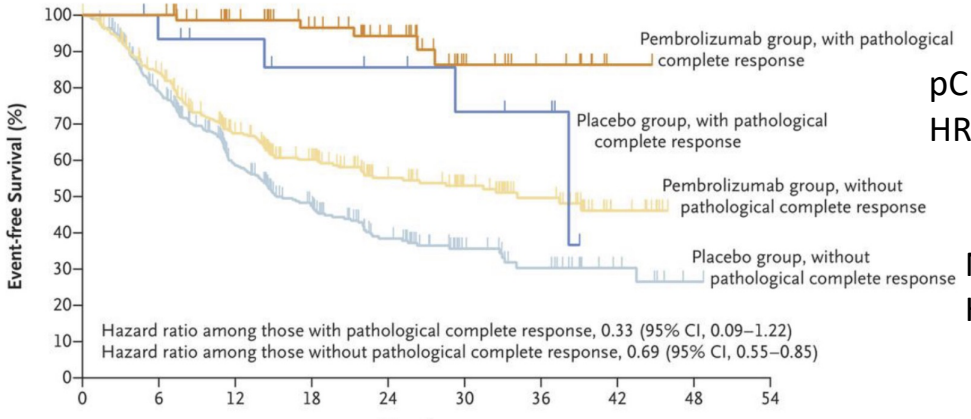
CheckMate 816 (neoadjuvant)



pCR:
HR not calculated

No pCR:
HR 0.84

KEYNOTE-671 (perioperative)

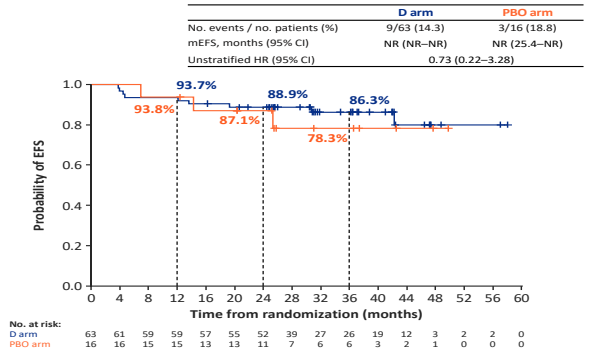


pCR:
HR 0. 33

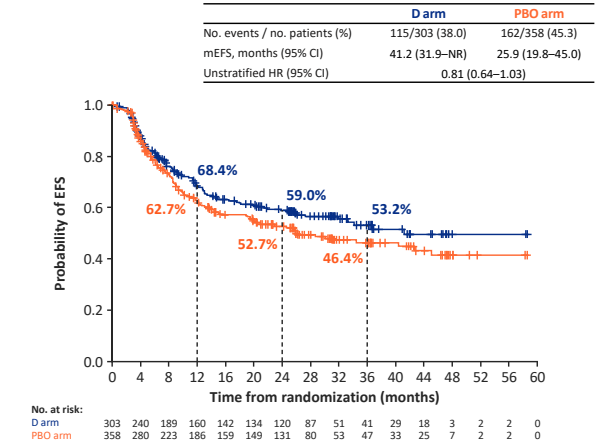
No pCR:
HR 0.69

AEGEAN (perioperative)

pCR



No pCR

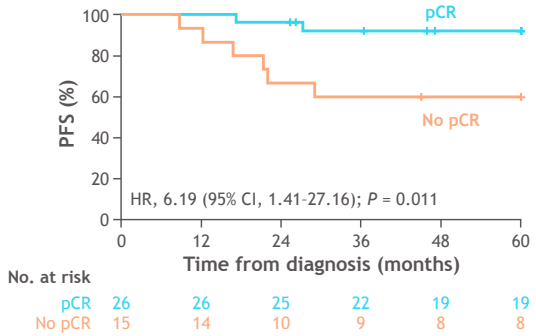


Wakelee et al NEJM 2023; Forde et al NJEM 2022 Heymach JV WCLC2024

Clincal Efficacy Signal: Efficacy and pCR/MPR as a surrogate of Benefit

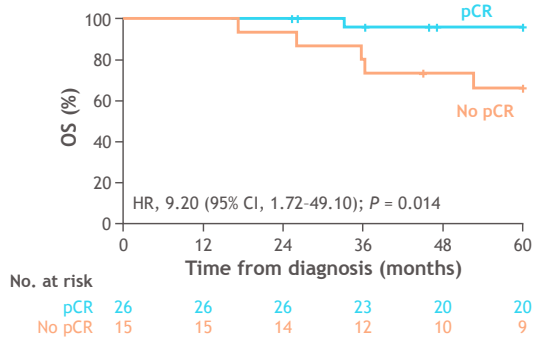
PFS and OS by pathologic response in resected patients NADIM II

PFS



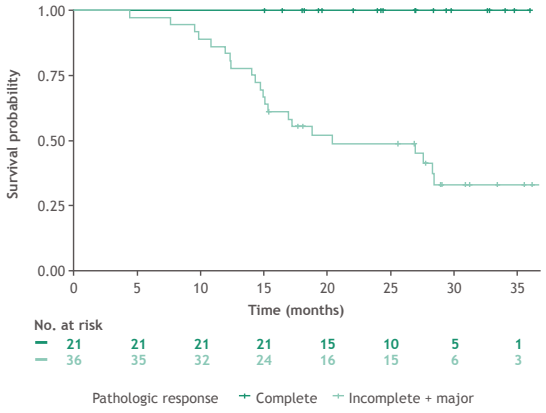
5-year PFS rates
- pCR: 92.0% (95% CI, 70.5-97.9)
- No pCR: 60.0% (95% CI, 31.8-79.7)

OS

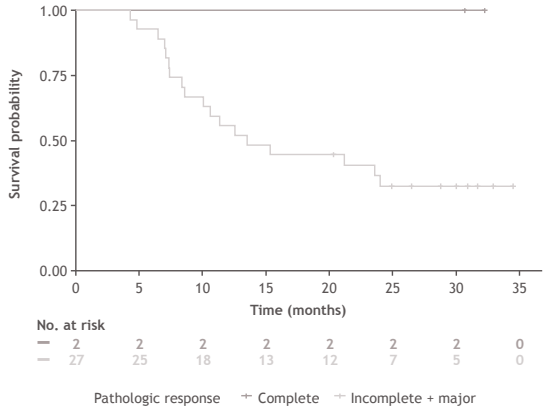


5-year OS rates
- pCR: 95.8% (95% CI, 73.9-99.4)
- No pCR: 66.0% (95% CI, 36.5-84.3)

NIVO + chemo



Chemo



Adapted with permission.

pCR is the most critical prognostic factor, with dramatic improvements in both PFS and OS.

Achieving pathological complete response should be a primary treatment goal

The treatment comparison suggests modest differences between regimens, but pCR status appears more impactful than the specific treatment approach

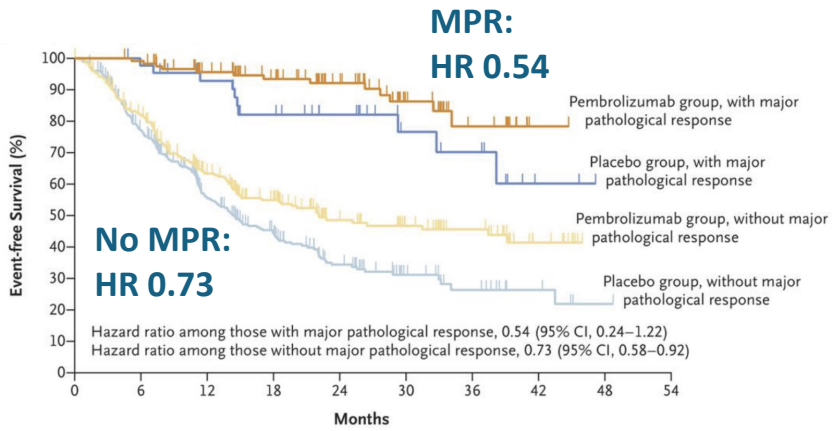
These findings support pCR as a valid surrogate endpoint for long-term outcomes in neoadjuvant therapy

Provencio M J Clin Oncol. 2022 Sep 1;40(25):2924-2933

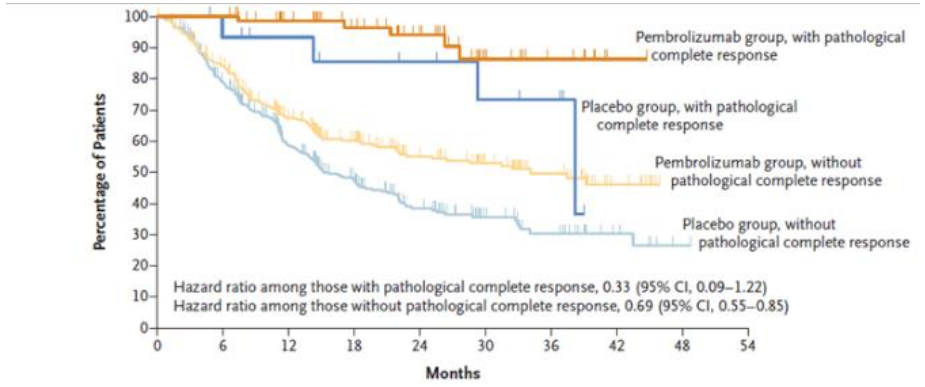
Clincal Efficacy Signal: Efficacy and pCR/MPR as a surrogate of Benefit

Tailoring Treatment: Subgroup Analyses by MPR

KEYNOTE-671



No. at Risk										
With major pathological response										
Pembrolizumab group	120	117	99	79	60	30	15	1	0	0
Placebo group	44	42	36	28	22	12	10	2	0	0
Without major pathological response										
Pembrolizumab group	277	213	137	93	57	42	27	10	0	0
Placebo group	356	252	147	96	52	26	14	7	1	0



No. at Risk										
With pathological complete response										
Pembrolizumab group	72	72	59	46	33	15	8	1	0	0
Placebo group	16	14	12	10	9	5	4	0	0	0
Without major pathological response										
Pembrolizumab group	325	258	177	126	84	57	34	10	0	0
Placebo group	384	280	171	114	65	33	20	9	1	0

mPR was 30.2% (95% CI, 25.7-35.0) in the pembrolizumab group and 11.0% (95% CI, 8.1-14.5) in the placebo group (difference, 19.2; 95% CI, 13.9-24.7; P<0.0001).

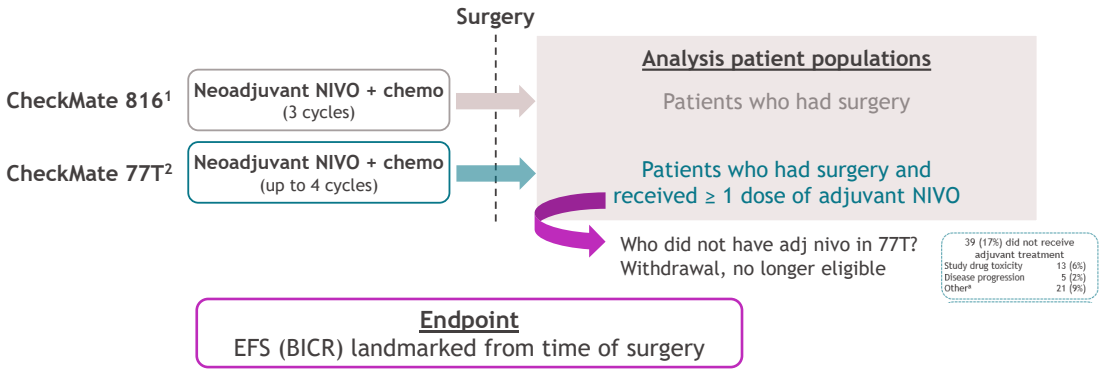
Pathological complete response occurred in 72 subjects (18.1%; 95% CI, 14.5-22.3) in the pembrolizumab group and in 16 subjects (4.0%; 95% CI, 2.3-6.4) in the placebo group (difference, 14.2; 95% CI, 10.1-18.7; P<0.001).

Spicer JD Lancet 2024

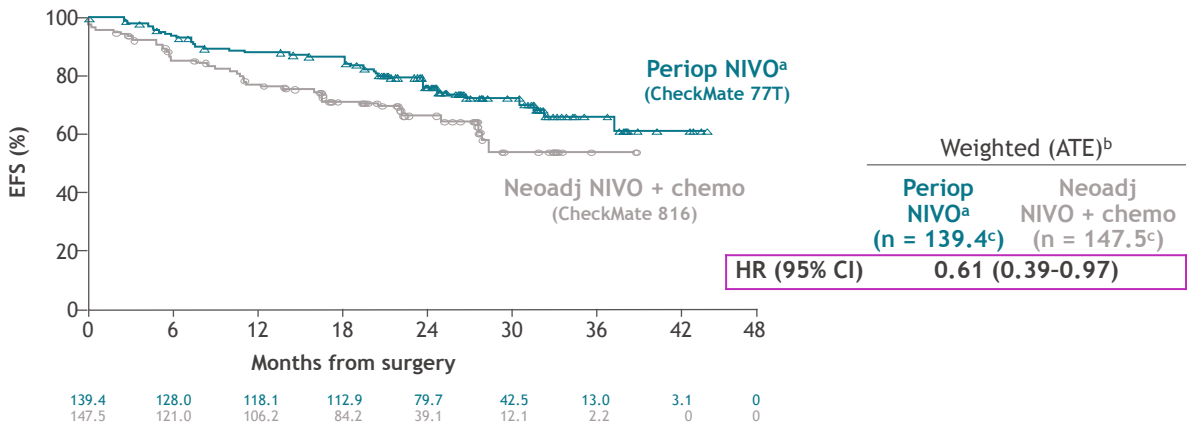
Clincal Efficacy Signal: Efficacy and pCR/MPR as a surrogate of Benefit

Individual Patient Level Analysis of CM816 and CM77T

Perioperative NIVO vs Neoadjuvant NIVO + chemo



EFS (BICR) from definitive surgery



	Weighted (ATE)[b]	
	Periop NIVO[a] (n = 139.4[c])	Neoadj NIVO + chemo (n = 147.5[c])
HR (95% CI)	0.61 (0.39-0.97)	

- HR (95% CI): ATT[d] weighted analysis, 0.56 (0.35-0.90); unweighted analysis, 0.59 (0.38-0.92)

Baseline characteristics: analysis populations

	Unweighted	
	Perioperative NIVO (n = 139), %	Neoadjuvant NIVO + chemo (n = 147), %
Age < 65 years	48	52
Male	73	69
Asian	27	50
ECOG PS ≥ 1	33	25
Disease stage		
Stage IB-II	35	37
Stage III non-N2	24	16
Stage III N2	40	47
Squamous NSCLC	50	46
Current/former smoker,[b]	94	90
Tumor PD-L1 expression ≥ 1%	58	50

- In lieu of a head-to-head trial, exploratory propensity score weighting analyses (ATTa and ATEb) were performed to allow simplified reproduction of a randomized trial by adjusting for clinically relevant baseline demographics and disease characteristicsc between study populations and reducing the confounding effects of these factors
- Median duration of follow-upd: 29.5 months (CheckMate 816) and 33.3 months (CheckMate 77T)

Approximately 40% reduction in risk of disease recurrence or death after surgery was observed in patients who received ≥ 1 dose of adjuvant NIVO following neoadjuvant NIVO + chemo treatment and surgery compared with those who did not receive adjuvant NIVO

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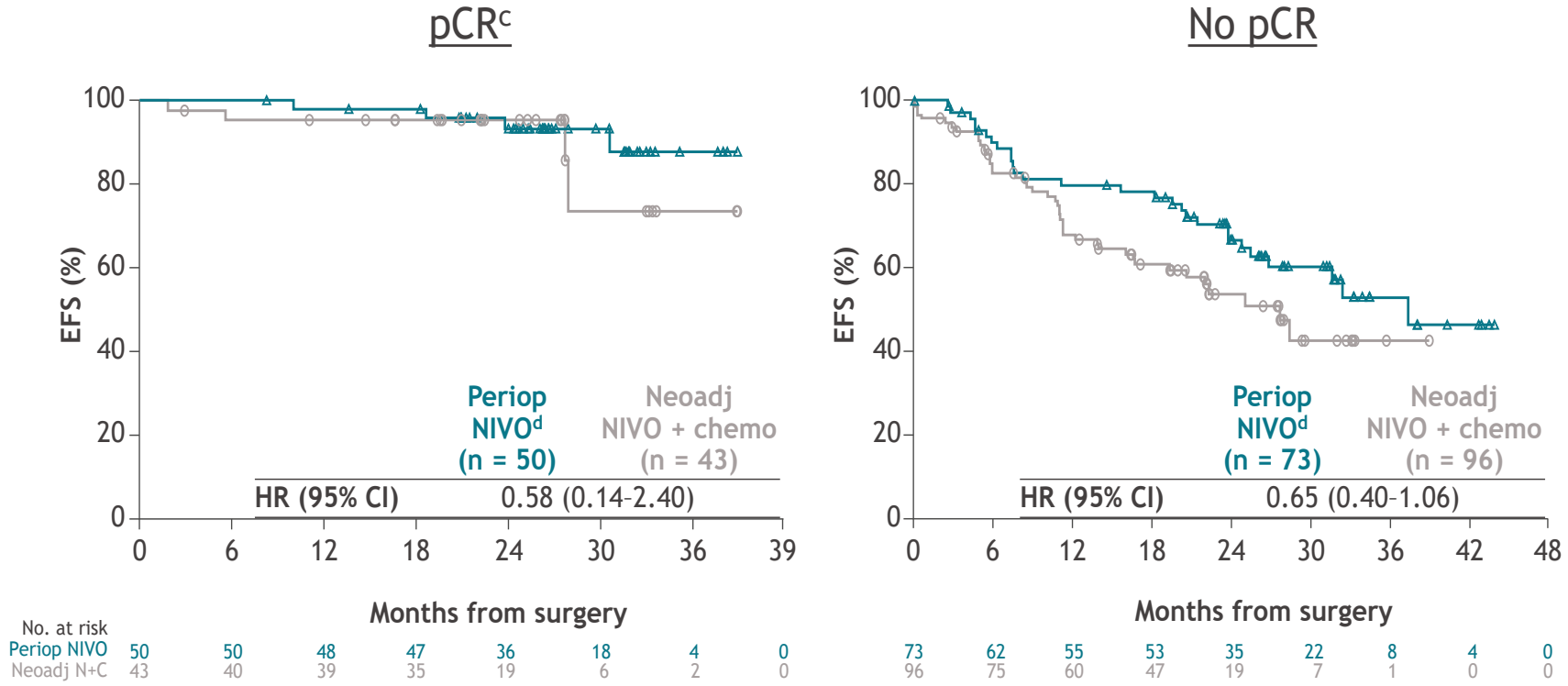
Clincal Efficacy Signal: Efficacy and pCR/MPR as a surrogate of Benefit

Individual Patient Level Analysis of CM816 and CM77T



Among patients without pathological complete response, we observe a decline in EFS over time in both arms.

EFS drops to approximately 40-45% by 48 months in both groups.

The hazard ratio is 0.65 (95% CI: 0.40-1.06), showing a trend favoring perioperative NIVO, though not statistically significant

Median follow-up: CheckMate 816, 29.5 months; CheckMate 77T, 33.3 months. [a]Patients with non-evaluable pCR status were excluded. [b]Unweighted analyses.
[c]pCR rates in this analysis population: perioperative NIVO, 40.7%; neoadjuvant NIVO + chemo, 30.5%. [d]Includes only patients who received ≥ 1 dose of adjuvant NIVO.

In patients achieving pathological complete response, both treatment arms show excellent outcomes with EFS remaining above 85% at 39 months.
The hazard ratio is 0.58 with a 95% confidence interval of 0.14 to 2.40, suggesting no significant difference between groups.
This demonstrates that regardless of treatment approach, achieving pCR is associated with favorable prognosis.

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Clincal Efficacy Signal: Efficacy and pCR/MPR as a surrogate of Benefit

ADOPT-LUNG

- Resectable stage IIB-IIIB
- Neoadjuvant chemo + durvalumab (3-4 cycles)
- R0 or R1 resection
- Path response documented.

RANDOMIZE

Adjuvant Durvalumab (12 cycles)

Observation

NCT06284317 (ETOP 25-23)

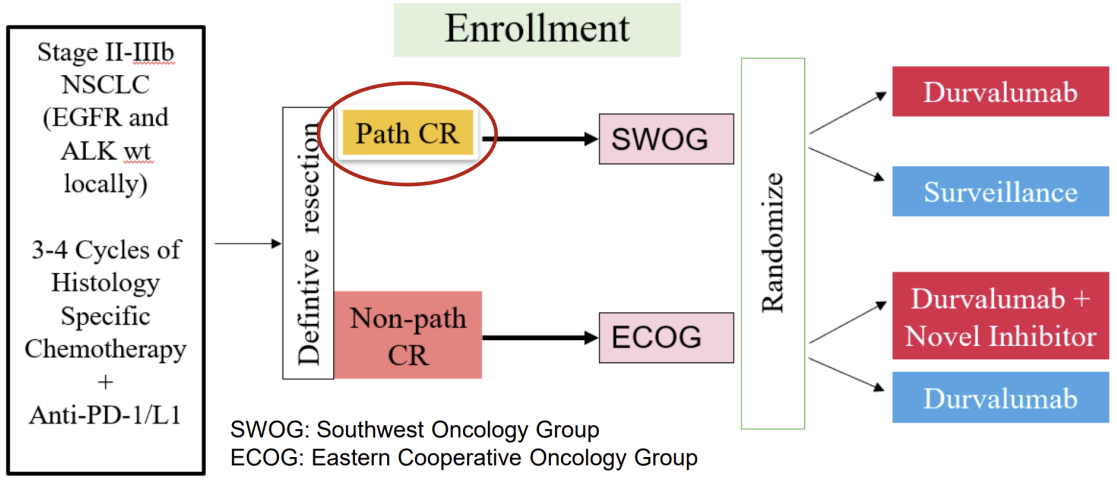
Primary Endpoint:
- DFS in non-PCR group

Sample Size:
- 290

Study Start:
- Oct 2024

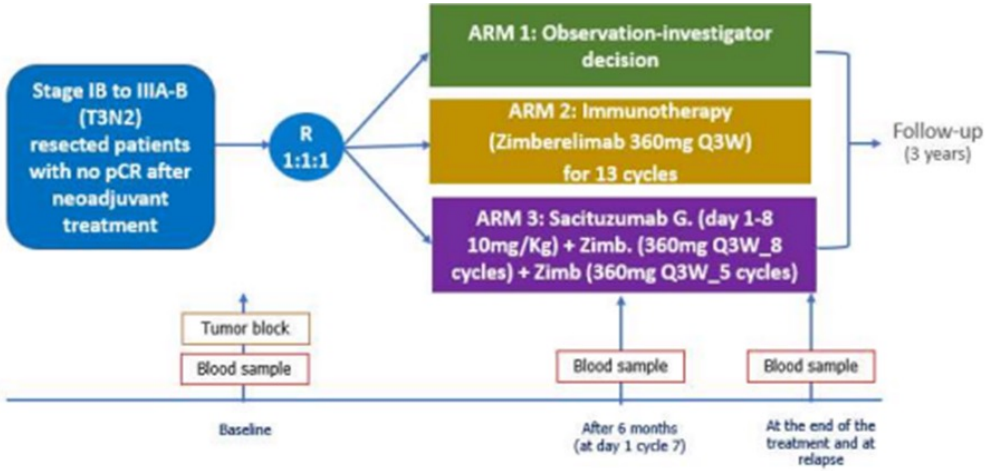
Study Completion:
- Mar 2030

CLEAR-INSIGHT



SWOG: Southwest Oncology Group
ECOG: Eastern Cooperative Oncology Group

ARIAN



Risks and Attrition: Progression or toxicity preventing surgery

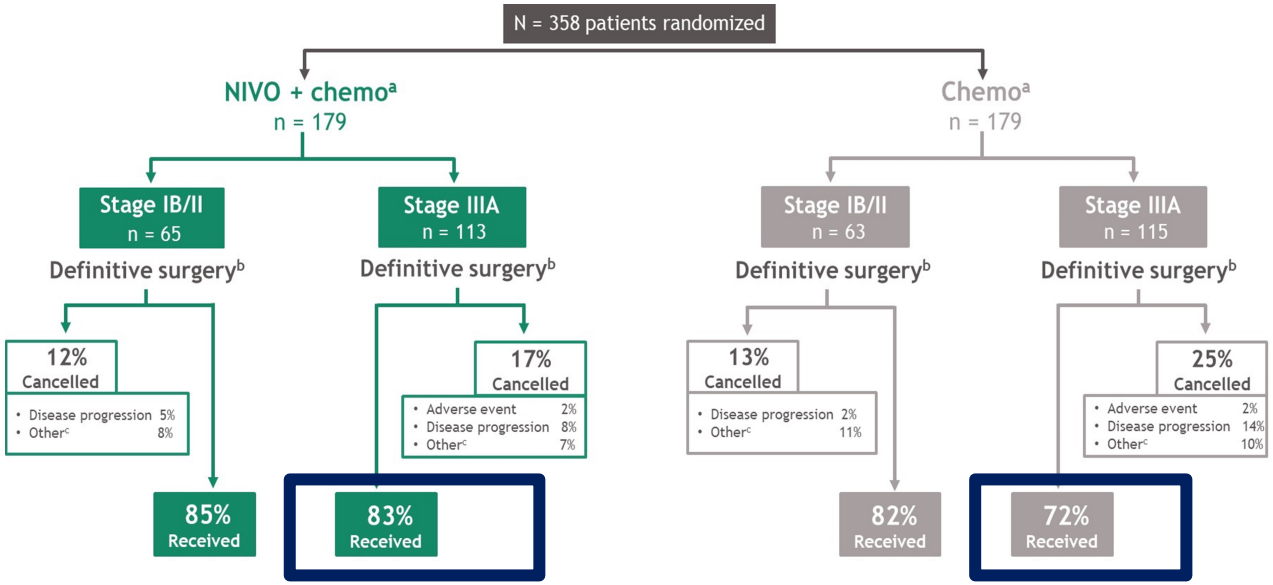
Neotorch[1]

	Toripalimab +Chemo (N=202)	Placebo + Chemo (N=202)
No surgery performed n(%)	36 (17.8)	54 (26.7)
Patient underwent surgery n(%)	166 (82.2)	148 (73.3)
R0 resection n(%*)	159 (95.8)	137 (92.6)
95% CI	91.5, 98.3	87.1, 96.2
Differences between arms	3.2	
95% CI	-2.0, 8.4	

AEGEAN[3]

Study phase*		D arm (N=366)	PBO arm (N=374)
Surgery	Underwent surgery†, n (%)	295 (80.6)	302 (80.7)
	Did not undergo surgery†‡, n (%)	71 (19.4)	72 (19.3)
	Completed surgery†, n (%)	284 (77.6)	287 (76.7)
	– R0 resection, n (% of completed surgery)	269 (94.7)	262 (91.3)
	Did not complete surgery†, n (%)	11 (3.0)	15 (4.0)

CheckMate 816[2]



KEYNOTE 671[4]

	Pembro Arm	Placebo Arm
Underwent in-study surgery	325 (82.1%)	317 (79.4%)

1. Lu S, Oral Presentation ASCO Plenary Series 2023; 2. Spicer Oral Presentation ASCO Annual Meeting 2022; 3. Heymach JV, Oral Presentation AACR Annual Meeting 2023; 4. Wakelee H, Oral Presentation ASCO Annual Meeting 2023

Treatment Delivery and Adherence: Neoadjuvant feasibility/ Adjuvant non-compliance

Contents lists available at ScienceDirect

Lung Cancer

journal homepage: www.elsevier.com/locate/lungcan

Research Paper

Attrition with adjuvant, neoadjuvant, and perioperative immunotherapy-based treatment protocols in patients with resectable non-small-cell lung cancer. A meta-analysis of prospective trials

Francesco Guerrera [a,b,1], Filippo Tommaso Gallina [c,1,*], Eleonora Balzani [d,1], Francesca Ambrosi [e,f], Alessandro Di Federico [g,h], Eleonora Faccioli [i], Giorgio Facheris [j], Roberto Ferrara [k,l], Alessandra Ferro [m], Federica Filipello [n], Raffaele Giusti [o], Carlo Greco [p,q], Marco Mammana [r], Daniele Marinelli [r], Antonio Nuccio [k,l], Alessandra Pittaro [s], Matteo Sepulcri [t], Giuseppe Viscardi [u], Pietro Bertoglio [v]

Feature / Metric	Neoadjuvant (Preoperative)	Adjuvant (Postoperative)
Scheduled Compliance Rate	**93%**	**61%**
Treatment Omission Rate	**0.6%**	**9.6%**
Incomplete Treatment Cycles	**11.3%**	**34.6%**
Grade 3–4 Adverse Events	**23.5%**	**21.5%**
R0 Resection Rate	**97%**	N/A (Surgery occurs before)
Surgical Dropout Rate	**16.3%**	N/A

Guerrero F Lung Cancer 2025

Clinical Trade-offs→Timing of systemic therapy/ Cost and real-world implications

Key Concerns After Prior Neoadjuvant Therapy: Finantial Toxicity and Patient Time

- Cost-effectiveness studies for neoadjuvant, adjuvant, and perioperative strategies have all shown the addition of IO to be cost-effective
- Total cost of neoadjuvant regimen is lower owing to less cycles of chemo-IO
- IF all have similar efficacy, the financial toxicity of adjuvant/perioperative regimens COULD be much higher

Table 1. ICER per QALY

Settings	ICER (cost) per QALY
Neoadjuvant	
CheckMate-816 (no PD-L1 selection)	$32,846
Perioperative	
KEYNOTE-671 (no PD-L1 selection)	$94,222
Adjuvant	
IMpower010 (PD-L1 50% cutoff for use)	$68,858

Abbreviations: ICER, incremental cost-effectiveness ratio; QALY, quality adjust life year.

Table: 1287P

IO status at Recurrence	Neo Nivo		Adj Atezo	
	Stage IB-IIIA, any PD-L1	Stage IB-IIIA, PD-L1≥1%	Stage II-IIIA, PD-L1≥1%	Stage II-IIIA, PD-L1≥50%
No IO	–$86,599	–$95,405	–$20,112	–$39,641
Ineffective IO	–$57,250	–$87,387	$34,051	–$24,670
Effective IO	–$103,924	–$100,339	–$58,101	–$42,318

- Difference in number of infusions for each strategy:
  - Neoadjuvant: 3
  - Adjuvant: 16-20
  - Perioperative: 16-17
- Potential substantial differences in costs for co-pays, parking, time off work, caregiver burden, and even direct financial costs to patients

Muthusamy Annals of Onc 2023; Tian Front. Immunol 2023

Take home mesages

- **Surgery is the cornerstone** of early-stage NSCLC treatment.
- **Perioperative therapy should be tailored** by the multidisciplinary Tumor Board.
- **Neoadjuvant therapy primes the immune system** and controls micrometastatic disease early.
- **Higher adherence and fewer infusions** reduce patient burden and financial toxicity.
- **R0 resection rates remain excellent**, making neoadjuvant strategies a compelling option despite attrition risk.

GRacias!

II JORNADA TRASLACIONAL DE ONCOLOGÍA DE PRECISIÓN: A TRAVÉS DE LAS VÍAS DE SEÑALIZACIÓN

SEVILLA, 6 Y 7 DE FEBRERO DE 2025