City of Hope | ORANGE COUNTY

Role of Neoadjuvant and Adjuvant Systemic Therapy in Resectable Non-small Cell Lung Cancer

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Disclosures

- Consultant for Mirati therapeutics, Avellino, GlaxoSmithKline, and Roche

This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their product(s) and/or other business interests.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

This presentation has been peer-reviewed and no conflicts were noted.

Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:

The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:

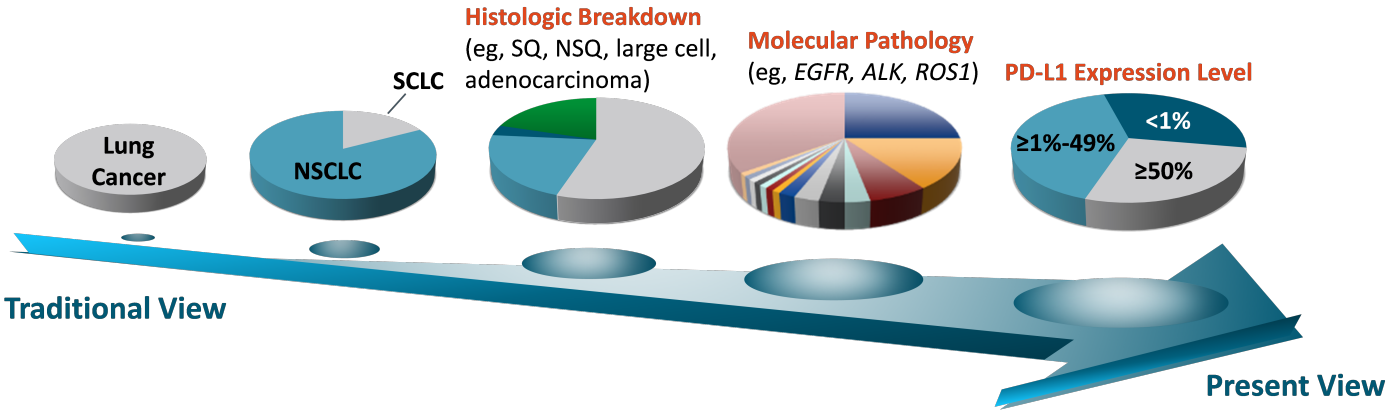
Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

The following CLC & IB components will be addressed in this presentation:

- *Will mention underserved populations in clinical research.*
- *Will mention biomarker testing and those that are not tested who are then not served correctly.*

Resectable Lung Cancer:

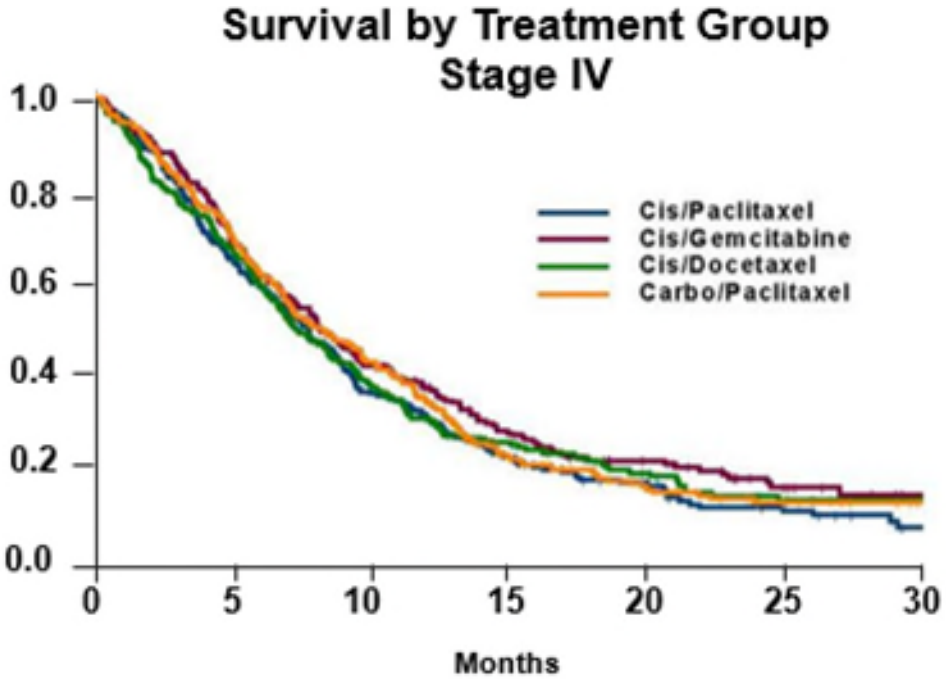
- 45-75% of Patients diagnosed with resectable NSCLC have high risk for recurrence based on stage



Cooper. Pathology. 2011;43:103. Langer. JCO. 2010;28:5311. Galon. Immunity. 2013;39:11. Pao. Lancet Oncol. 2011;12:175. Krigsfeld. AACR 2017. Abstr CT143.

Lung Cancer Treatment 2000: Poor Outcomes

- Nonsquamous and squamous histologies
- No differences
- Efficacy not so encouraging
- Easy for providers to “take home a message”
- “Treat with any doublet you would like



Schiller et al 2002. N Engl J Med; 346:92-98

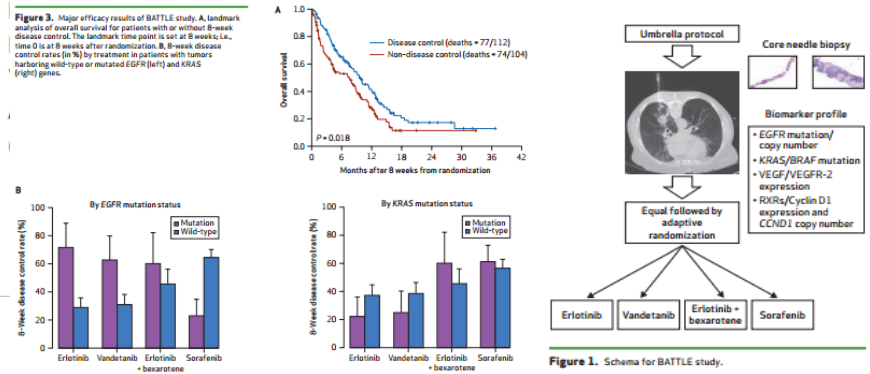
BATTLE Trial 2007

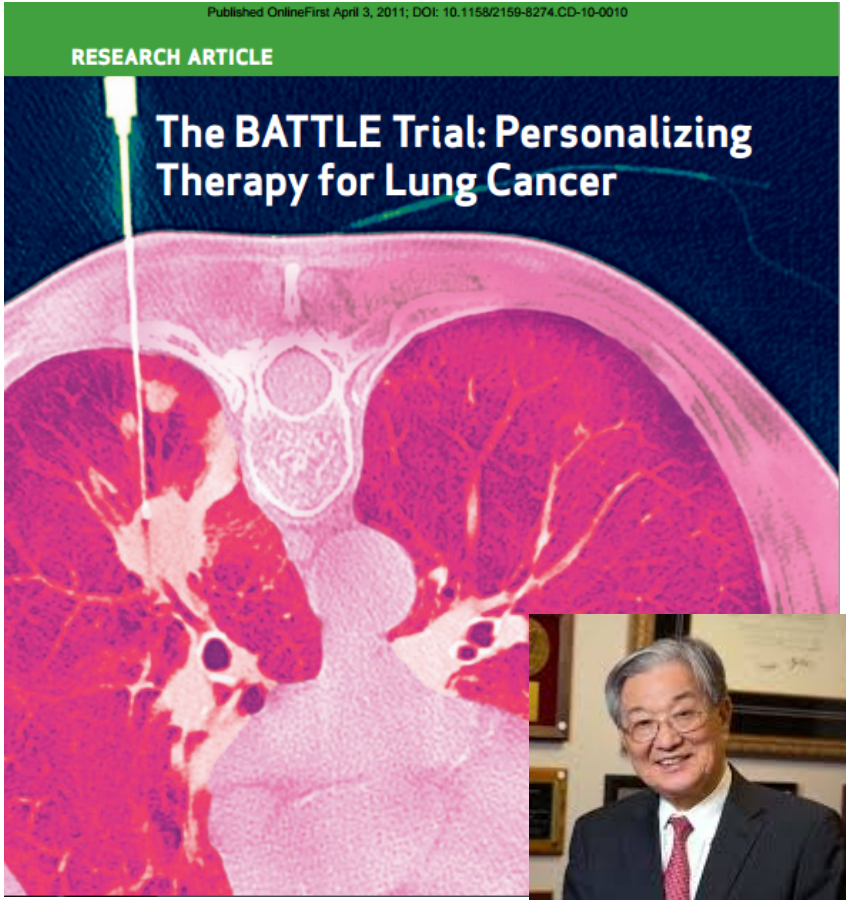
Published in final edited form as:
Cancer Discov. 2011 June ; 1(1): 44–53. doi:10.1158/2159-8274.CD-10-0010.

The BATTLE Trial: Personalizing Therapy for Lung Cancer

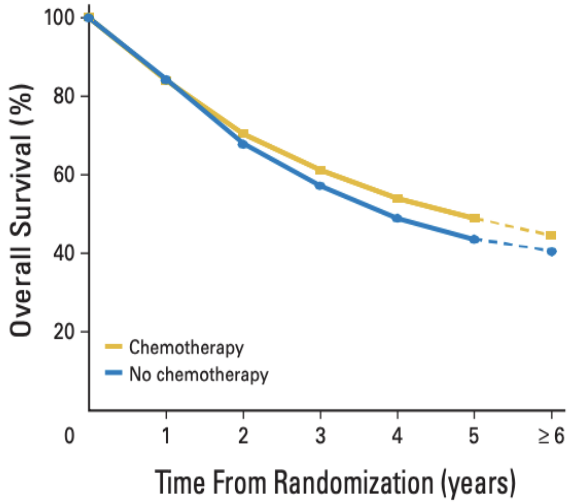
Edward S. Kim, M.D., Roy S. Herbst, M.D., Ph.D., Ignacio I. Wistuba, M.D., J. Jack Lee, Ph.D., George R. Blumenschein Jr., M.D., Anne Tsao, M.D., David J. Stewart, M.D., Marshall E. Hicks, M.D., Jeremy Erasmus Jr., M.D., Sanjay Gupta, M.D., Christine M. Alden, R.N., Suyu Liu, M.S., Ximing Tang, M.D., Ph.D., Fadlo R. Khuri, M.D., Hai T. Tran, Pharm.D., Bruce E. Johnson, M.D., John V. Heymach, M.D., Ph.D., Li Mao, M.D., Frank Fossella, M.D., Merrill Kies, M.D., Vassiliki Papadimitrakopoulou, M.D., Suzanne E. Davis, M.M.S., M.B.A., Scott M. Lippman, M.D.†, and Waun K. Hong, M.D.†

departments of Thoracic/Head and Neck Medical Oncology (E.S.K., R.S.H., I.I.W., G.R.B., A.T., ...gy (I.I.W.), ...University of ...versity, ...d, Baltimore





Early-Stage NSCLC: Role of Adjuvant Chemo

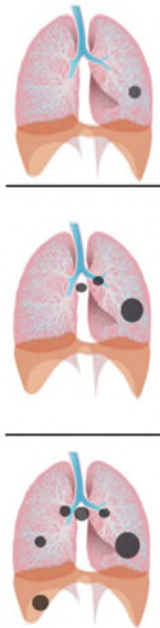


Deaths / person years by period	Years 0-3	Years 4-5	Years ≥ 6
Control	966 / 5,155	239 / 1,668	49 / 720
Chemotherapy	857 / 5,181	203 / 1,817	76 / 790

- Adjuvant chemotherapy is considered for patients with resected stage IB and higher NSCLC, including those with tumors >4 cm
- Adjuvant chemotherapy conferred a 5-year absolute benefit of ~5% (OS HR 0.89)
- **Given the advances we have made in NSCLC since 2008, what is the role of newer therapies (specifically targeted therapy) in early-stage disease?**

LACE meta-analysis. Pignon JP, et al. *J Clin Oncol*. 2008;26:3552-3559.

Resectable Lung Cancer:



Stage-guided treatment strategy for NSCLC

AJCC Stage	Stage grouping (Lung TNM 8th edition)[7]	Frequency at diagnosis[10] (unknown 6%)	Treatment[32,33]	5-year survival for clinical staging[7]	Adjuvant chemotherapy[28]	Adjuvant Osimertinib[30] (EGFR L858R or Exon 19 Deletion)	Adjuvant ICI (Atezolizumab[36] or Pembrolizumab[36]) (EGFR wild type)
IA1	T1miN0M0 T1aN0M0	30%	Surgery or definitive radiation (for medically inoperable patients)	92%	N/A	N/A	N/A
IA2	T1bN0M0			83%			
IA3	T1cN0M0			77%			
IB	T2aN0M0		Surgery followed by adjuvant systemic therapy	68%	+5% absolute survival at 5 years (stage IB-IIIA)		+12% DFS and +3% OS (PD-L1 expression >50%) at 3 years with Atezolizumab (stage IIA-IIIA) +28% DFS at 3 years with Pembrolizumab (stage IB-IIIA) (OS is not mature)
IIA	T2bN0M0	9%	Or Neoadjuvant ICI-chemotherapy followed by surgery	60%			
IIB	T1a-T2bN1M0 T3N0M0			53%		+46% DFS at 2 years (stage IIA-IIIA)	
IIIA	T1a-T2bN2M0 T3N1M0 T4N0 or N1M0	18%	For unresected stage III: definitive concurrent chemoradiation followed by consolidation PD-L1 inhibitor	36%			
IIIB	T1-T2N3M0 T3N2M0 or T4N2M0		For unresected stage III: definitive concurrent chemoradiation followed by consolidation PD-L1 inhibitor	26%	N/A	+14.7% DFS	N/A
IIIC	T3N3M0 or T4N3M0			13%			
IVA	AnyTAnyNM1a or M1b	37%	Palliative systemic therapy	10%			
IVB	AnyTAnyNM1c			0%		N/A	

Godoy et al 2023. Biomarker research

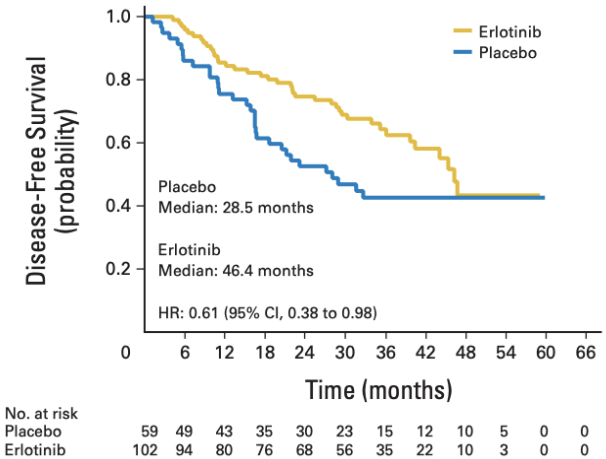
Current Molecular Testing Guidelines

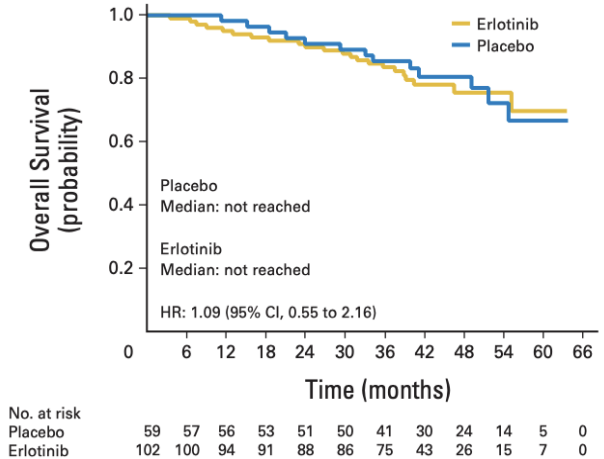
- Recommended
- Recommended as part of larger panel (not stand-alone)
- preferred, consider if available
- Consider if DNA-based testing negative
- Recommended for all squamous cell
- Recommended only if clinical features indicate a higher probability of an oncogenic driver (age<50 years, never smoker, former light smoker< 15 years, quit smoking >15 years ago)

	NCCN	ESMO	Pan-Asian[£]	Updated CAP/ IASLC/AMP
Year [Reference]	2023 [33]	2023 [96]	2019 [97]	2018 [10]
Multi-panel testing				
RNA-based testing				
Testing for SqCC				
Testing for non-sqCC				
ALK*				
ROS-1				
EGFR***				
BRAF				
KRAS G12C				
HER2				
NTRK				
METex14				
RET				

Older Studies of Adjuvant EGFR-Directed Therapy Did Not Show Definitive Benefit

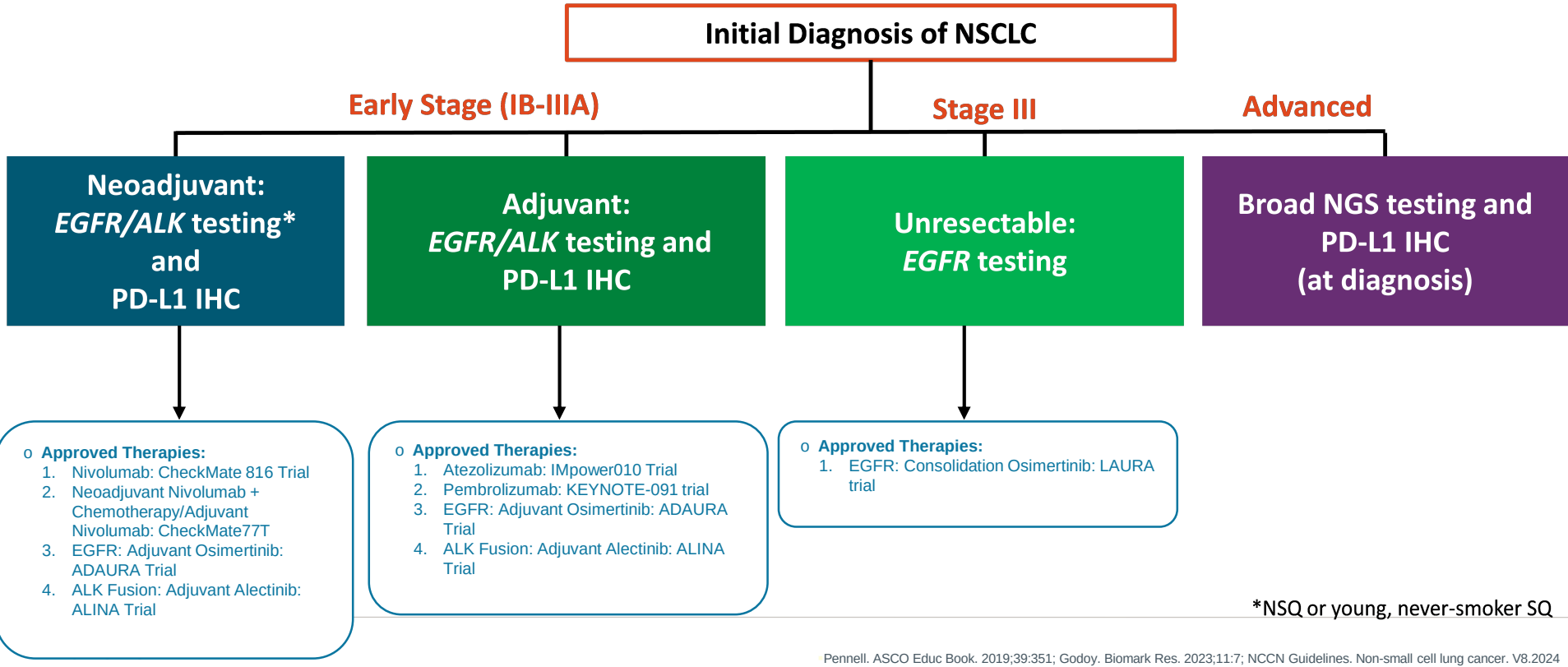
- The RADIANT trial randomized patients to 2 years of adjuvant erlotinib vs placebo, but only a small subset (161/973 patients) had *EGFR*-positive NSCLC
- Among these patients, a **trend toward improved disease-free survival was seen with adjuvant erlotinib**





Kelly K, et al. *J Clin Oncol*. 2015;33:4007-4014.

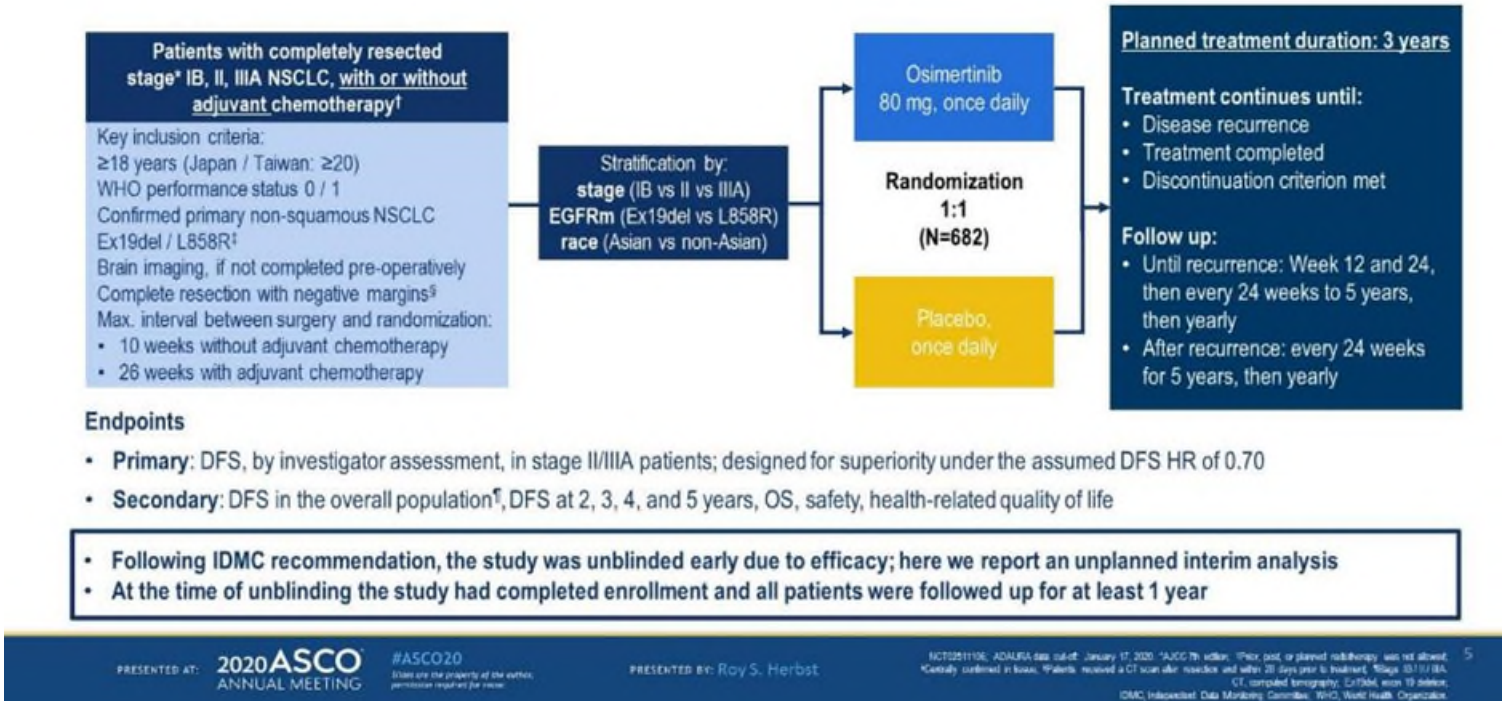
Molecular and PD-L1 Testing



*NSQ or young, never-smoker SQ

Pennell. ASCO Educ Book. 2019;39:351; Godoy. Biomark Res. 2023;11:7; NCCN Guidelines. Non-small cell lung cancer. V8.2024

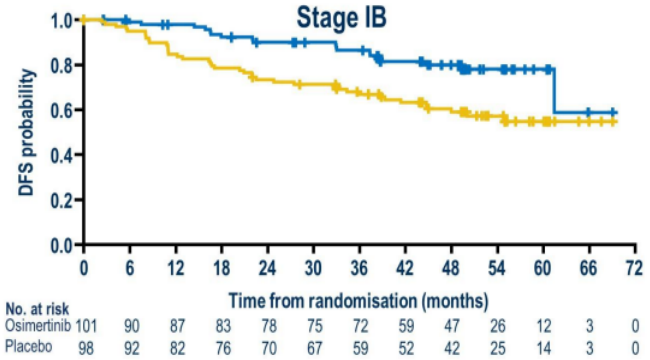
ADAURA Trial: Phase III

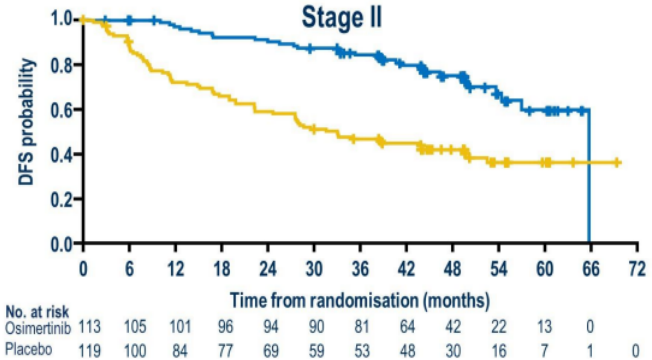


* At the time of recruitment, staging was determined according to the 7th edition of the *Cancer Staging Manual* of the AJCC

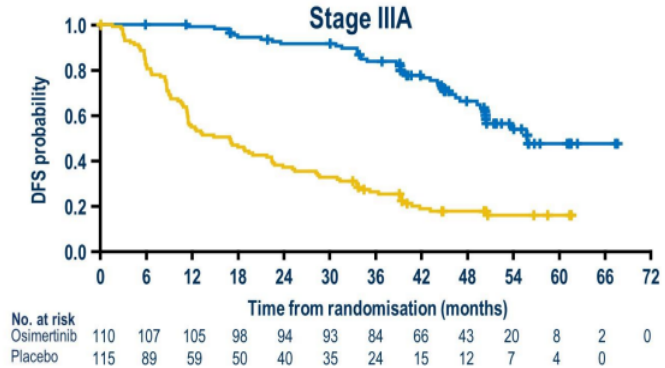
Wu Y-L R, et al. *N Engl J Med*. 2020;383:1711-1723.

ADAURA: Updated DFS (INV) by Stage (8th Edition AJCC)



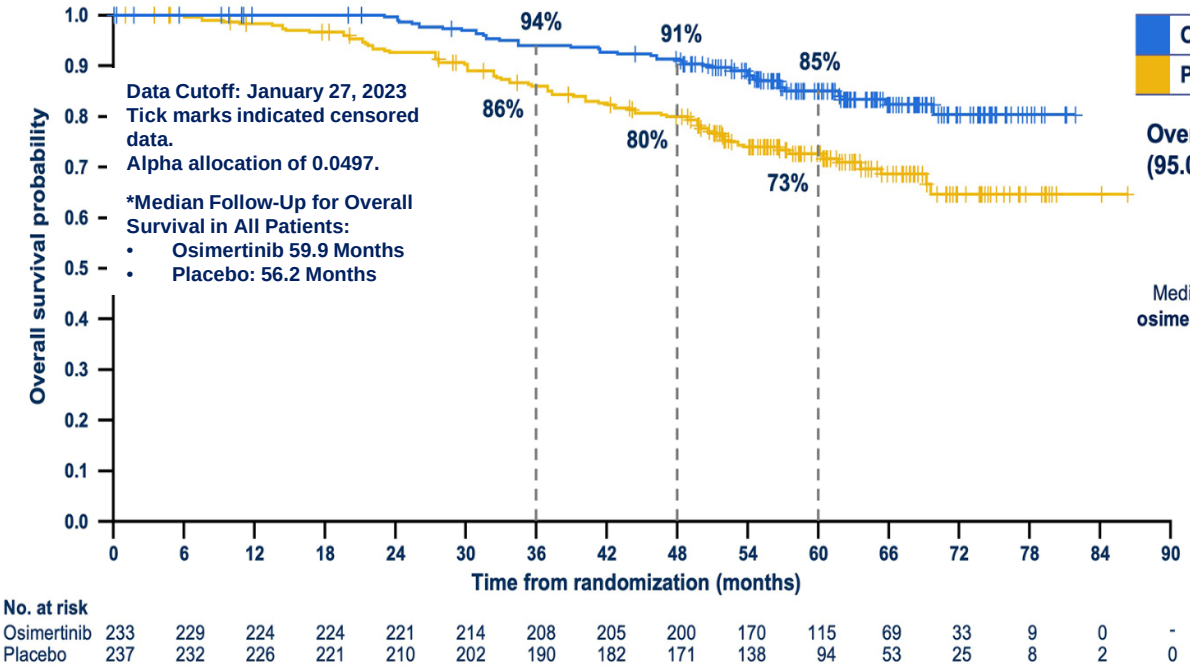


	Stage IB	Stage II	Stage IIIA
4 year DFS rate, % (95% CI)			
– Osimertinib	80 (69, 87)	75 (65, 83)	66 (55, 75)
– Placebo	60 (49, 69)	43 (34, 52)	16 (10, 24)
Overall HR (95% CI)	**0.44 (0.25, 0.76)**	**0.33 (0.21, 0.50)**	**0.22 (0.15, 0.31)**



Tsuboi M, et al. ESMO 2022. Abstract LBA47.

ADAURA: Final OS Analysis



5-year OS rate, % (95% CI)	
Osimertinib (N = 233)	85 (79, 89)
Placebo (N = 237)	73 (66, 78)

Overall OS HR (95.03% CI) **0.49 (0.33, 0.73); *P* = .0004**

Maturity: 21%
osimertinib 15%, placebo 27%

Median follow-up for OS* (censored patients):
osimertinib 61.7 months, placebo 60.4 months

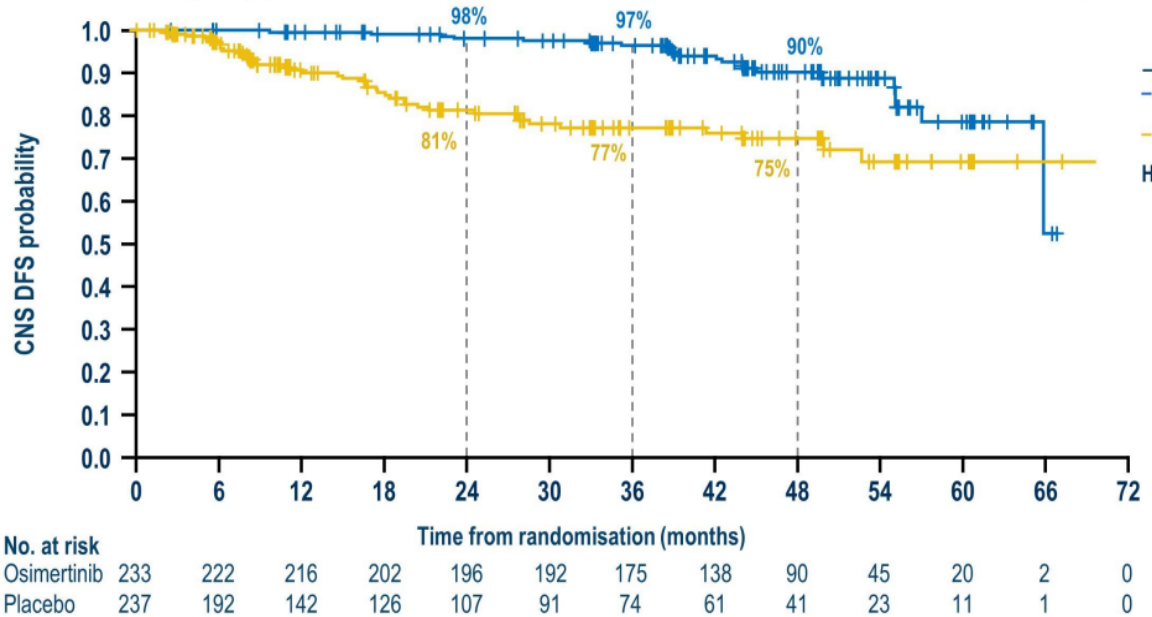
- **Consistent OS benefit**
  - **Consistent across all patient subgroups, including those with stage IB, II, or IIIA disease and in patients who did or did not receive prior adjuvant chemotherapy.**

Data cut-off: January 27, 2023.
Tick marks indicate censored data. Alpha allocation of 0.0497. *Median follow-up for OS (all patients): osimertinib 59.9 months, placebo 56.2 months.

Herbst RS, et al. *J Clin Oncol*. 2023;41(10):1830-1840.

ADAURA: Full Analysis Set (INV): Updated CNS Patients With Stage II/IIA Disease

- Overall, 63 patients (osimertinib n=22, placebo n=41) had CNS DFS events:*
  - 3 (14%) patients were on treatment at the time of CNS recurrence with osimertinib, versus 29 (71%) with placebo

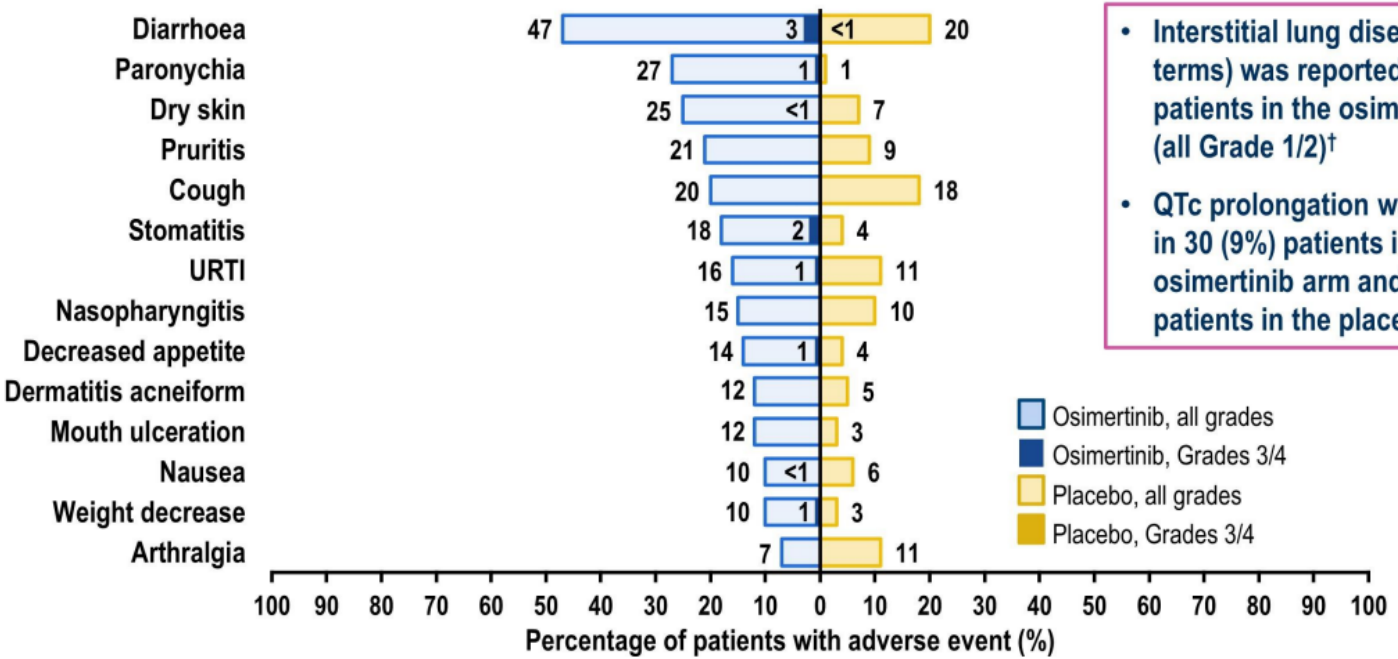


Median CNS DFS, months (95% CI)	
– Osimertinib	NR (65.8, NC)
– Placebo	NR (NC, NC)
HR (95% CI)	**0.24 (0.14, 0.42)**

Maturity 13%:
osimertinib 9%, placebo 17%

Herbst RS, et al. *J Clin Oncol*. 2023;41(10):1830-1840.

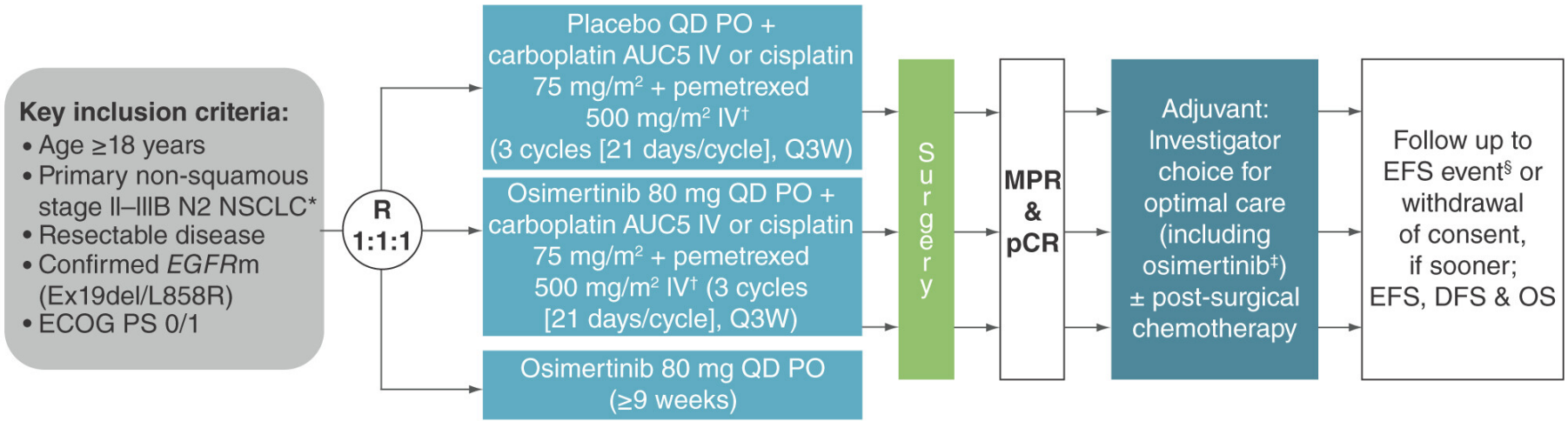
ADAURA: All Causality Adverse Events (≥10% of patients)



- Interstitial lung disease (grouped terms) was reported in 11 (3%)* patients in the osimertinib arm (all Grade 1/2)†
- QTc prolongation was reported in 30 (9%) patients in the osimertinib arm and 8 (2%) patients in the placebo arm‡

Herbst RS, et al. *J Clin Oncol*. 2023;41(10):1830-1840.

NeoADAURA Trial: Phase III



Tsuboi et al 2021. Fut Oncol

Treatment of Early-Stage NSCLC with Immunotherapy

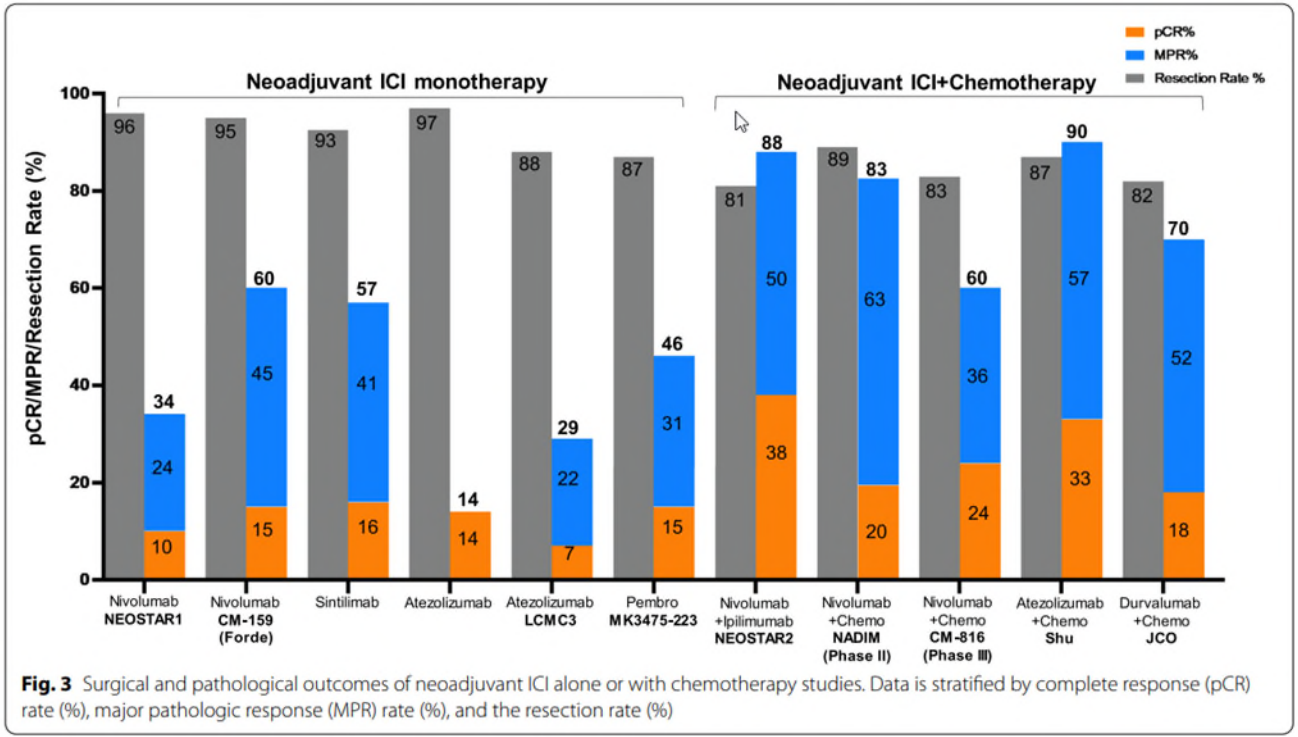


Fig. 3 Surgical and pathological outcomes of neoadjuvant ICI alone or with chemotherapy studies. Data is stratified by complete response (pCR) rate (%), major pathologic response (MPR) rate (%), and the resection rate (%)

Godoy LA, et al. Biomarker Research 2023.

Adjuvant Immunotherapy in Resected NSCLC

IMpower010[1-3]

Chemotherapy mandatory

Stratification by sex, stage, histology, PD-L1 status

Adults with completely resected stage IB-IIIA NSCLC per UICC/AJCC v7 (includes tumors ≥4 cm) (N = 1280)

→ **Adjuvant cisplatin-based CT*** for 4 cycles

→ **Atezolizumab** 1200 mg IV Q3W x 16

→ **Best supportive care**

*Cisplatin + pemetrexed (nonsquamous), gemcitabine, docetaxel, or vinorelbine.

- **Primary endpoint:** DFS by investigator among 3 populations: stage II-IIIA with PD-L1 TC ≥1%, all stage II-IIIA, and ITT population (randomized stage IB-IIIA)

PEARLS/KEYNOTE-091[4-6]

Chemotherapy not mandatory

Stratified by stage, PD-L1 status, prior adjuvant CT, geographic location

Adults with stage IB-IIIA NSCLC (includes tumors ≥4 cm); complete surgical resection with disease-free margins (R0); with or without adjuvant CT (N = 1177)

→ **Pembrolizumab** 200 mg IV Q3W x ~1 yr

→ **Placebo** IV Q3W x ~1 yr

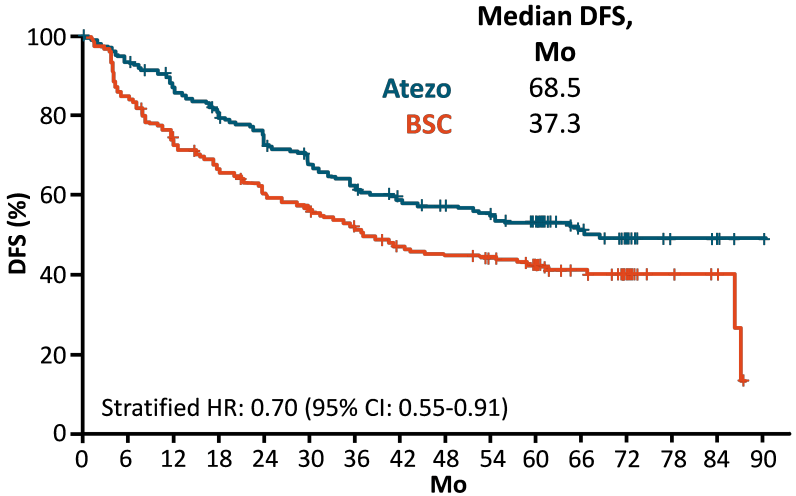
- **Primary endpoint:** DFS in overall and PD-L1 TPS ≥50% population

NOTE: Cross-trial comparisons have significant limitations.
This information is presented to generate discussion, not to make direct comparisons between study results.

1. NCT02486718. 2. Felip. Lancet. 2021;398:1344. 3. Felip. WCLC 2022. Abstr PL03.09. 4. NCT02504372. 5. O'Brien. Lancet Oncol.2022;23:1274. 6. Pas-Arez. ESMO 2022. Abstr VP3-2022.
5. Clin Care Options 2024

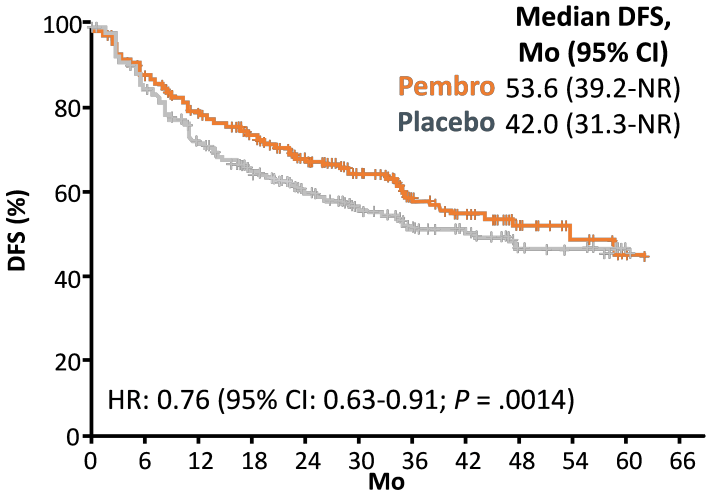
Adjuvant Immunotherapy in Resected NSCLC

IMpower 010: Stage II-IIIA NSCLC With PD-L1 TC ≥1%



FDA approved in October 2021 as **adjuvant treatment** following resection and platinum-based CT for adults with stage II-IIIA NSCLC and PD-L1 expression on ≥1% of tumor cells[3]

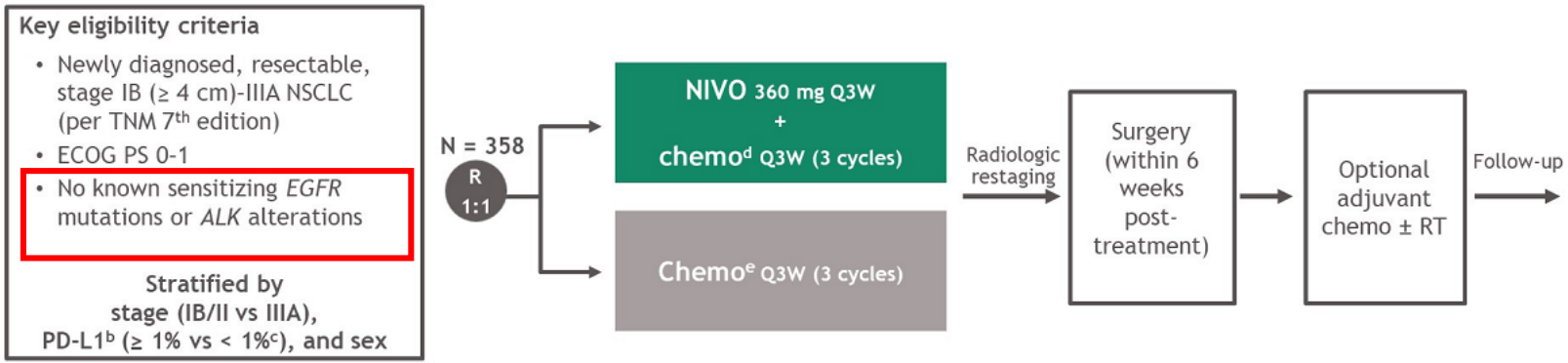
PEARLS/KEYNOTE-091: Overall Population[4,5]



FDA approved in January 2023 as **adjuvant treatment** following resection and platinum-based CT for adult patients with stage IB-IIIA, including T2a ≥4 cm, NSCLC[6]

1. Felip. Lancet. 2021;398:1344. 2. Wakelee. ASCO 2024. Abstr LBA8035. 3. Atezolizumab PI. 4. Paz-Ares. ESMO Virtual 2022. Abstr VP3-2022. 5. O'Brien. Lancet Oncol. 2022;23:1274. 6. Pembrolizumab PI. 2. Clin Care Options 2024

Neoadjuvant Immunotherapy: CheckMate 816



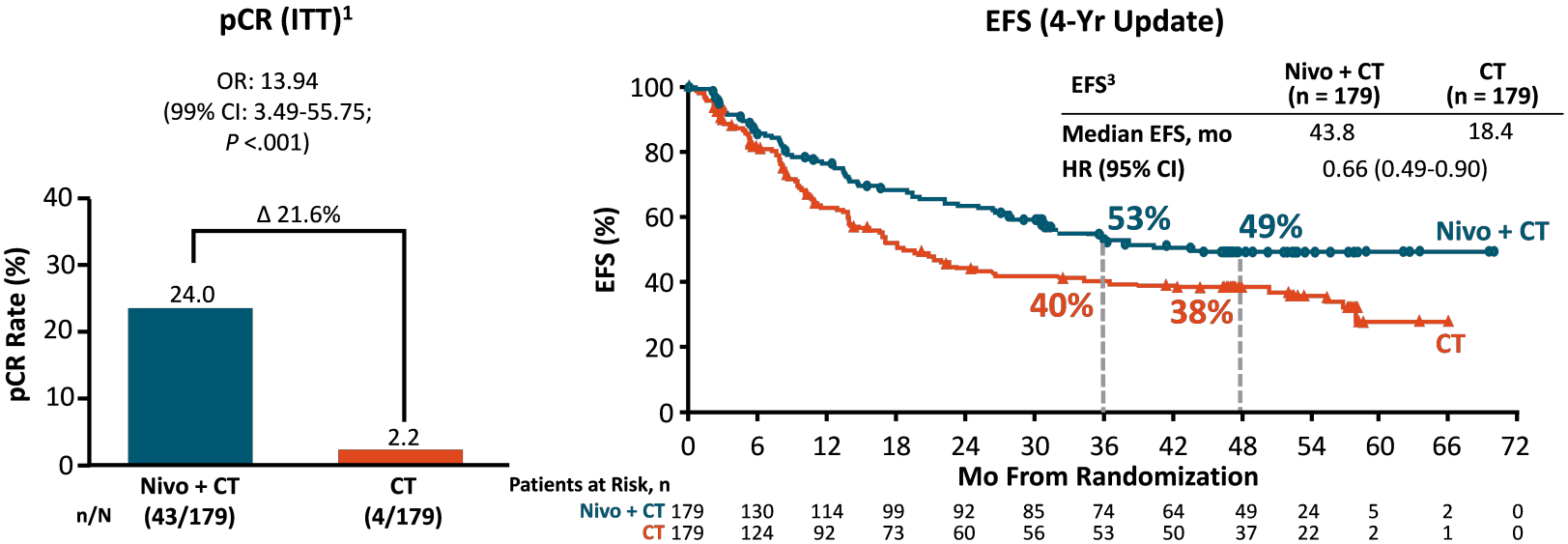
Primary endpoints
- pCR by BIPR
- EFS by BICR

Key secondary endpoints
- MPR by BIPR
- OS
- Time to death or distant metastases

Key exploratory endpoints included
- ORR by BICR
- **Feasibility of surgery; peri- and post-operative surgery-related AEs**

Spicer J, et al. ASCO 2021. Abstract 8503; Forde PM, et al. *N Engl J Med*. 2022;386:572-573.

CheckMate 816:

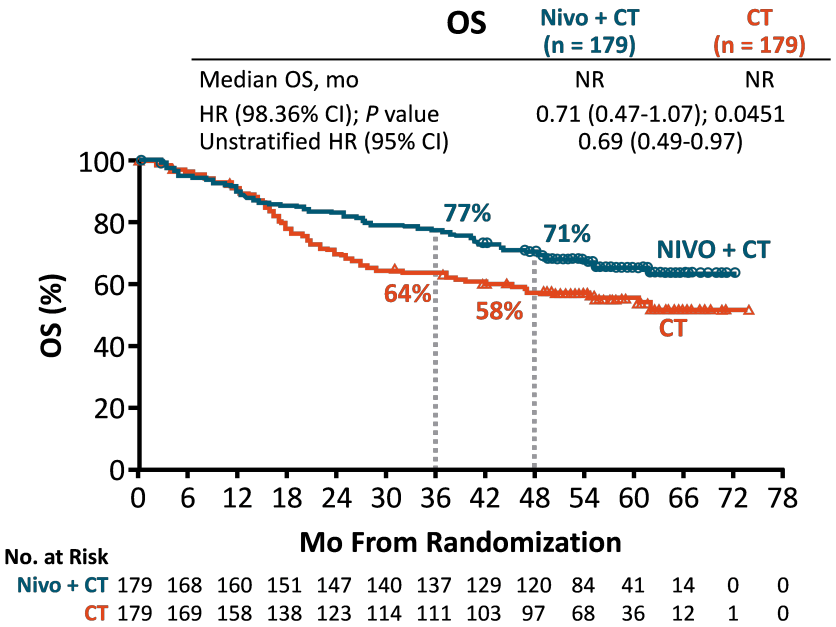


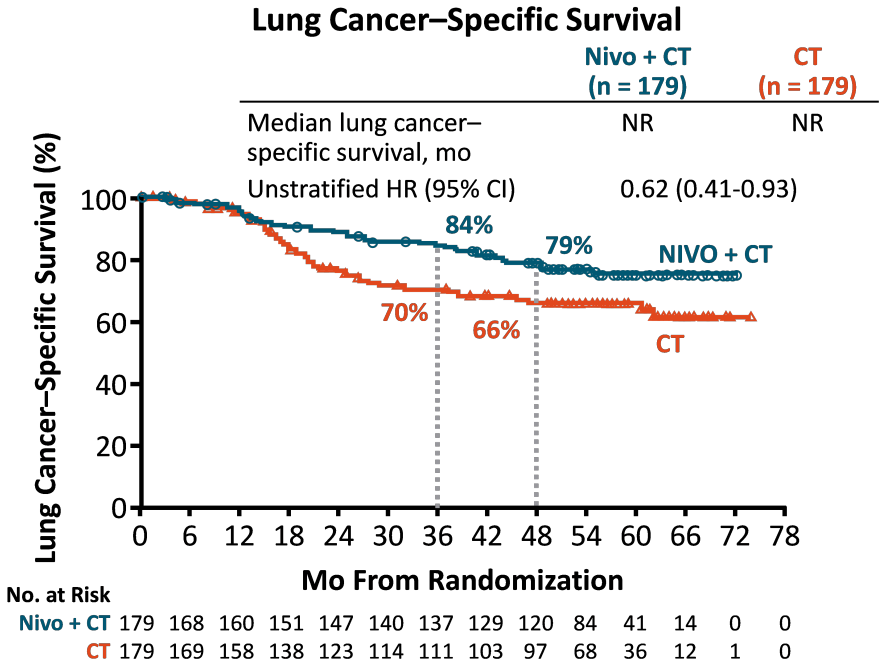
FDA-approved in March 2022 for adults with resectable NSCLC (tumors ≥4 cm or N+) in combination with platinum doublet CT in the neoadjuvant setting[2]

1. Forde. NEJM. 2022;386:1973. 2. Nivolumab PI. 3. Spicer. ASCO 2024. Abstr LBA8010.
2. Clin Care Options 2024

CheckMate 816:

- Patients who received Nivo + CT and had pCR continued to have improved OS vs those who did not (HR: 0.08; 95% CI: 0.02-0.34; **4-yr OS rates: 95% vs 63%**)





1. Spicer. ASCO 2024. Abstr LBA8010.
2. Clin Care Options 2024

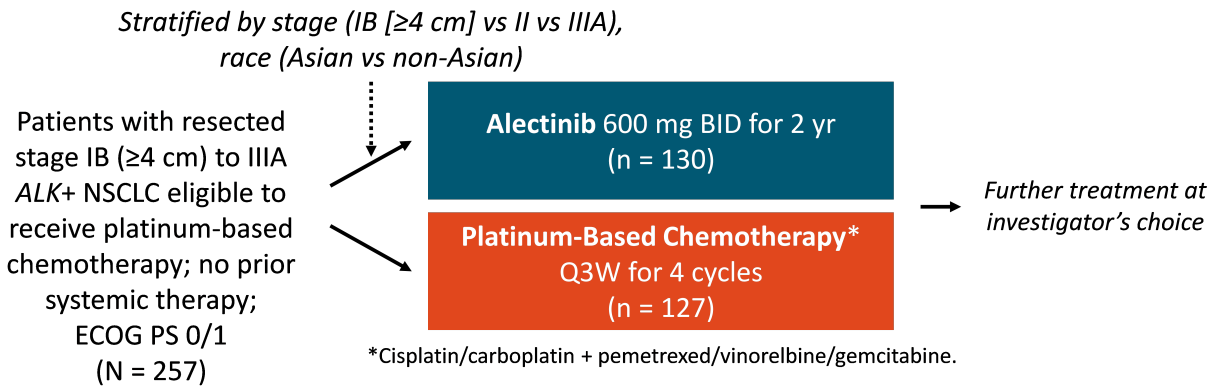
Lung Cancer: New FDA Approvals in Resectable NSCLC

- **Alectinib**
  - 04/2024 approved for adjuvant therapy for ALK positive NSCLC
  - ALINA trial
- **Durvalumab**
  - 08/2024 approved in combination with chemotherapy for neoadjuvant treatment for resectable NSCLC followed by adjuvant durvalumab treatment after surgery
  - AEGEAN trial
- **Neoadjuvant Nivolumab + Chemotherapy/Adjuvant Nivolumab**
  - 10/2024 approved in resectable NSCLC with no known EGFR mutations or ALK rearrangements
  - CheckMate 77T

ALINA Trial

FDA approves alectinib as adjuvant treatment for ALK-positive non-small cell lung cancer

- International, randomized, open-label phase III trial

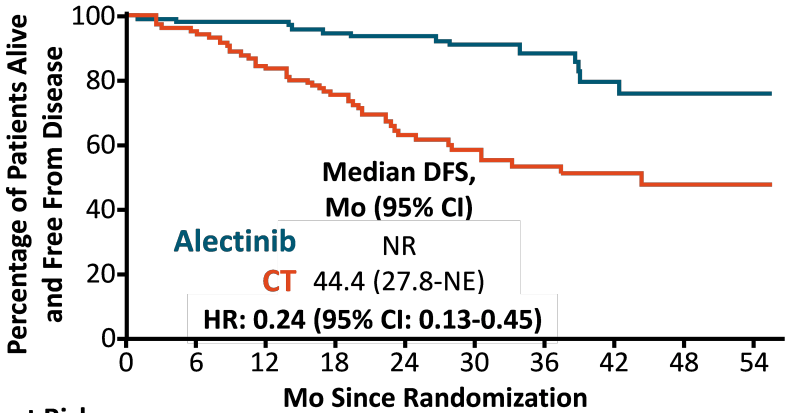


- **Primary endpoint:** DFS per investigator (hierarchical: stage II-IIIA; then stage IB-IIIA [ITT population])
- Secondary endpoints: CNS DFS, OS, safety

Wu. NEJM. 2024;390:1265. NCT03456076.

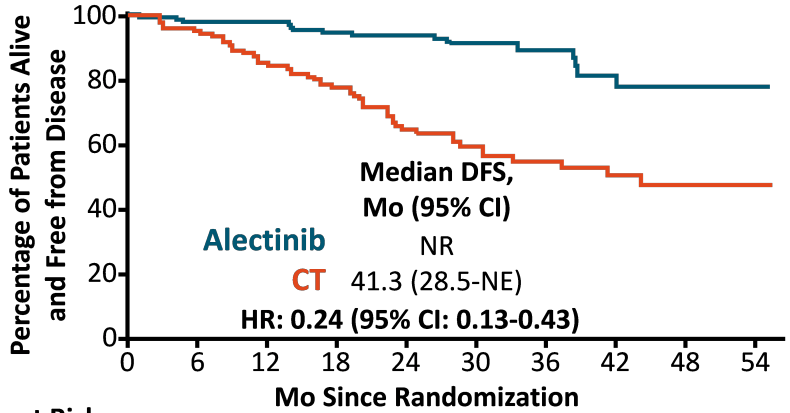
ALINA Trial

Patients With Stage II to IIIA Disease



No. at Risk										
Alectinib	116	111	111	107	67	49	35	21	10	3
CT	115	102	88	79	48	35	23	17	10	2

Overall Patient Population



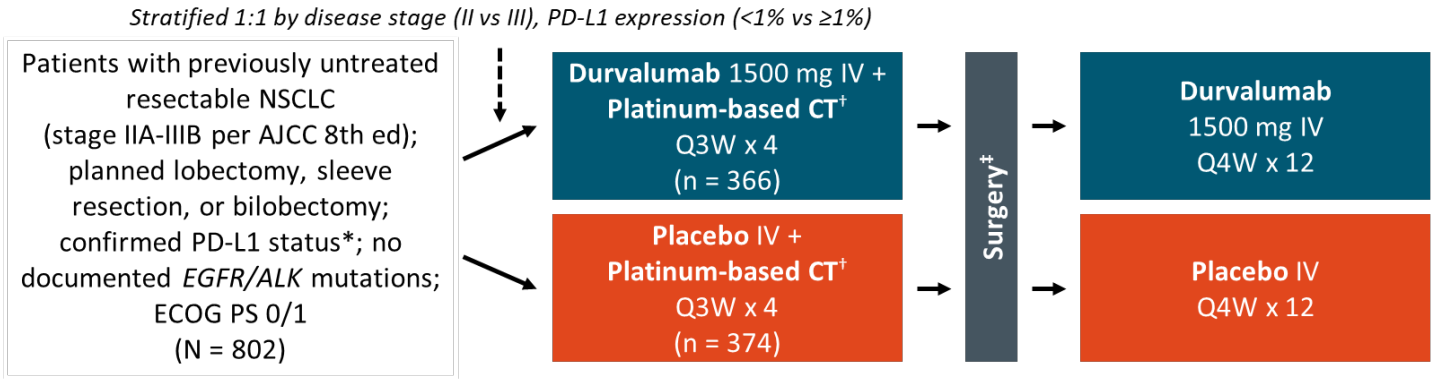
No. at Risk										
Alectinib	130	123	123	118	74	55	39	22	10	3
CT	127	112	98	89	55	41	27	18	11	2

- DFS benefit with alectinib vs chemotherapy observed across all subgroups of the ITT population, including age, sex, race, baseline ECOG PS, tobacco use history, tumor stage, and regional LN status

Wu. NEJM. 2024;390:1265. NCT03456076.

AEGEAN Trial

- International, randomized, double-blind phase III trial
  - Current analysis focuses on surgical outcomes using descriptive statistics (data cutoff: November 10, 2022)



*Per Ventana PD-L1 (SP263) IHC. †Based on histology and investigator decision: nonsquamous, cisplatin + pemetrexed or carboplatin + pemetrexed; squamous, carboplatin + paclitaxel, cisplatin + gemcitabine, or carboplatin + gemcitabine if comorbidities present and/or unlikely to tolerate cisplatin. ‡Postoperative RT permitted per local guidance.

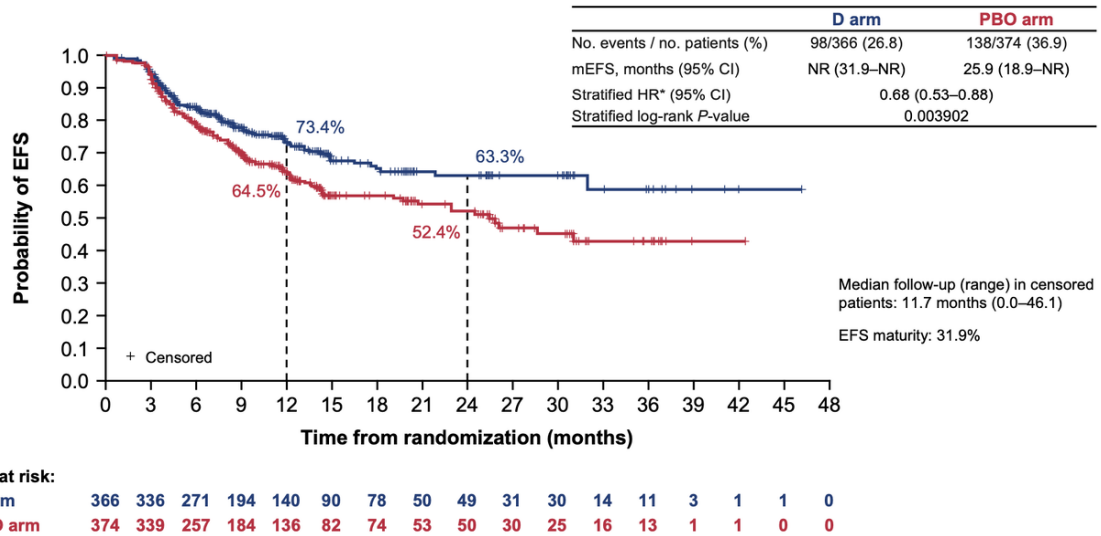
- **Primary endpoints:** pCR by central lab, EFS by BICR (RECIST v1.1)
- **Secondary endpoints:** MPR by central lab, DFS by BICR (RECIST v1.1), OS

NCT03800134. Mitsudomi. WCLC 2023. Abstr OA12.05. Heymach. AACR 2023. Abstr CT005. Clin Care Options, 2023

AEGEAN Trial

EFS using RECIST v1.1 (BICR) (mITT)

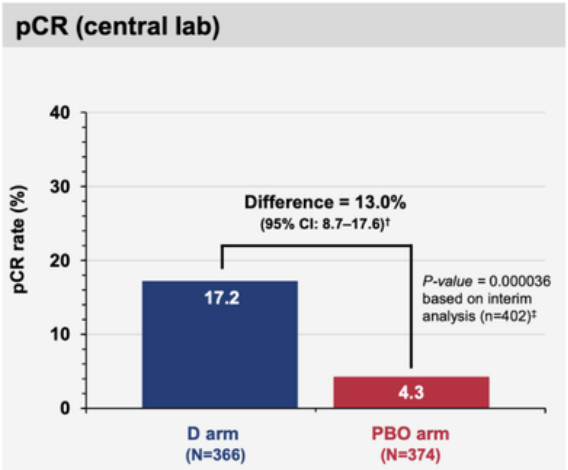
First planned interim analysis of EFS

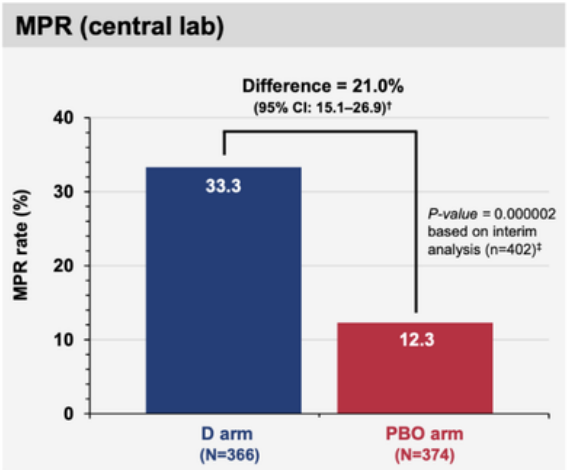


Heymach et al 2023. ACR

AEGEAN Trial

Pathologic response per IASLC 2020 methodology* (mITT)
Final analysis



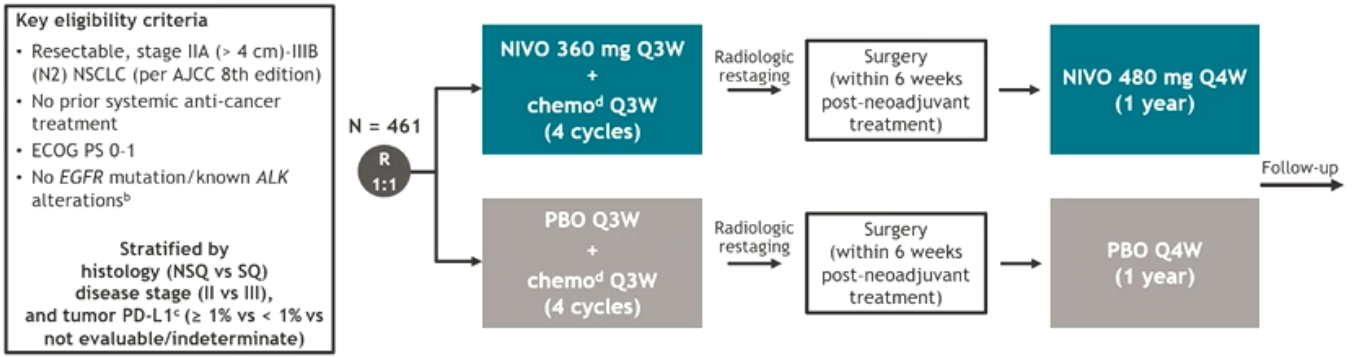


Heymach et al 2023. ACR

CheckMate 77T Trial

CheckMate 77T: perioperative NIVO in resectable NSCLC

CheckMate 77T[a] study design



Follow-up, median (range): 25.4 (15.7-44.2) months

Primary endpoint
- EFS by BICR

Secondary endpoints
- pCR[e] by BIPR
- MPR[e] by BIPR
- OS
- Safety

Exploratory analyses
- EFS by pCR/MPR
- EFS by adjuvant treatment

Database lock date: September 6, 2023.

[a]NCT04025879. [b]*EGFR* testing was mandatory in all patients with NSQ histology. *ALK* testing was done in patients with a history of *ALK* alterations. *EGFR*/*ALK* testing done using US FDA/local health authority-approved assays. [c]Determined by the PD-L1 IHC 28-8 pharmDx assay (Dako). [d]NSQ: cisplatin + pemetrexed, carboplatin + pemetrexed, or carboplatin + paclitaxel; SQ: cisplatin + docetaxel or carboplatin + paclitaxel. [e]Assessed per immune-related pathologic response criteria.[1] BICR, blinded independent central review; BIPR, blinded independent pathological review. 1. Cottrell TR, et al. *Ann Oncol* 2018;29:1853-1860.

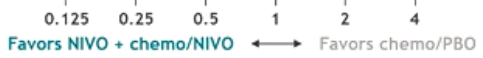
Cascone et al 2024. ESMO

CheckMate 77T Trial

CheckMate 77T: perioperative NIVO in resectable NSCLC

EFS analysis by key subgroups

	Median EFS,[a] mo		Unstratified HR (95% CI)	Unstratified HR (95% CI)
	NIVO + chemo/NIVO (n = 229)	Chemo/PBO (n = 232)		
Overall (N = 461)	NR	18.4		0.59 (0.44-0.79)
< 65 years (n = 202)	NR	16.7		0.55 (0.36-0.85)
≥ 65 years (n = 259)	NR	20.1		0.61 (0.41-0.91)
Male (n = 327)	NR	16.7		0.53 (0.37-0.75)
Female (n = 134)	30.2	18.8		0.71 (0.41-1.20)
North America (n = 44)	30.2	9.4		0.59 (0.25-1.38)
Europe (n = 250)	NR	23.7		0.61 (0.40-0.92)
Asia (n = 115)	NR	13.9		0.47 (0.26-0.86)
ECOG PS 0 (n = 288)	NR	20.1		0.57 (0.39-0.83)
ECOG PS 1 (n = 173)	29.0	17.3		0.61 (0.39-0.97)
Stage II (n = 162)	NR	NR		0.81 (0.46-1.43)
Stage III (n = 297)	30.2	13.4		0.51 (0.36-0.72)
N0 (n = 167)[b]	NR	NR		0.80 (0.48-1.32)
N1 (n = 108)[b]	NR	28.1		0.58 (0.29-1.16)
N2 (n = 182)[b,c]	30.2	10.0		0.46 (0.30-0.70)
Single-station (n = 112)	30.2	10.0		0.49 (0.29-0.84)
Multi-station (n = 69)	NR	10.0		0.43 (0.21-0.88)
Squamous (n = 234)	NR	17.0		0.46 (0.30-0.72)
Non-squamous (n = 227)	28.9	18.4		0.72 (0.49-1.07)
Current/former smoker (n = 417)	NR	17.0		0.54 (0.40-0.74)
Never smoker (n = 44)	19.7	25.0		1.32 (0.54-3.20)
PD-L1 < 1% (n = 186)[d]	29.0	19.8		0.73 (0.47-1.15)
PD-L1 ≥ 1% (n = 256)[d]	NR	15.8		0.52 (0.35-0.78)
PD-L1 1-49% (n = 159)[e]	30.2	28.1		0.76 (0.46-1.25)
PD-L1 ≥ 50% (n = 97)	NR	8.0		0.26 (0.12-0.55)
Cisplatin (n = 97)	27.0	15.8		0.61 (0.35-1.08)
Carboplatin (n = 347)	NR	17.3		0.53 (0.37-0.75)



Median follow-up (range): 25.4 months (15.7-44.2).

[a]Per BICR. [b]Nodal status was N3 in 4 patients. [c]N2 subcategory was not reported in 1 patient.Baseline characteristics were similar across treatment arms in the N2 nodal status subgroup, which comprised ~40% of patients. [d]Tumor PD-L1 expression was not evaluable/indeterminate in 19 patients. [e]Most patients in this subgroup had low PD-L1 expression (median 10% across both arms).

Cascone et al 2024. ESMO

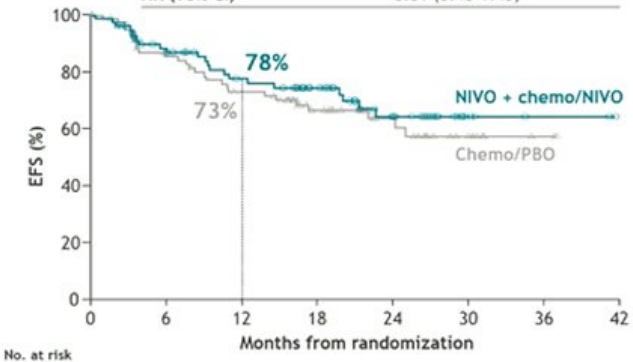
CheckMate 77T Trial

CheckMate 77T: perioperative NIVO in resectable NSCLC

EFS by baseline disease stage

Stage II

	NIVO + chemo/NIVO (n = 81)	Chemo/PBO (n = 81)
Median EFS, mo (95% CI)	NR (22.6-NR)	NR (24.2-NR)
HR (95% CI)	0.81 (0.46-1.43)	

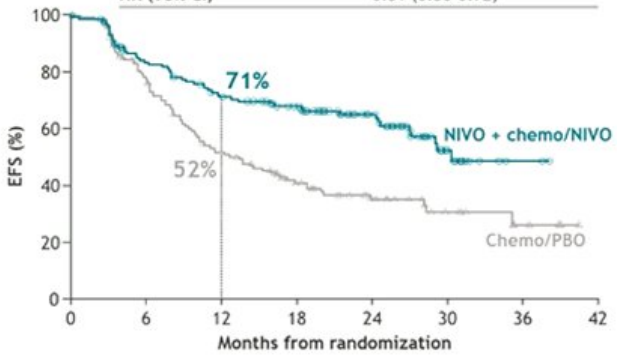


No. at risk

NIVO + chemo/NIVO	81	62	49	37	20	5	2	0
Chemo/PBO	81	63	51	34	20	8	2	0

Stage III

	NIVO + chemo/NIVO (n = 148)	Chemo/PBO (n = 149)
Median EFS, mo (95% CI)	30.2 (26.9-NR)	13.4 (9.8-17.7)
HR (95% CI)	0.51 (0.36-0.72)	

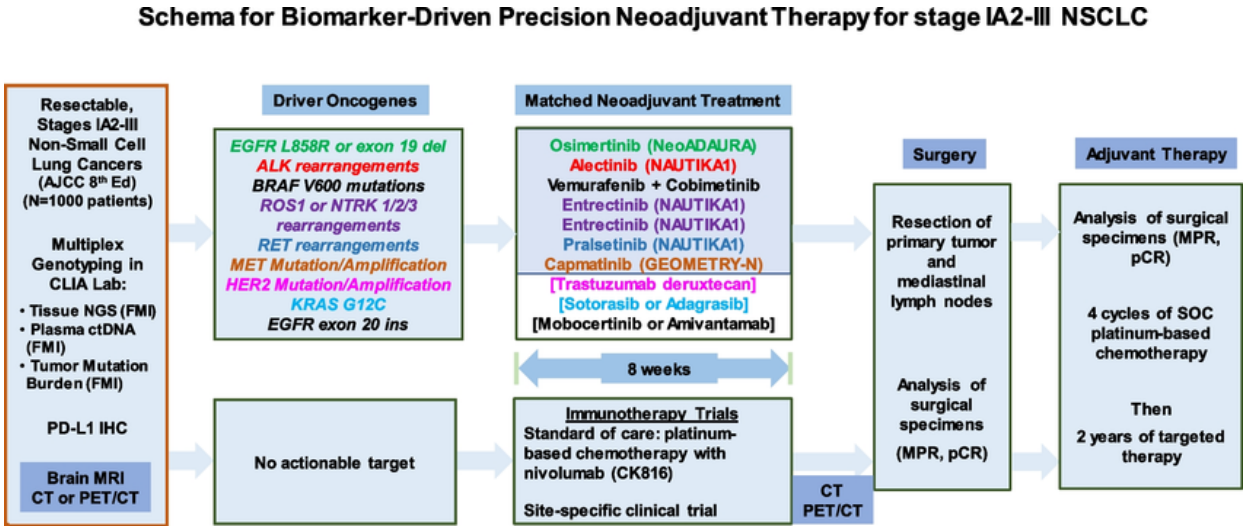


NIVO + chemo/NIVO	148	111	92	78	49	15	2	0
Chemo/PBO	149	102	67	44	24	11	4	0

Median follow-up (range): 25.4 months (15.7-44.2).

Cascone et al 2024. ESMO

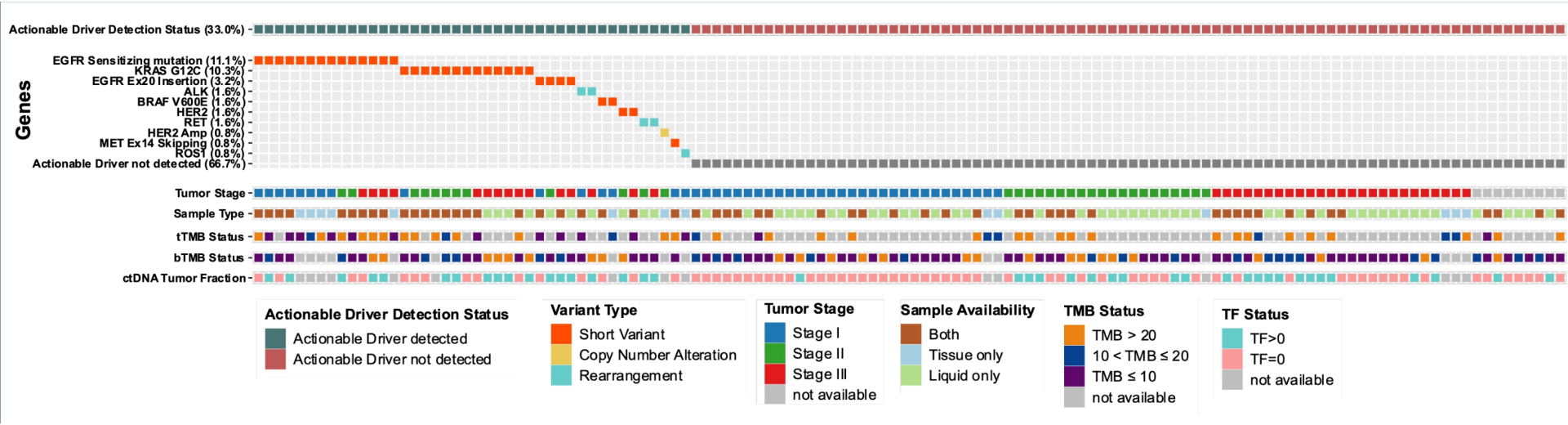
LEARN Trial



- **LCMCA (LEADER) Screening Trial**
  - Umbrella trial – detect actionable oncogenic drivers by NGS in patients with resectable, early-stage NSCLC
  - Oncogenic driver detected – matched to effective targted therapy for metastatic NSCLC
  - No oncogenic driver detected – standard of care or neoadjuvant nivolumab and chemotherapy

Godoy et al 2023. Biomarker research

LEARN Trial

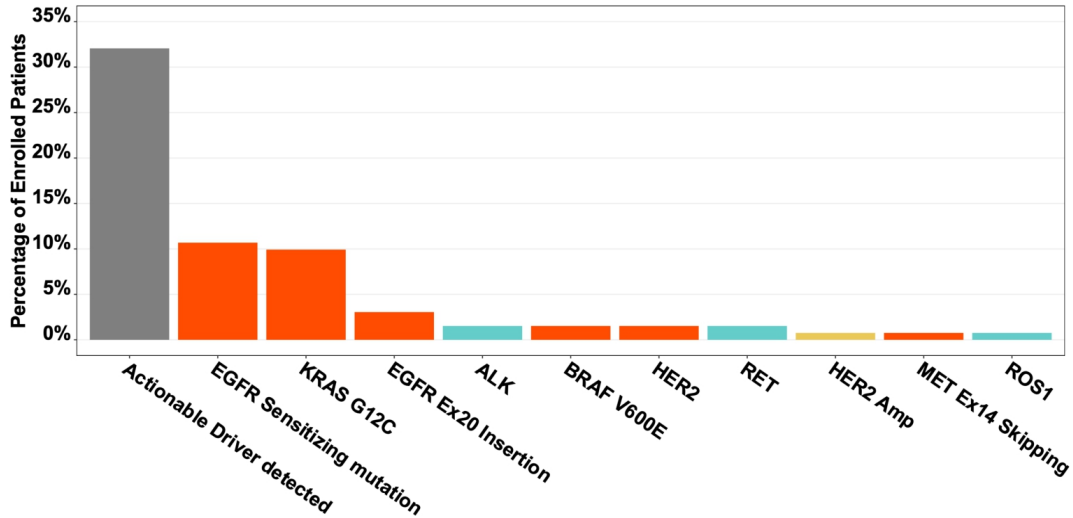


- **33% of patients with tissue and/or liquid testing had an actionable driver mutation**

Chaft et al 2024. ASCO abstract 8068

LEARN Trial

Prevalence of Actionable Alterations in Tissue and/or Liquid Samples (N=126)



Chaft et al 2024. ASCO abstract 8068

Expanding Eligibility Criteria

- **Initial recommendations prioritized assessment of specific eligibility criteria:**
  - Brain Metastases
  - Minimum Age
  - HIV/AIDS
  - Organ Dysfunction
  - Prior and Concurrent Malignancies

JOURNAL OF CLINICAL ONCOLOGY | ASCO SPECIAL ARTICLE

Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement

Edward S. Kim, Suanna S. Bruinooge, Samantha Roberts, Gwynn Ison, Nancy U. Lin, Lia Gore, Thomas S. Uldrick, Stuart M. Lichtman, Nancy Roach, Julia A. Beaver, Rajeshwari Sridhara, Paul J. Hesketh, Andrea M. Denicoff, Elizabeth Garrett-Mayer, Eric Rubin, Pratik Multani, Tatiana M. Prowell, Caroline Schenkel, Marina Kozak, Jeff Allen, Ellen Sigal, and Richard L. Schilsky

- **Expanded recommendations for eligibility criteria:**
  - Washout Periods and Concomitant Medications
  - Prior Therapies
  - Laboratory Reference Ranges and Test Intervals
  - Performance Status

Published OnlineFirst February 9, 2021; DOI: 10.1158/1078-0432.CCR-20-3852

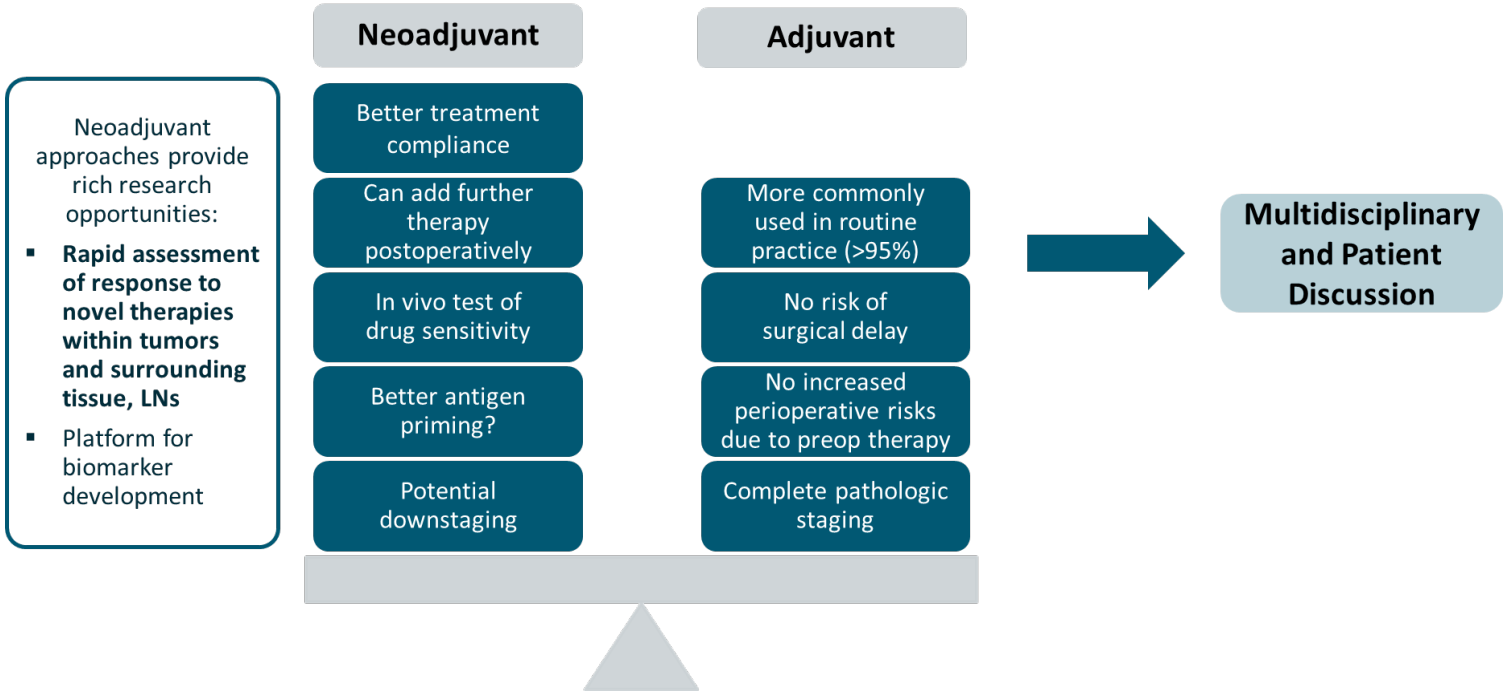
CLINICAL CANCER RESEARCH | PERSPECTIVES

Continuing to Broaden Eligibility Criteria to Make Clinical Trials More Representative and Inclusive: ASCO–Friends of Cancer Research Joint Research Statement

Edward S. Kim[1], Thomas S. Uldrick[2], Caroline Schenkel[3], Suanna S. Bruinooge[3], R. Donald Harvey[4], Allison Magnuson[5], Alexander Spira[6], James L. Wade[7], Mark D. Stewart[8], Diana Merino Vega[8], Julia A. Beaver[9], Andrea M. Denicoff[10], Gwynn Ison[9], S. Percy Ivy[10], Suzanne George[11], Raymond P. Perez[12], Patricia A. Spears[13], William D. Tap[14], and Richard L. Schilsky[3]

ABSTRACT

Multidisciplinary Approach



Conclusions

- Lung cancer has dramatically changed the landscape of precision medicine
- Neoadjuvant/adjuvant therapies can help improve outcomes and reduce recurrences
- Biomarker-driven therapy extending from advanced stage to early-stage NSCLC requires a multidisciplinary approach

Thank you!

City of Hope

linkedin.com/in/ed-kim-1a416260/