



# Perioperative Immunotherapy for NSCLC

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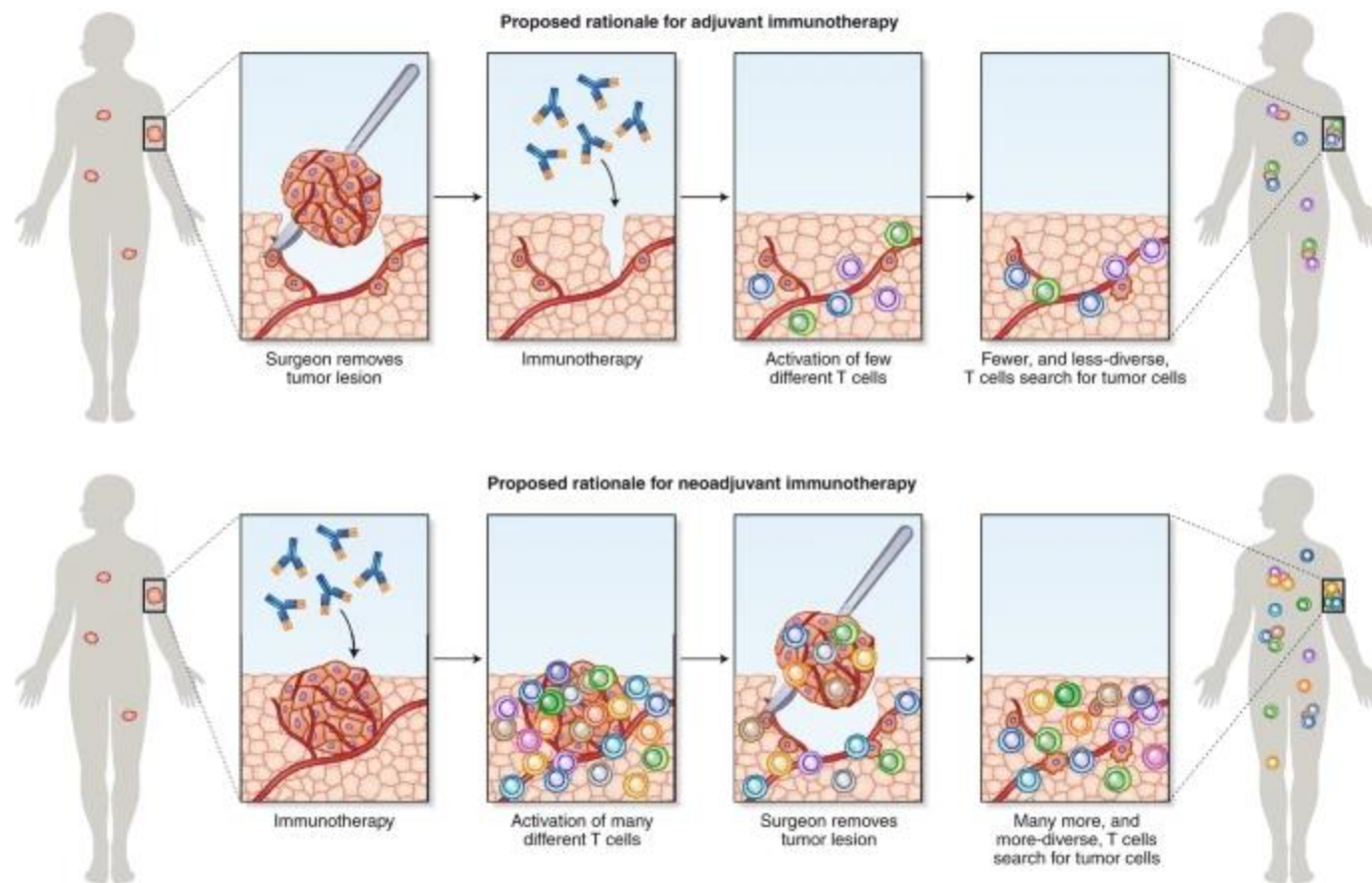
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**Fig. 1: Neoadjuvant and adjuvant approaches to immunotherapy.**



In adjuvant approaches, shown above, immunotherapy (as indicated by the antibodies) is given after surgery, which results in the activation of T cells directed to different antigens, as indicated by the different colors. In neoadjuvant approaches, therapy is given before surgery, which results in the raising of a more diverse T cell response.



# Neoadjuvant Immunotherapy in NSCLC

- Checkmate 816
- NADIM II



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# CheckMate 816 study design<sup>a</sup>

## Key Eligibility Criteria

- Newly diagnosed, resectable, stage IB ( $\geq 4$  cm)-IIIA NSCLC (per TNM 7<sup>th</sup> edition)
- ECOG performance status 0-1
- No known sensitizing *EGFR* mutations or *ALK* alterations

Stratified by  
Stage (IB-II vs IIIA),  
PD-L1<sup>b</sup> ( $\geq 1\%$  vs  $< 1\%$ <sup>c</sup>), and sex

N = 358

R  
1:1

## Primary analysis population

NIVO 360 mg Q3W  
+  
chemo<sup>d</sup> Q3W (3 cycles)

Chemo<sup>e</sup> Q3W (3 cycles)

NIVO 3 mg/kg Q2W (3 cycles)  
+ IPI 1 mg/kg (cycle 1 only)<sup>f</sup>

**FDA approved 3/2022**

Radiologic  
restaging

Surgery  
(within 6  
weeks  
post-  
treatment)

Optional  
adjuvant  
chemo  $\pm$  RT<sup>g</sup>

Follow-up

### Primary endpoints

- pCR by BIPR
- EFS by BICR

### Secondary endpoints

- MPR by BIPR
- OS
- Time to death or distant metastases

### Exploratory endpoints

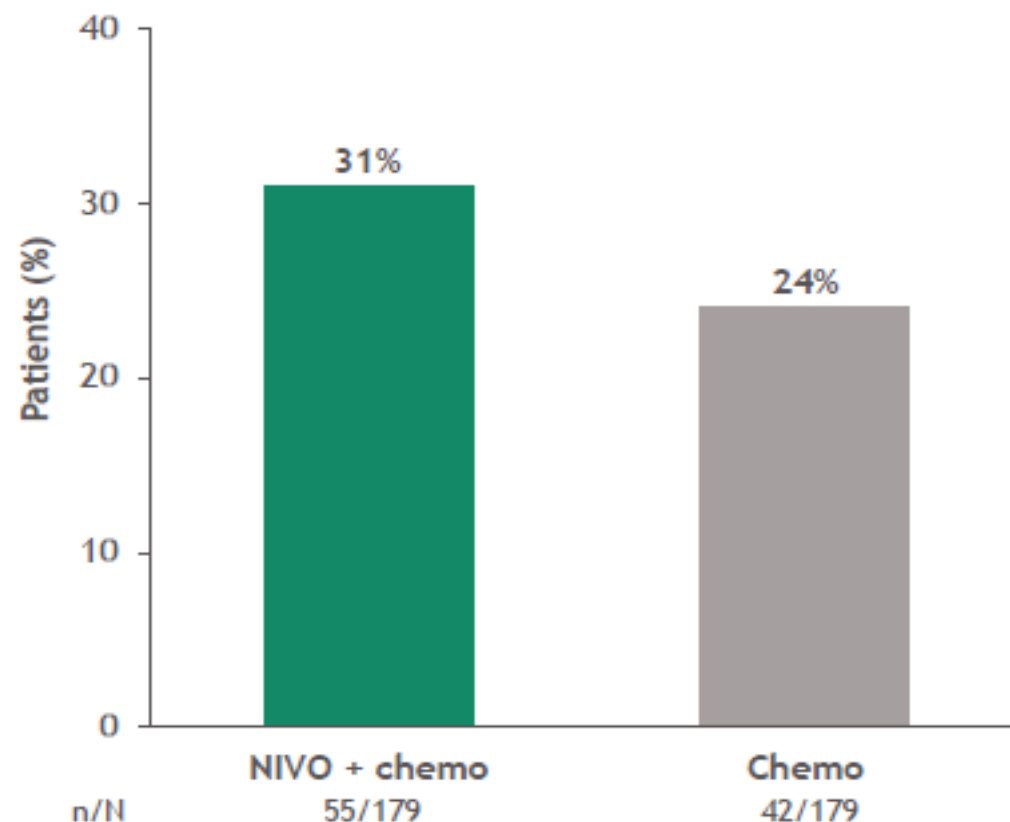
- ORR by BICR
- Predictive biomarkers (PD-L1, TMB, ctDNA<sup>h</sup>)

# Objective response rate and radiographic down-staging

## Objective response rate

| Patients, n (%)              | NIVO + chemo<br>(n = 179) | Chemo<br>(n = 179)   |
|------------------------------|---------------------------|----------------------|
| ORR <sup>a</sup>             | 96 (54) <sup>b</sup>      | 67 (37) <sup>b</sup> |
| <b>Best overall response</b> |                           |                      |
| Complete response            | 1 (1)                     | 3 (2)                |
| Partial response             | 95 (53)                   | 64 (36)              |
| Stable disease               | 70 (39)                   | 88 (49)              |
| Progressive disease          | 8 (4)                     | 11 (6)               |
| Not evaluable                | 1 (1)                     | 1 (1)                |
| Not reported                 | 4 (2)                     | 12 (7)               |

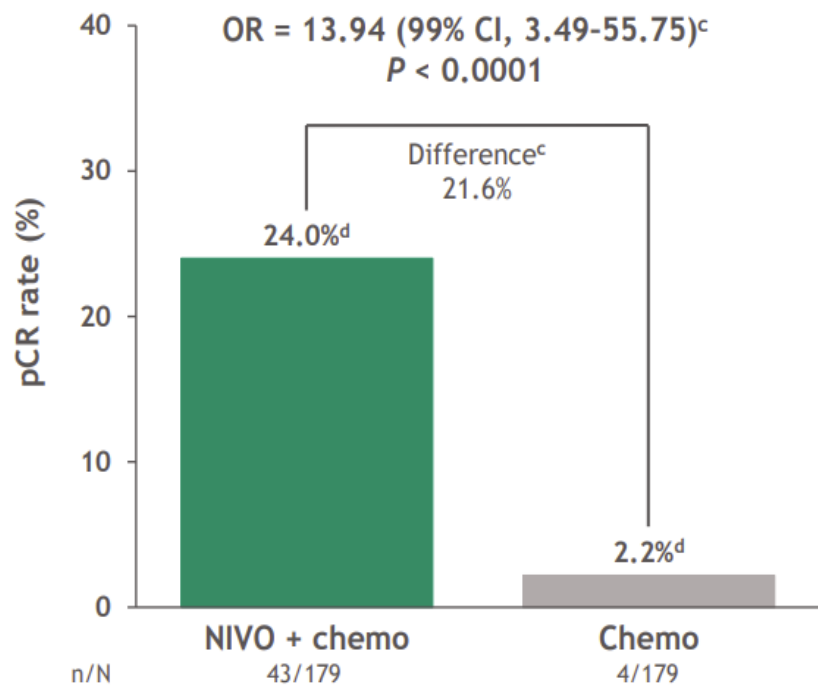
## Patients with radiographic down-staging<sup>c</sup>



<sup>a</sup>Objective response rate was up to the presurgical scan; <sup>b</sup>ORR rates 95% CI: NIVO + chemo, 46-61; chemo, 30-45; <sup>c</sup>Decrease in stage from baseline to presurgical scan.

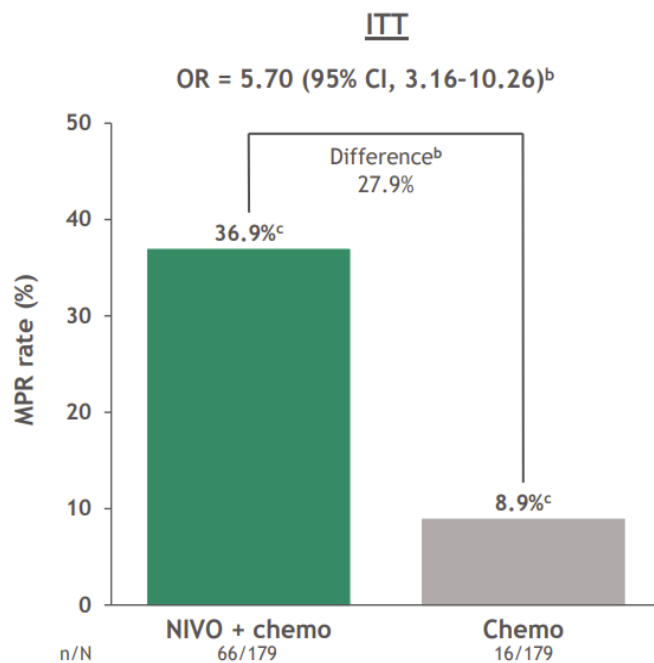
## Primary endpoint: pCR<sup>a</sup> rate with neoadjuvant NIVO + chemo vs chemo

### Primary endpoint: ITT (ypT0N0)<sup>b</sup>

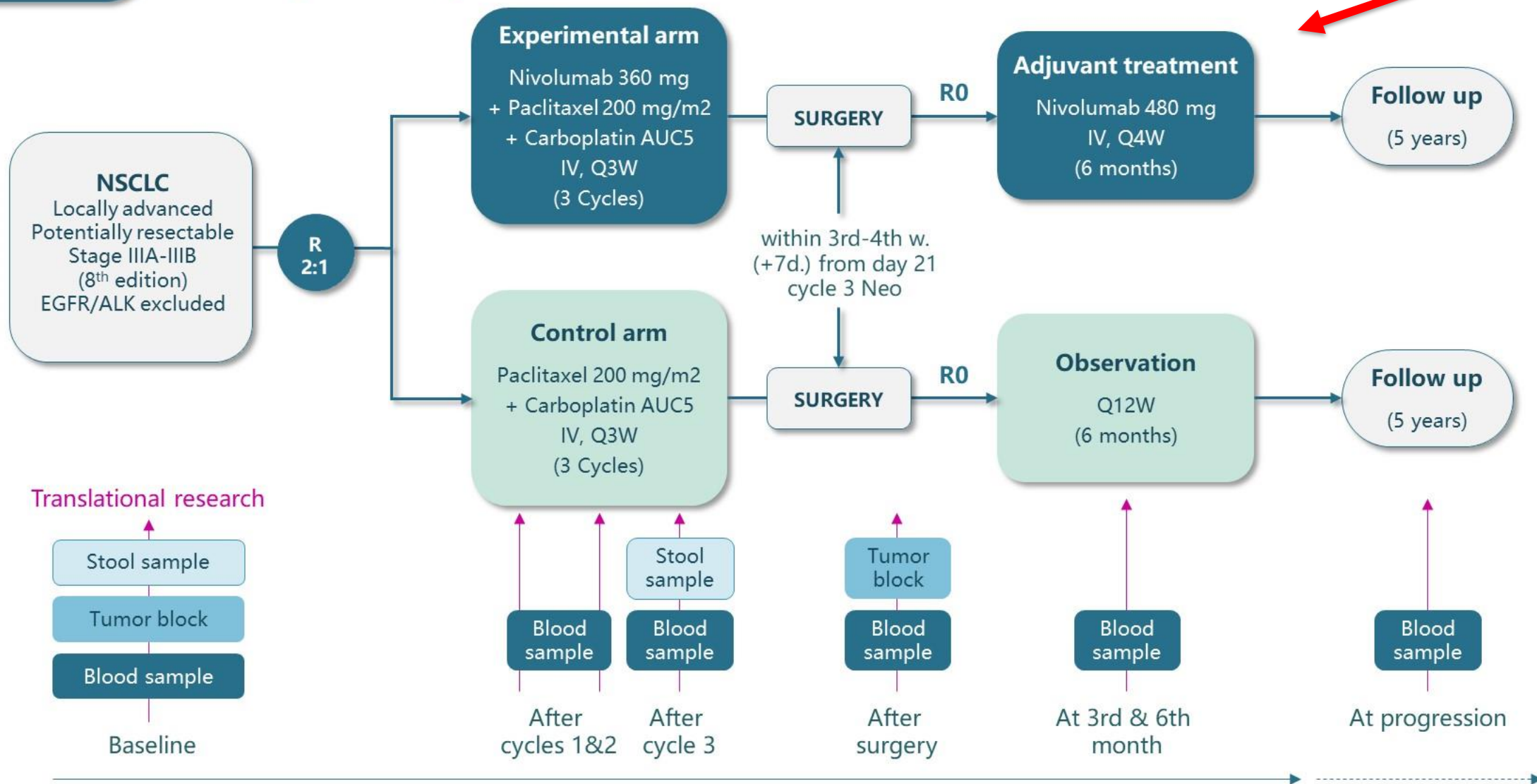


CheckMate 816: pCR with neoadjuvant NIVO + chemo in resectable NSCLC

## MPR<sup>a</sup> rate with neoadjuvant NIVO + chemo vs chemo

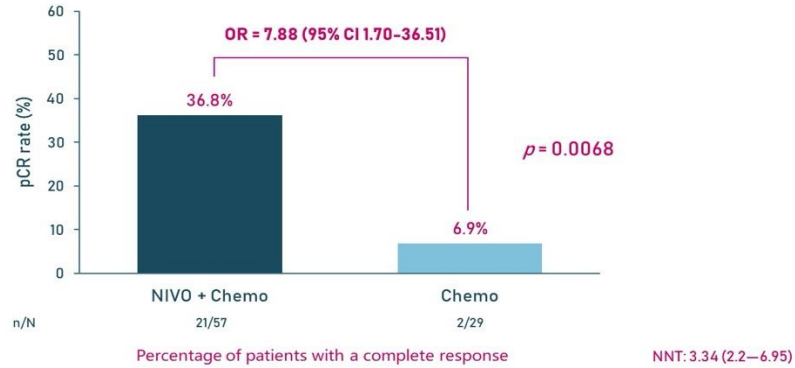


<sup>a</sup>Per BIPR; MPR: ≤ 10% residual viable tumor cells in both the primary tumor (lung) and sampled lymph nodes; <sup>b</sup>Calculated by stratified Cochran-Mantel-Haenszel method; <sup>c</sup>MPR rates 95% CI: NIVO + chemo, 29.8-44.4; chemo, 5.2-14.1.



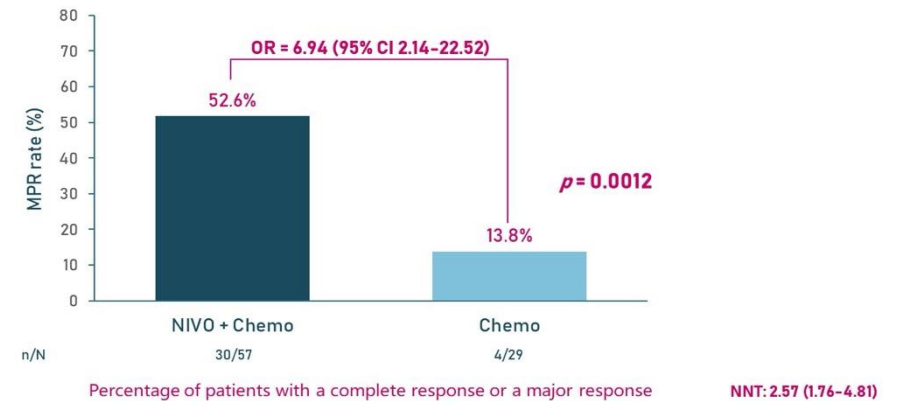
NADIM II (NCT03838159) is a randomized, phase 2, open-label, multicentre study evaluating nivolumab + chemotherapy vs chemotherapy as neoadjuvant treatment for potentially resectable NSCLC

pCR<sup>a</sup> rate with neoadjuvant NIVO + CT vs CT in the ITT population<sup>b</sup>



<sup>a</sup>pCR was defined as 0% residual viable tumor cells in both primary tumor (lung) and sampled lymph nodes; <sup>b</sup>Patients who did not undergo surgery were considered as non-responders  
Chemo, chemotherapy; ITT, intention-to-treat; Nivo, nivolumab; pCR, pathological complete response; RR, risk ratio

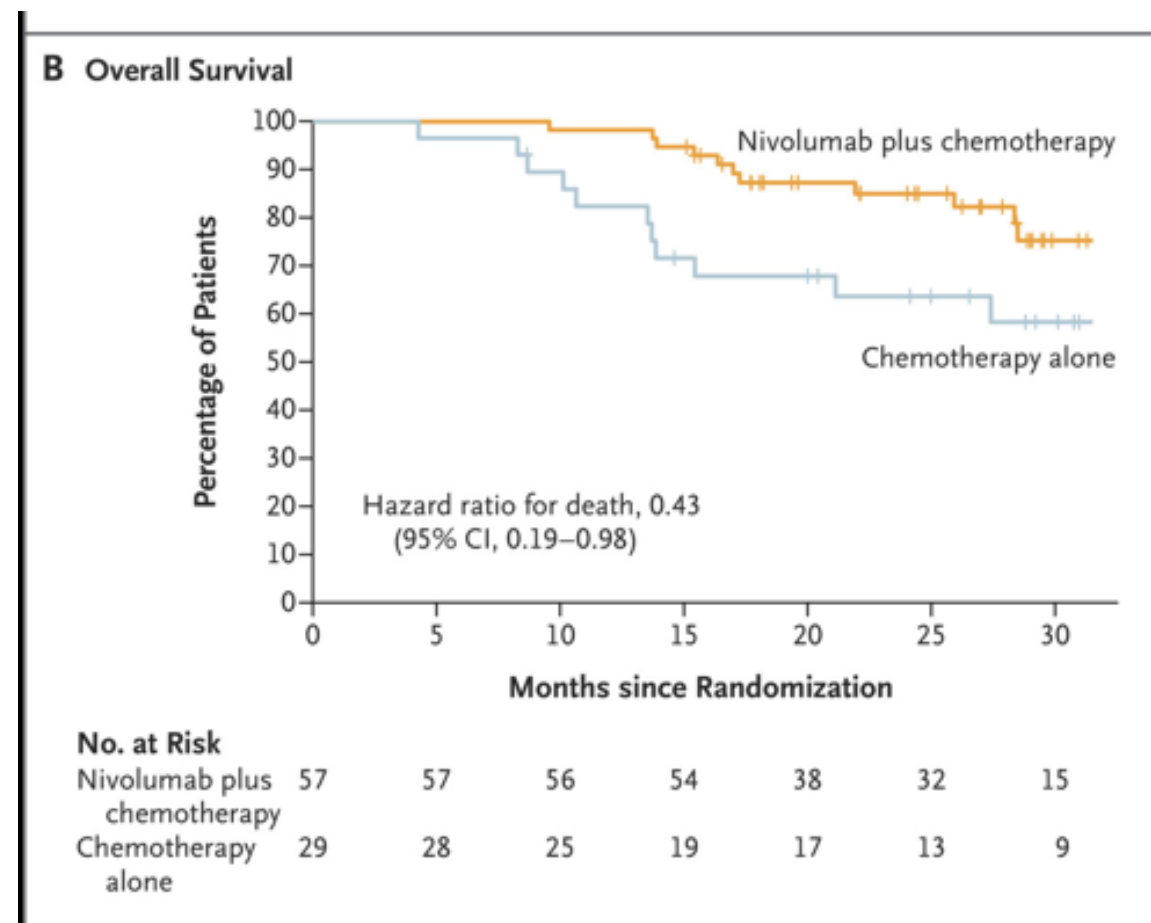
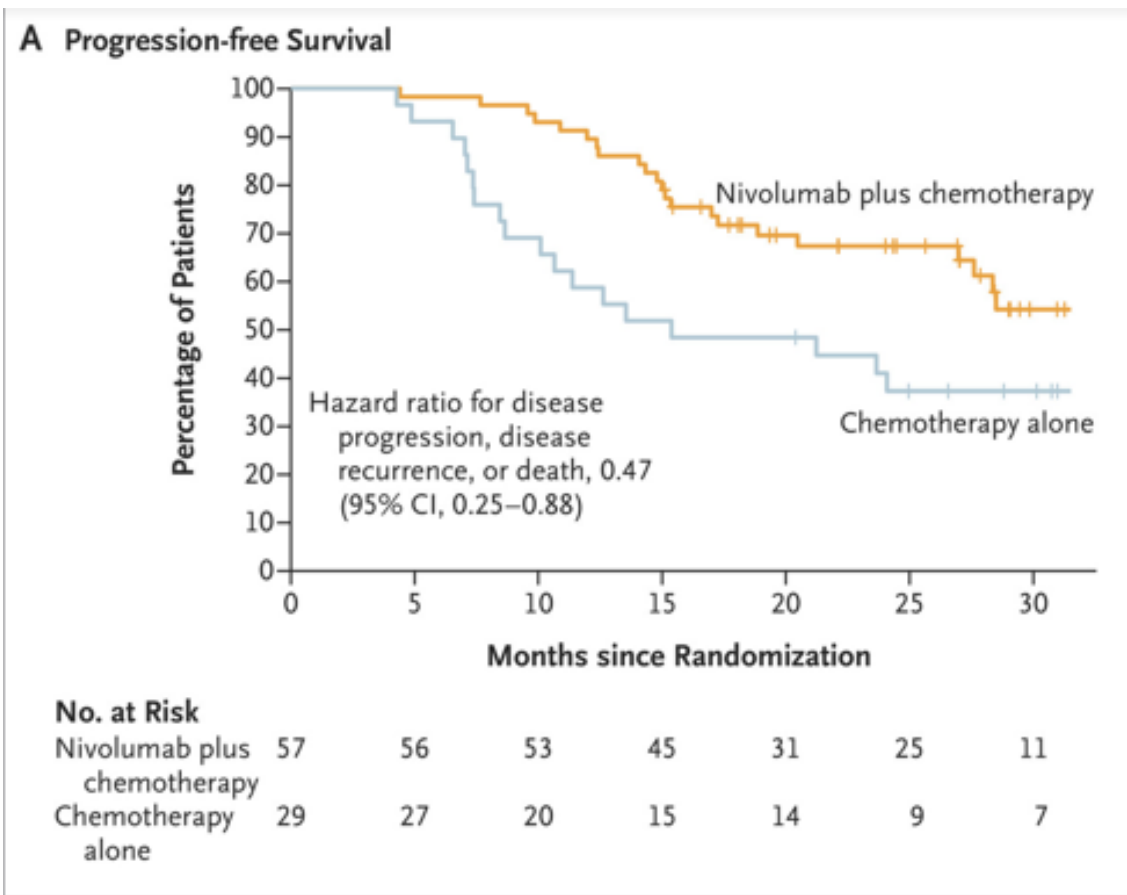
MPR<sup>a</sup> rate with neoadjuvant NIVO + CT vs CT in the ITT population<sup>b</sup>



<sup>a</sup>MPR was defined as ≤10% residual viable tumor cells in both the primary tumor (lung) and sampled lymph nodes; <sup>b</sup>Patients who did not undergo surgery were considered as non-responders  
Chemo, chemotherapy; ITT, intention-to-treat; MPR, major pathological response; Nivo, nivolumab; RR, risk ratio



# Neoadjuvant Nivolumab and Chemotherapy in Stage III Non-Small-Cell Lung Cancer





# ADJUVANT IMMUNOTHERAPY IN NSCLC

\*IMPOWER 010

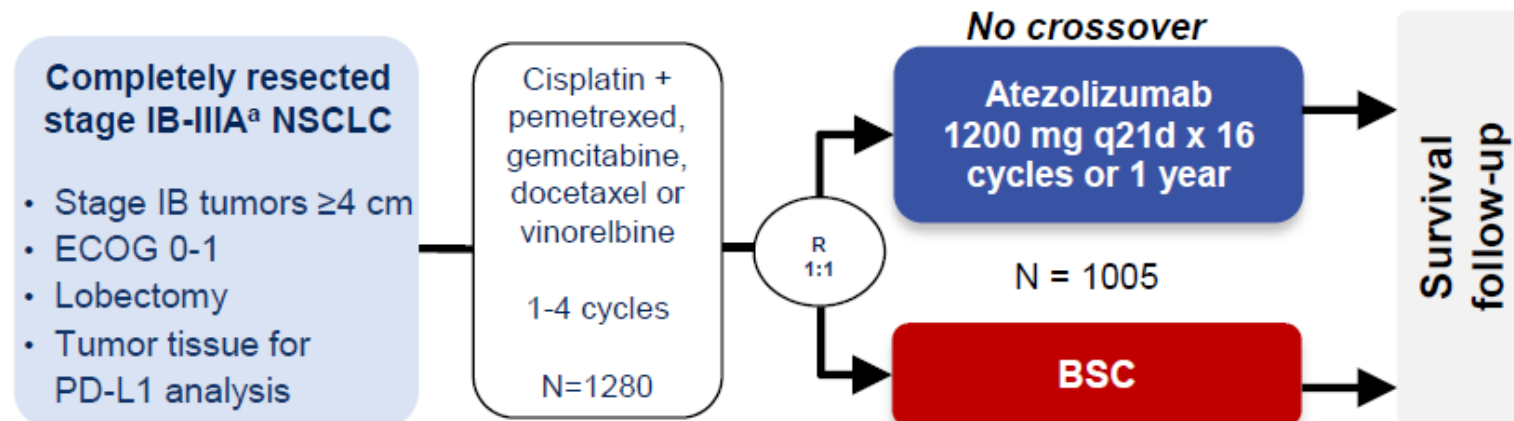
\*Keynote 091



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# IMpower010: Phase III randomised trial of atezolizumab vs BSC in early-stage NSCLC



## Stratification factors

- Sex | Stage | Histology | PD-L1 status

## Primary endpoint

- Investigator-assessed DFS tested hierarchically

## Key secondary endpoints

- OS in ITT | DFS in PD-L1 TC  $\geq 50\%$  | 3-yr and 5-year DFS

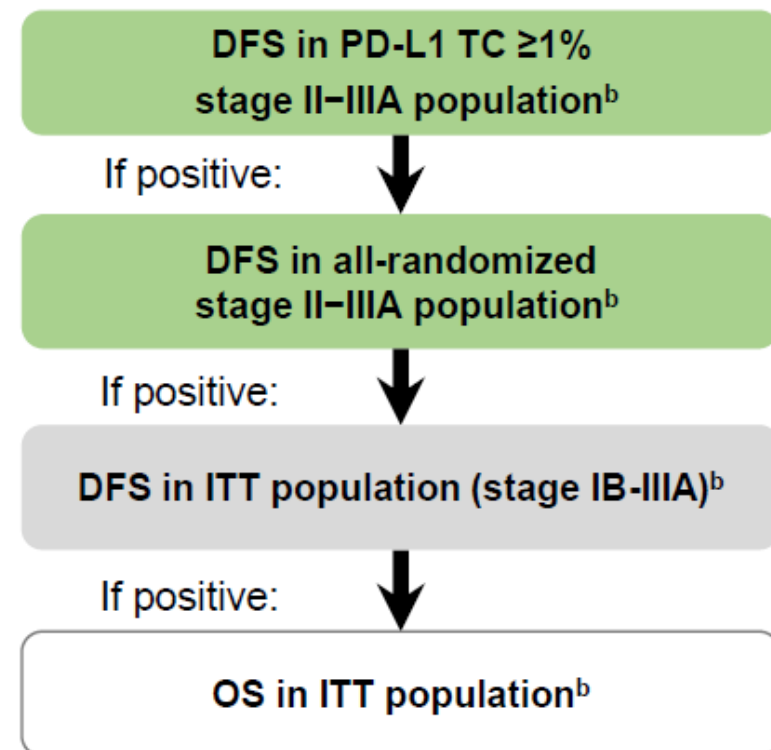
## Key exploratory endpoints

- OS biomarker analyses

Clinical cutoff: 18 April 2022. Both arms included observation and regular scans for disease recurrence on the same schedule. ECOG, Eastern Cooperative Oncology Group, q21d, every 21 days.

<sup>a</sup> Per UICC/AJCC staging system, 7th edition. <sup>b</sup> Two-sided  $\alpha=0.05$ .

## Hierarchical statistical testing of endpoints

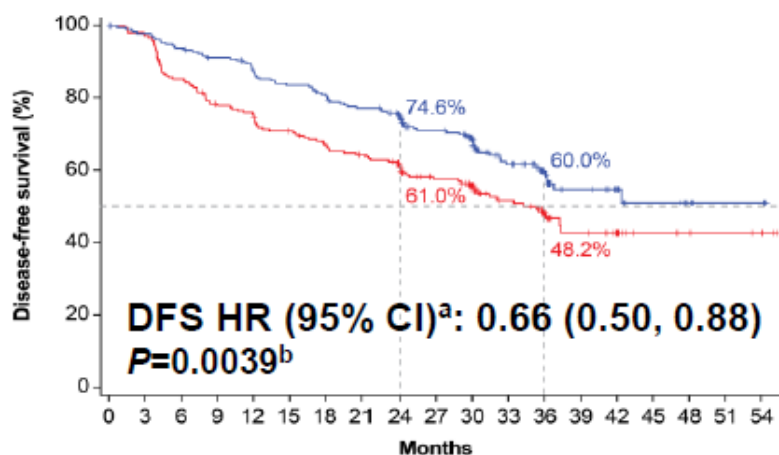


- Endpoint was met at DFS IA
- Endpoint was not met at DFS IA and follow up is ongoing
- Endpoint was not formally tested

# Recap of DFS and OS data from the DFS IA<sup>1,2</sup>

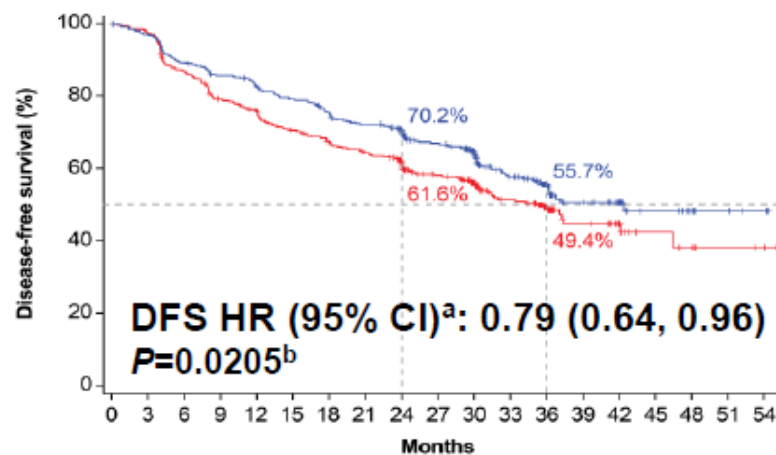
(data cutoff: 21 Jan '21, median follow-up: 32 months)

**DFS: PD-L1 TC  $\geq 1\%$   
stage II-IIIa population**



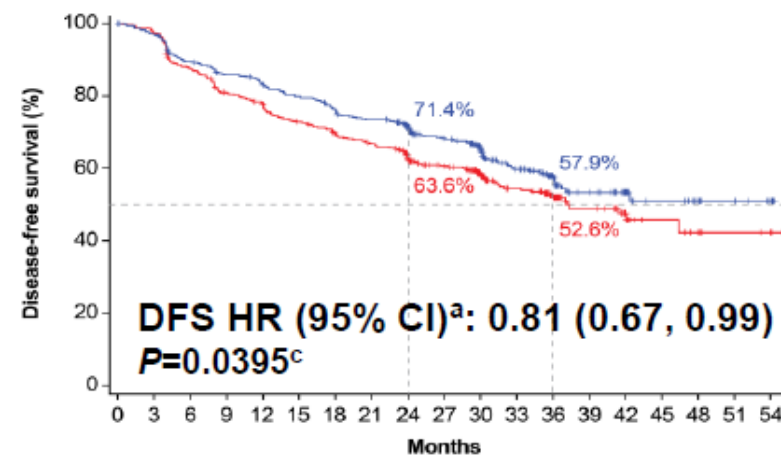
| No. at risk  | 0   | 3   | 6   | 9   | 12  | 15  | 18  | 21  | 24  | 27  | 30  | 33 | 36 | 39 | 42 | 45 | 48 | 51 | 54 |
|--------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----|----|----|----|----|----|----|----|
| Atezolizumab | 248 | 235 | 225 | 217 | 206 | 198 | 190 | 181 | 159 | 134 | 111 | 76 | 54 | 31 | 22 | 12 | 8  | 3  | 3  |
| BSC          | 228 | 212 | 188 | 169 | 160 | 151 | 142 | 135 | 117 | 97  | 80  | 59 | 38 | 21 | 14 | 7  | 6  | 4  | 3  |

**DFS: All-randomised  
stage II-IIIa population**



| No. at risk  | 0   | 3   | 6   | 9   | 12  | 15  | 18  | 21  | 24  | 27  | 30  | 33  | 36 | 39 | 42 | 45 | 48 | 51 | 54 |
|--------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----|----|----|----|----|----|----|
| Atezolizumab | 442 | 418 | 384 | 367 | 352 | 337 | 319 | 305 | 269 | 225 | 185 | 120 | 84 | 48 | 34 | 16 | 11 | 5  | 3  |
| BSC          | 440 | 412 | 366 | 331 | 314 | 292 | 277 | 263 | 230 | 182 | 148 | 102 | 71 | 35 | 22 | 10 | 8  | 4  | 3  |

**DFS: ITT (randomised  
stage IB-IIIa) population**



| No. at risk  | 0   | 3   | 6   | 9   | 12  | 15  | 18  | 21  | 24  | 27  | 30  | 33  | 36 | 39 | 42 | 45 | 48 | 51 | 54 |
|--------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|-----|----|----|----|----|----|----|----|
| Atezolizumab | 507 | 478 | 437 | 418 | 403 | 387 | 367 | 353 | 306 | 257 | 212 | 139 | 97 | 53 | 38 | 19 | 14 | 8  | 4  |
| BSC          | 498 | 467 | 418 | 383 | 365 | 342 | 324 | 309 | 269 | 219 | 173 | 122 | 90 | 46 | 30 | 13 | 10 | 5  | 4  |

- **OS data** were not mature (event to patient ratio in ITT was 19% in atezolizumab arm, 18% in BSC arm)
  - PD-L1 TC  $\geq 1\%$  stage II-IIIa population: OS HR, 0.77 (95% CI: 0.51, 1.17)<sup>a</sup>
  - All-randomised stage II-IIIa population: OS HR, 0.99 (95% CI: 0.73, 1.33)<sup>a</sup>
  - ITT (randomised stage IB-IIIa) population: OS HR, 1.07 (95% CI: 0.80, 1.42)<sup>a</sup>

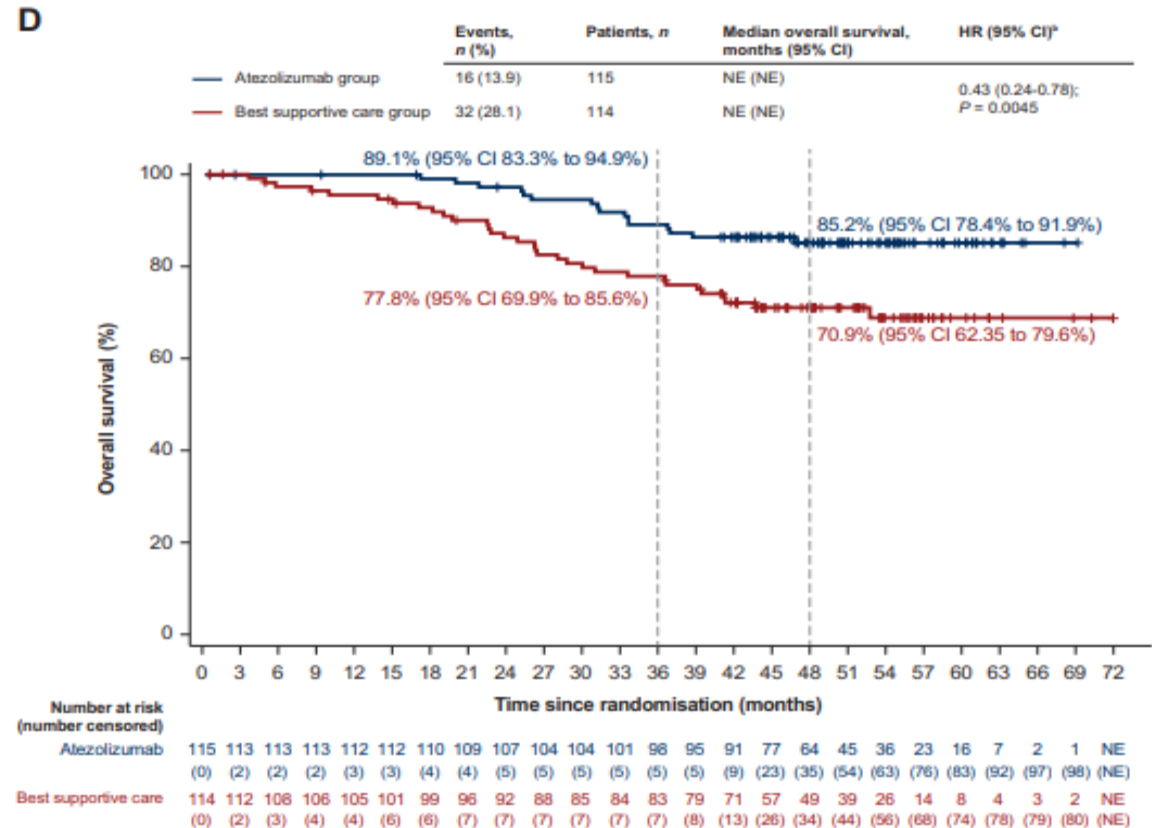
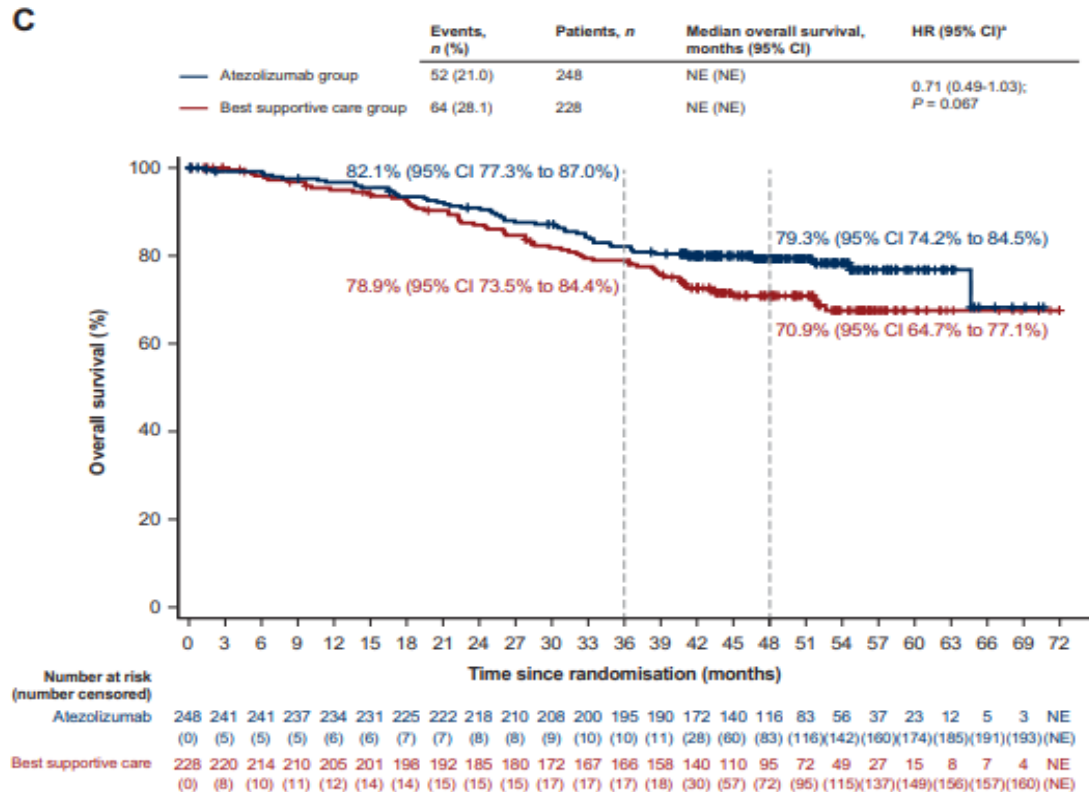
Clinical cutoff: 21 Jan 2021. <sup>a</sup> Stratified. <sup>b</sup> Statistical significance boundary for DFS crossed. <sup>c</sup> Statistical significance boundary for DFS not crossed.

1. Felip, E et al Lancet 2021; 938; 1344-1357; 2. Wakelee. HA et al ASCO 2021; abs #8500.

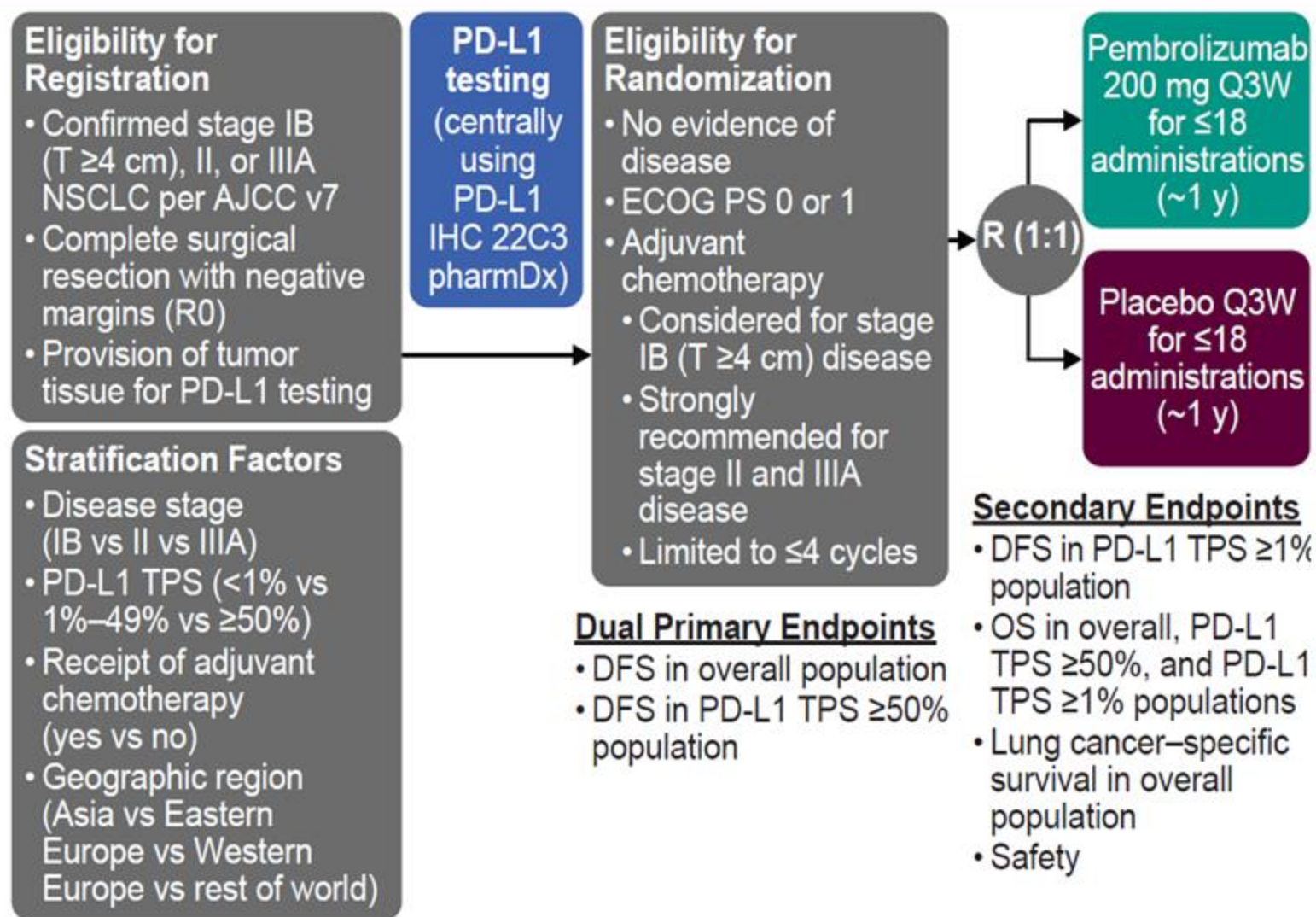
# Overall Survival (data immature)

## Stage II-III A PD-L1 TC >1%

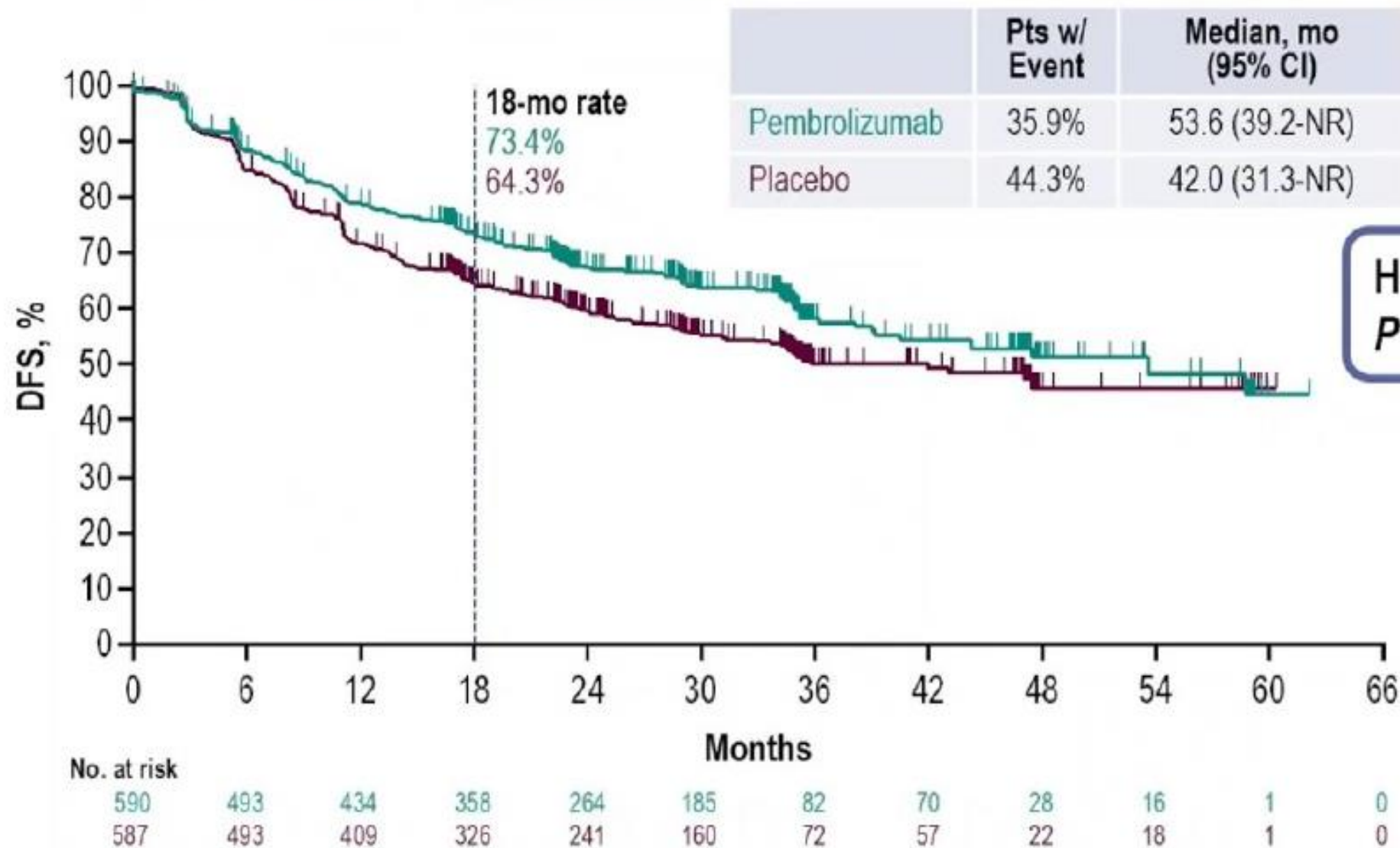
## Stage II-III A PD-L1 TC >50%



# PEARLS/KEYNOTE-091 Study Design

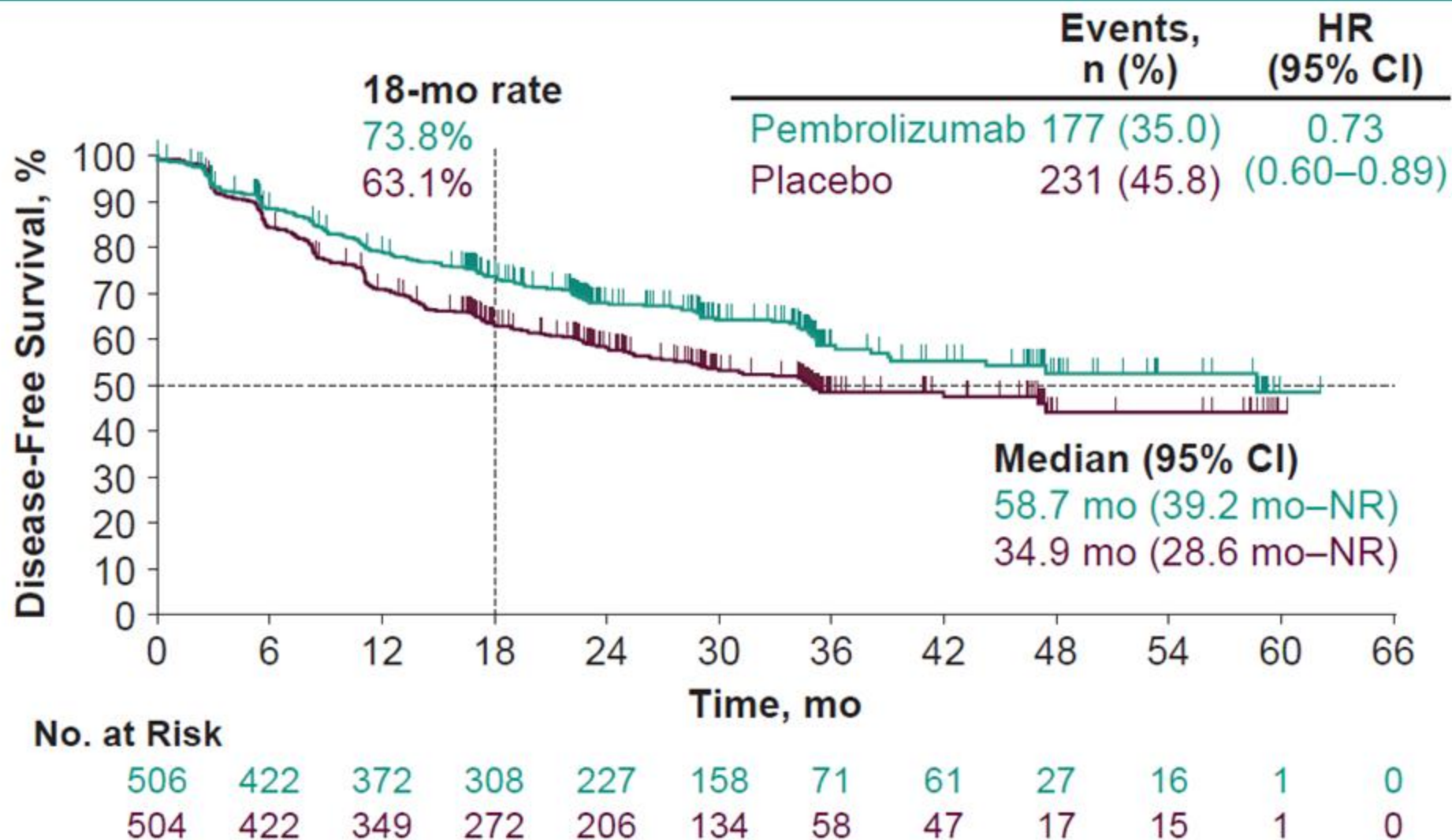


# DFS, Overall Population



**HR 0.76 (95% CI, 0.63-0.91)**  
**P = 0.0014**

# Disease-Free Survival in Patients Who Received $\geq 1$ Cycle of Adjuvant Chemotherapy





# Summary and Conclusions

- Pembrolizumab provided statistically significant, clinically meaningful DFS improvement versus placebo in the overall population
  - Median DFS of 53.6 months with pembrolizumab vs 42.0 months with placebo (HR, 0.76)
  - Generally consistent DFS benefit in participants with PD-L1 TPS <1%, 1-49%, and ≥50%
  - OS data are immature
  - DFS in the PD-L1-defined populations and OS will be tested at future analyses according to the analysis plan
- Pembrolizumab safety profile as expected
- **Data suggest pembrolizumab has the potential to be a new adjuvant treatment option for patients with stage IB (T ≥4 cm) to IIIA NSCLC following complete resection and adjuvant chemotherapy when recommended, regardless of PD-L1 expression**

**On January 26, 2023, the Food and Drug Administration (FDA) approved pembrolizumab for adjuvant treatment following resection and platinum-based chemotherapy for stage IB (T<sub>2a</sub> ≥4 cm), II, or IIIA non-small cell lung cancer (NSCLC), regardless PDL1**



# FDA Approved Adjuvant Immunotherapy for NSCLC

|                     | PD-L1 < 1% |               | PD-L1 1-49%  |               | PD-L1 > 50%  |               |
|---------------------|------------|---------------|--------------|---------------|--------------|---------------|
| <b>IB (&gt;4cm)</b> |            | Pembrolizumab |              | Pembrolizumab |              | Pembrolizumab |
| <b>II</b>           |            | Pembrolizumab | Atezolizumab | Pembrolizumab | Atezolizumab | Pembrolizumab |
| <b>IIIA</b>         |            | Pembrolizumab | Atezolizumab | Pembrolizumab | Atezolizumab | Pembrolizumab |

## Atezolizumab

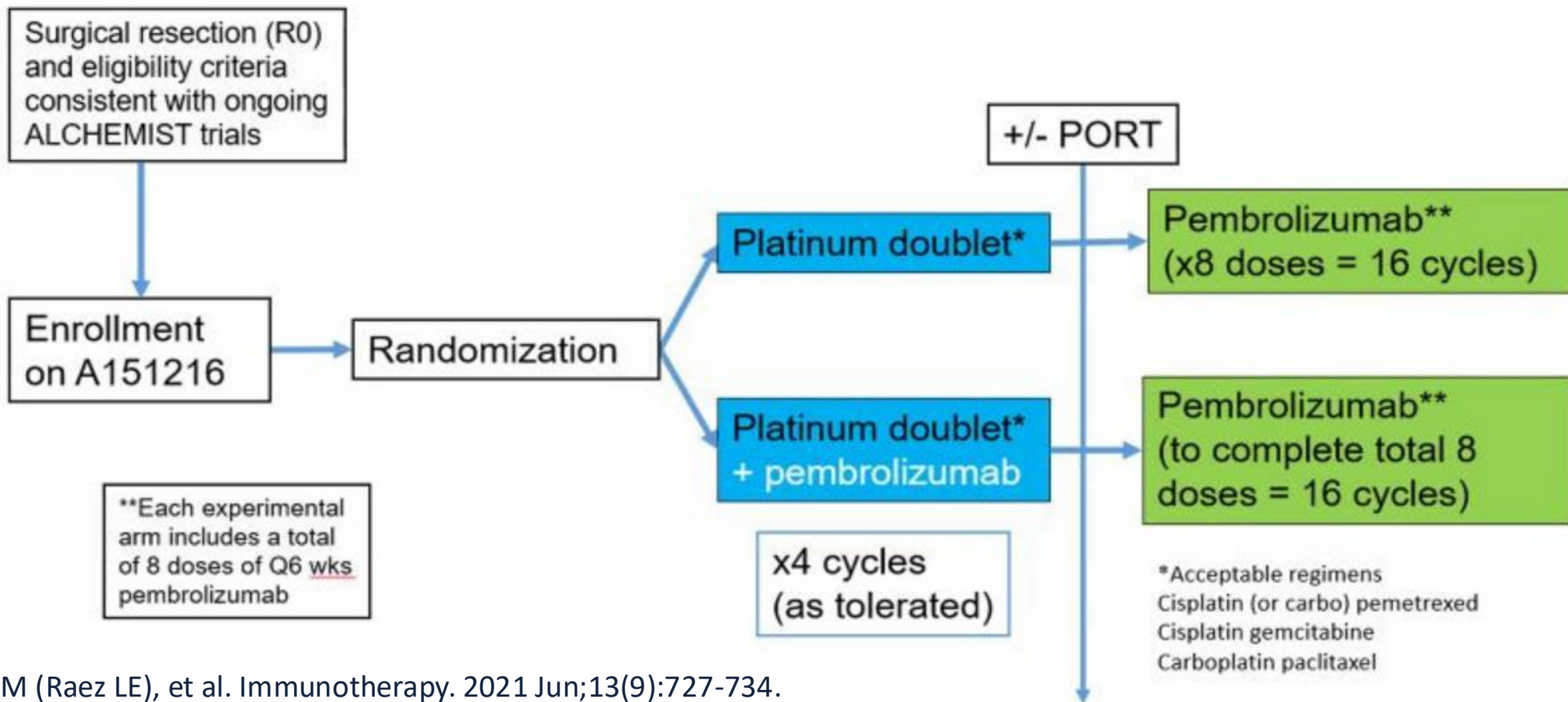
DFS HR 0.66 (95%CI 0.50-0.88) p=0.0039  
Stage II-III A, PD-L1 > 1%

## Pembrolizumab

DFS HR 0.76 (95%CI 0.63-0.91) p=0.0014  
Stage IB(>4cm)-III A, regardless PD-L1

# Study Design

Alliance ACCIO: A081801  
 Clinicaltrials.gov: NCT04071223



\*\*Each experimental arm includes a total of 8 doses of Q6 wks pembrolizumab

\*Acceptable regimens  
 Cisplatin (or carbo) pemetrexed  
 Cisplatin gemcitabine  
 Carboplatin paclitaxel



# NEOADJUVANT PLUS ADJUVANT (PERIOPERATIVE) IMMUNOTHERAPY IN NSCLC

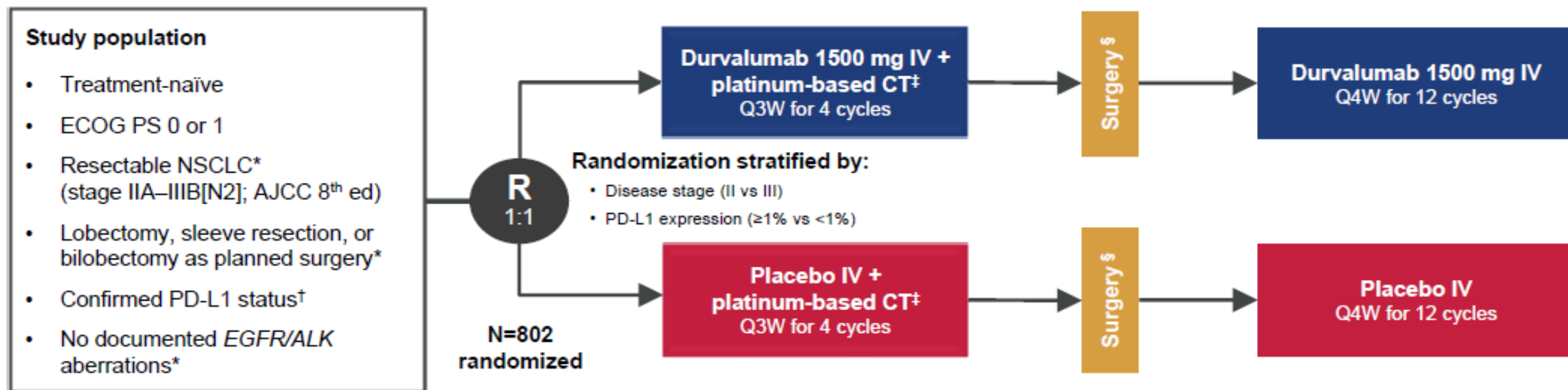
- \*AEGEAN
- \*Keynote 671
- \*Checkmate 77T



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# AEGEAN: a phase 3, global, randomized, double-blind, placebo-controlled study



**Endpoints:** All efficacy analyses performed on a modified population that excludes patients with documented *EGFR/ALK* aberrations<sup>¶</sup>

## Primary:

- pCR by central lab (per IASLC 2020<sup>1</sup>)
- EFS using BICR (per RECIST v1.1)

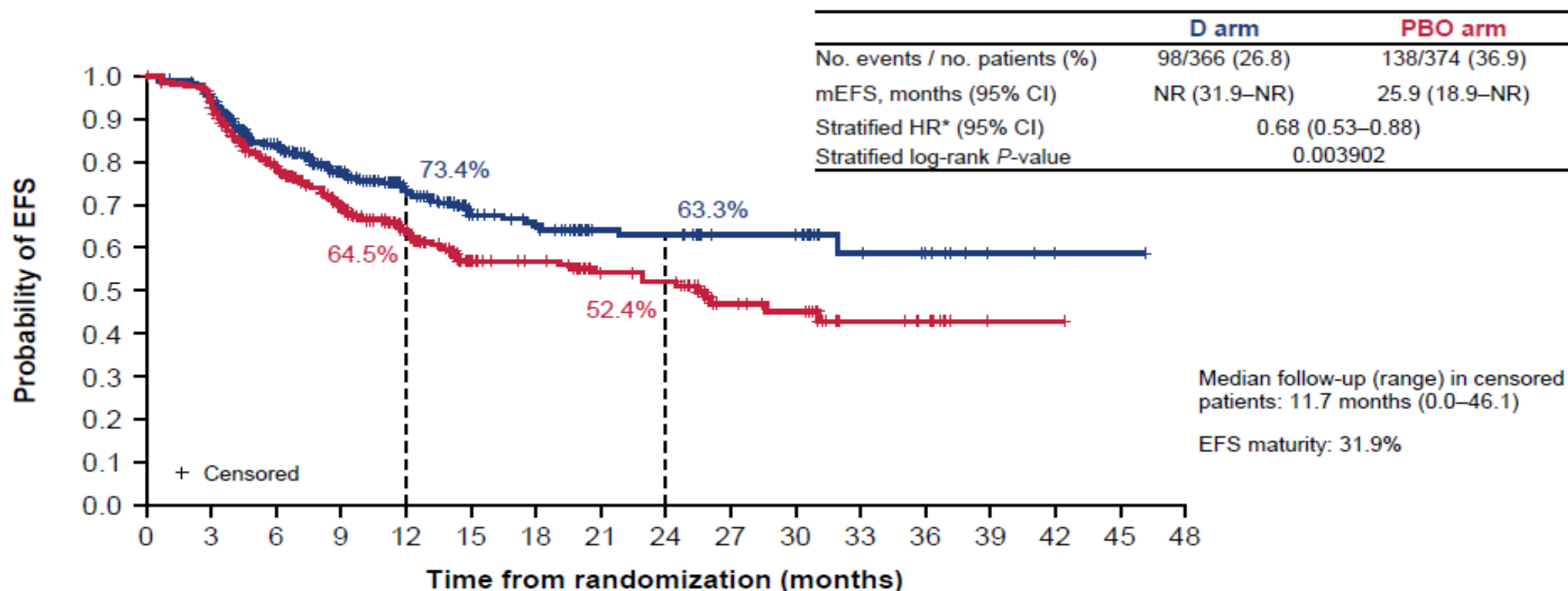
## Key secondary:

- MPR by central lab (per IASLC 2020<sup>1</sup>)
- DFS using BICR (per RECIST v1.1)
- OS

\*The protocol was amended while enrollment was ongoing to exclude (1) patients with tumors classified as T4 for any reason other than size; (2) patients with planned pneumonectomies; and (3) patients with documented *EGFR/ALK* aberrations. <sup>†</sup>Ventana SP263 immunohistochemistry assay. <sup>‡</sup>Choice of CT regimen determined by histology and at the investigator's discretion. For non-squamous: cisplatin + pemetrexed or carboplatin + pemetrexed. For squamous: carboplatin + paclitaxel or cisplatin + gemcitabine (or carboplatin + gemcitabine for patients who have comorbidities or who are unable to tolerate cisplatin per the investigator's judgment). <sup>§</sup>Post-operative radiotherapy (PORT) was permitted where indicated per local guidance. <sup>¶</sup>All efficacy analyses reported in this presentation were performed on the mITT population, which includes all randomized patients who did not have documented *EGFR/ALK* aberrations. AJCC, American Joint Committee on Cancer; BICR, blinded independent central review; DFS, disease-free survival; EFS, event-free survival; mITT, modified intent-to-treat; MPR, major pathologic response; pCR, pathologic complete response.

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

First planned interim analysis of EFS



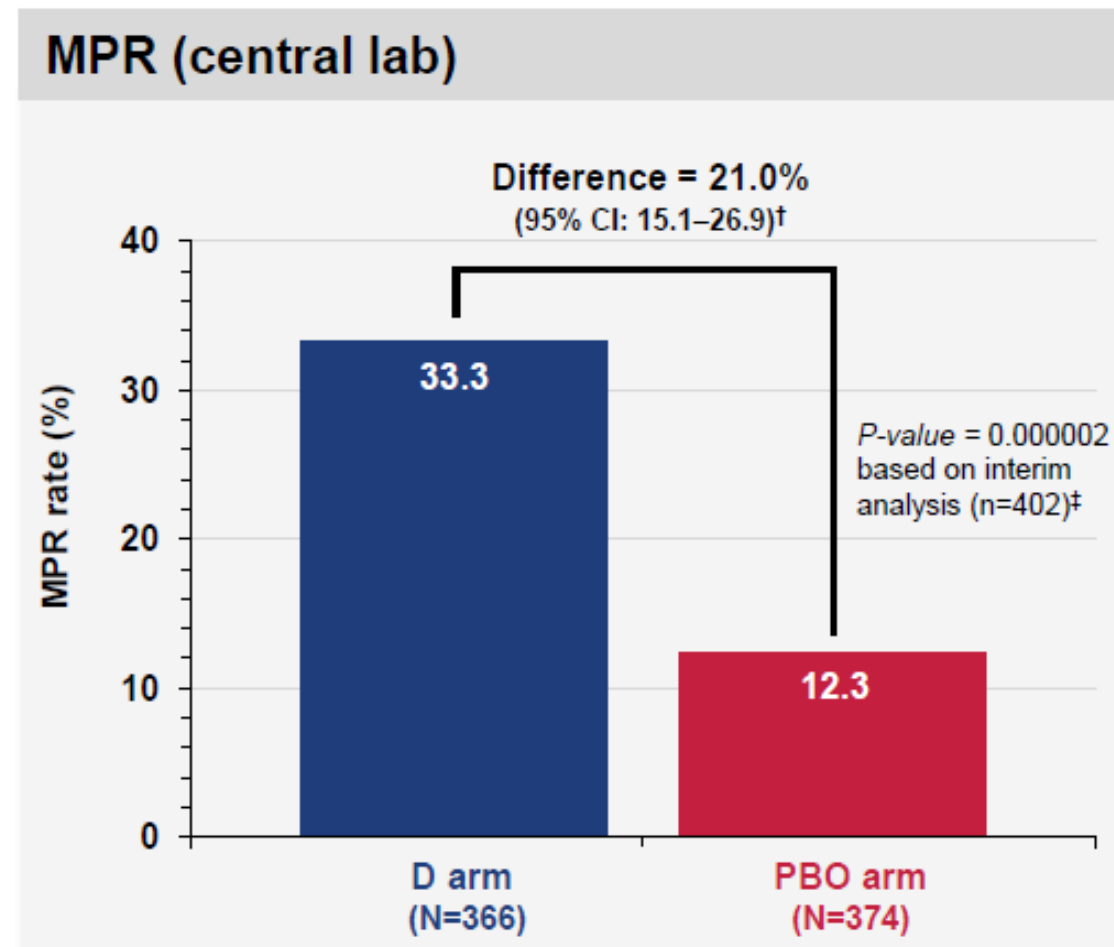
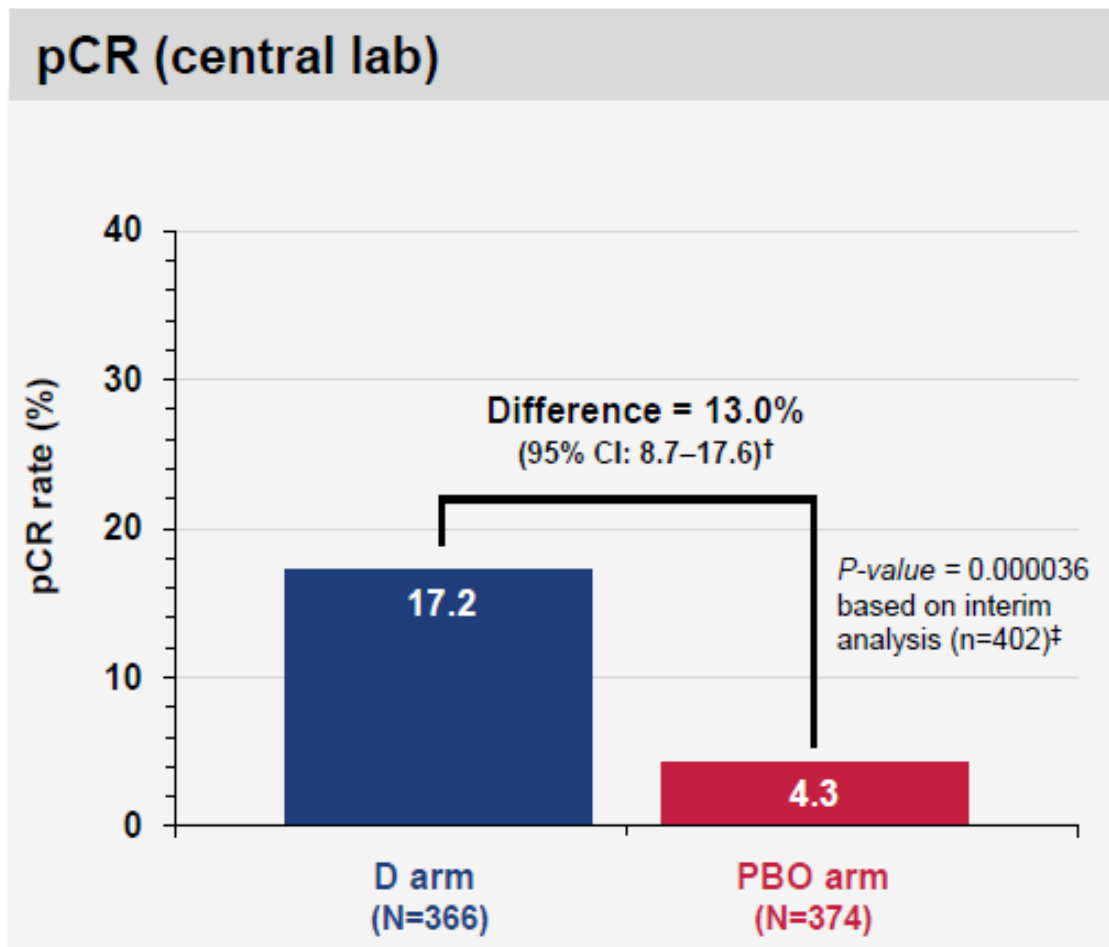
No. at risk:

|         |     |     |     |     |     |    |    |    |    |    |    |    |    |   |   |   |   |
|---------|-----|-----|-----|-----|-----|----|----|----|----|----|----|----|----|---|---|---|---|
| D arm   | 366 | 336 | 271 | 194 | 140 | 90 | 78 | 50 | 49 | 31 | 30 | 14 | 11 | 3 | 1 | 1 | 0 |
| PBO arm | 374 | 339 | 257 | 184 | 136 | 82 | 74 | 53 | 50 | 30 | 25 | 16 | 13 | 1 | 1 | 0 | 0 |

DCO = Nov 10, 2022. EFS is defined as time from randomization to the earliest of: (A) progressive disease (PD) that precludes surgery; (B) PD discovered and reported by the investigator upon attempting surgery that prevents completion of surgery; (C) local/distant recurrence using BICR per RECIST v1.1; or (D) death from any cause. \*HR <1 favors the D arm versus the PBO arm. Median and landmark estimates calculated using the Kaplan–Meier method; HR calculated using a stratified Cox proportional hazards model; and P-value calculated using a stratified log rank test. Stratification factors: disease stage (II vs III) and PD-L1 expression status (<1% vs ≥1%). Significance boundary = 0.009899 (based on total 5% alpha), calculated using a Lan-DeMets alpha spending function with O'Brien Fleming boundary. mEFS, median EFS; NR, not reached.

# Pathologic response per IASLC 2020 methodology\* (mITT)

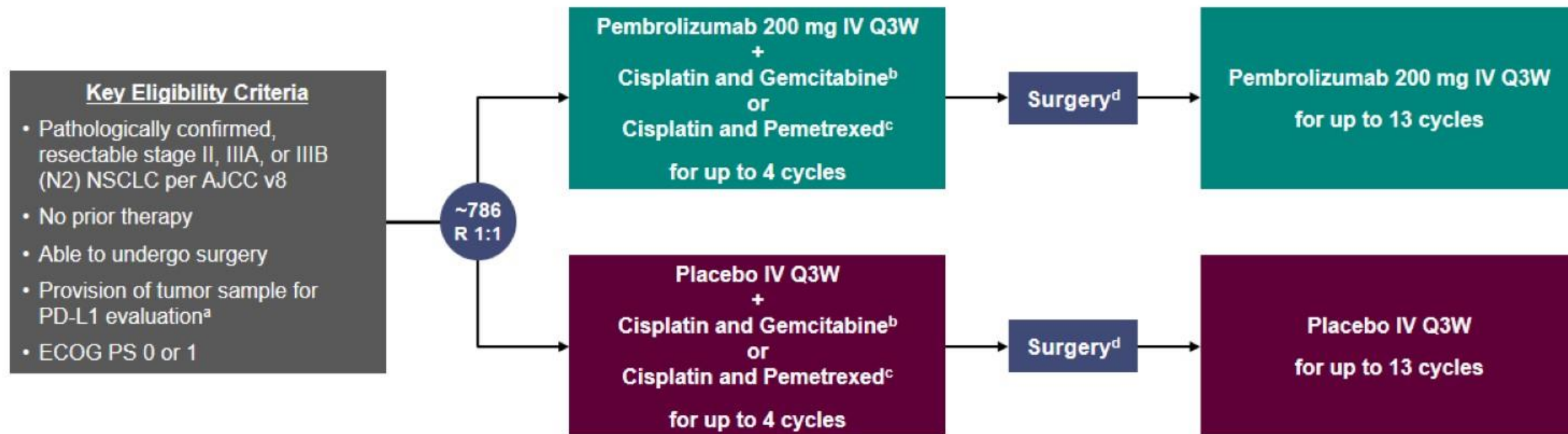
Final analysis



\*Using IASLC recommendations for pathologic assessment of response to therapy, including gross assessment and processing of tumor bed (Travis WD, et al. *J Thorac Oncol* 2020;15:709-40). pCR = a lack of any viable tumor cells after complete evaluation of the resected lung cancer specimen and all sampled regional lymph nodes. MPR = less than or equal to 10% viable tumor cells in lung primary tumor after complete evaluation of the resected lung cancer specimen. To be eligible for pathologic assessment, patients needed to have received three cycles of neoadjuvant study Tx per protocol. Patients who were not evaluable were classified as non-responders. <sup>†</sup>CI: calculated by stratified Miettinen and Nurminen method. <sup>‡</sup>No formal statistical testing was performed at the pCR final analysis (DCO: Nov 10, 2022; n=740 [data shown]). Statistical significance was achieved at the interim pCR analysis (DCO: Jan 14, 2022; n=402; *P*-value for pCR/MPR calculated using a stratified Cochran-Mantel-Haenszel test with a significance boundary = 0.000082 calculated using a Lan-DeMets alpha spending function with O'Brien Fleming boundary).

# KEYNOTE-671 Study Design

## Randomized, Double-Blind, Phase 3 Trial



### Stratification Factors

- Disease stage (II vs III)
- PD-L1 TPS<sup>a</sup> (<50% vs ≥50%)
- Histology (squamous vs nonsquamous)
- Geographic region (east Asia vs not east Asia)

**Dual primary end points:** EFS per investigator review and OS

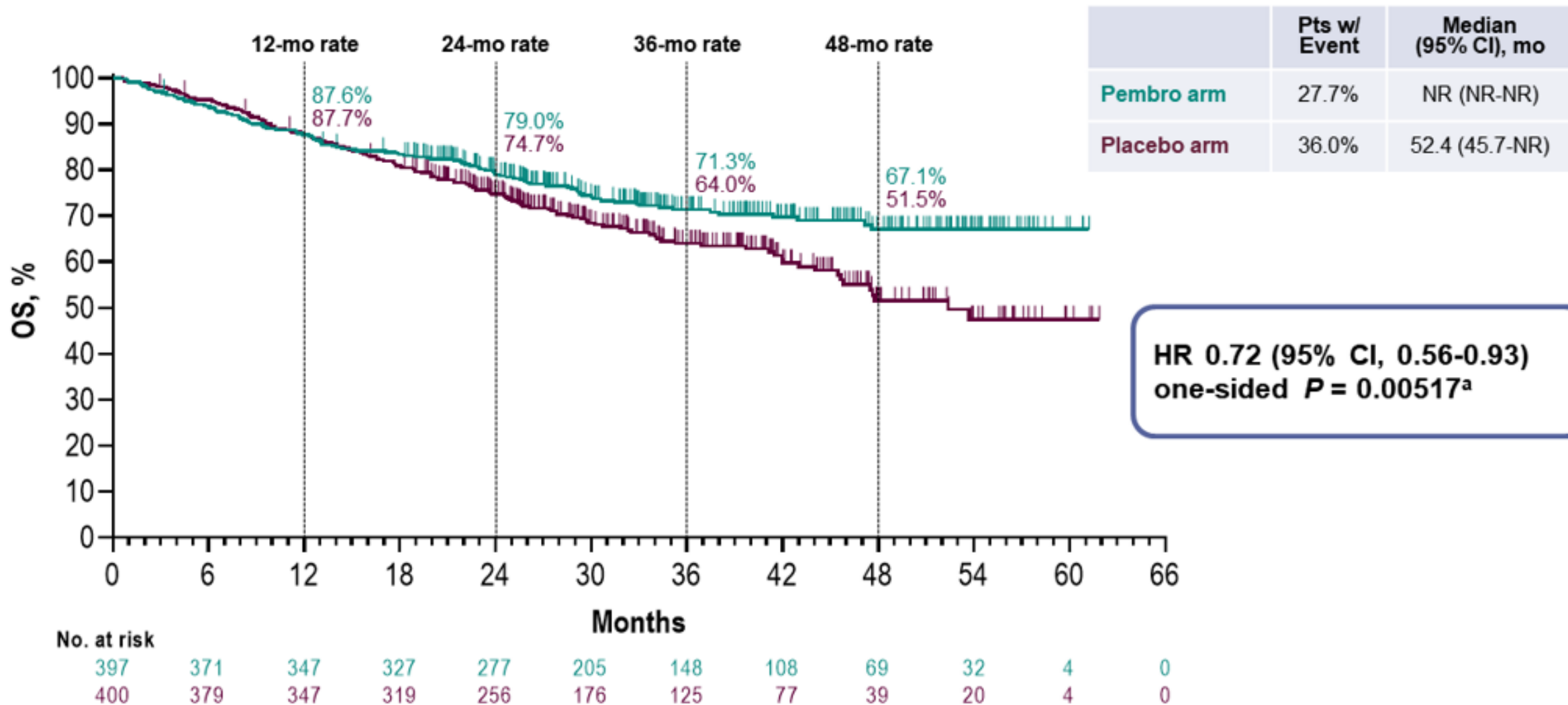
**Key secondary end points:** mPR and pCR per blinded, independent pathology review, and safety

<sup>a</sup> Assessed at a central laboratory using PD-L1 IHC 22C3 pharmDx. <sup>b</sup> Cisplatin 75 mg/m<sup>2</sup> IV Q3W + gemcitabine 1000 mg/m<sup>2</sup> IV on days 1 and 8 Q3W was permitted for squamous histology only. <sup>c</sup> Cisplatin 75 mg/m<sup>2</sup> IV Q3W + pemetrexed 500 mg/m<sup>2</sup> IV Q3W was permitted for nonsquamous histology only. <sup>d</sup> Radiotherapy was to be administered to participants with microscopic positive margins, gross residual disease, or extracapsular nodal extension following surgery and to participants who did not undergo planned surgery for any reason other than local progression or metastatic disease. ClinicalTrials.gov identifier: NCT03425643.



# Overall Survival, IA2

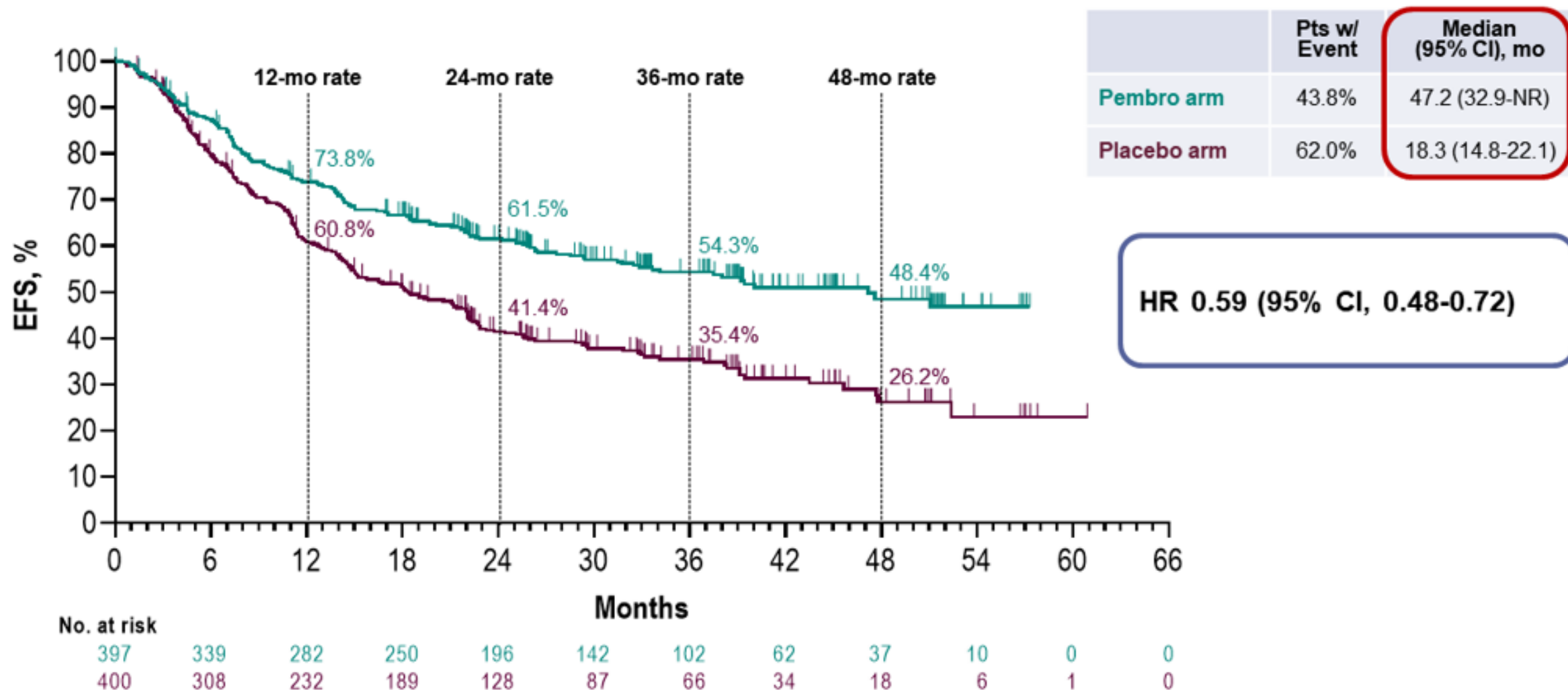
Median Follow-Up: 36.6 months (range, 18.8-62.0)



OS defined as time from randomization to death from any cause. <sup>a</sup> Significance boundary at IA2, one-sided P = 0.00543. Data cutoff date for IA2: July 10, 2023.

# Event-Free Survival, IA2

Median Follow-Up: 36.6 months (range, 18.8-62.0)



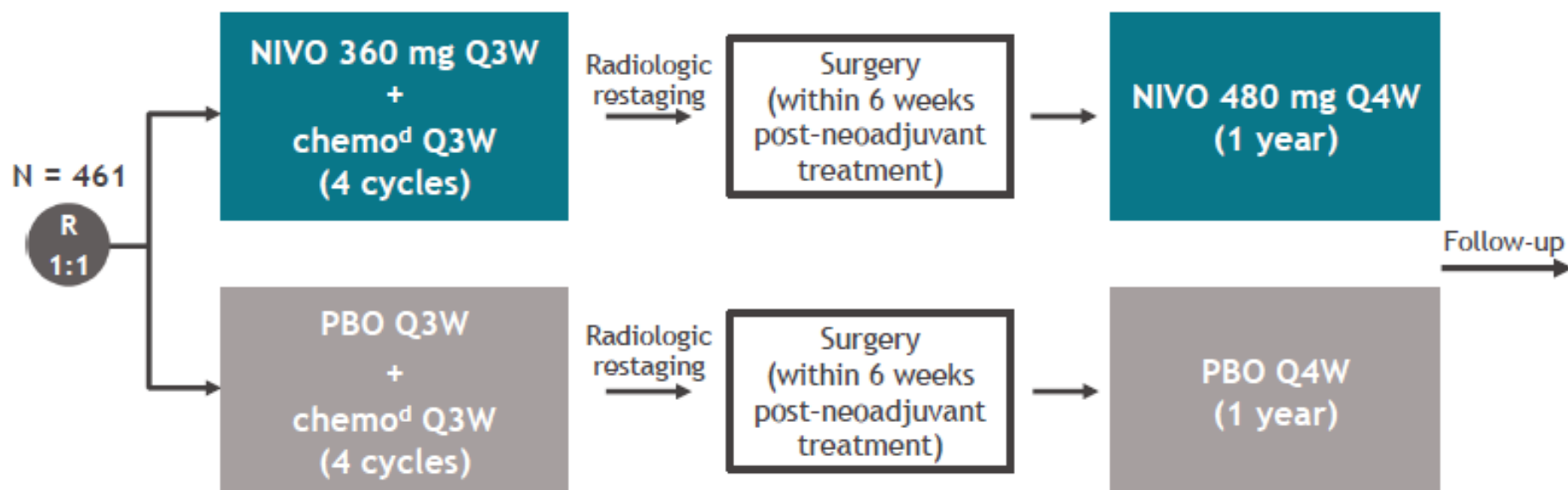
EFS defined as time from randomization to first occurrence of local progression precluding planned surgery, unresectable tumor, progression or recurrence per RECIST v1.1 by investigator assessment, or death from any cause. Data cutoff date for IA2: July 10, 2023.

# CheckMate 77T<sup>a</sup> study design

## Key eligibility criteria

- Resectable, stage IIA (> 4 cm)-IIIB (N2) NSCLC (per AJCC 8th edition)
- No prior systemic anti-cancer treatment
- ECOG PS 0-1
- No *EGFR* mutation/known *ALK* alterations<sup>b</sup>

Stratified by  
histology (NSQ vs SQ)  
disease stage (II vs III),  
and tumor PD-L1<sup>c</sup> ( $\geq 1\%$  vs  $< 1\%$  vs  
not evaluable/indeterminate)



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

### Primary endpoint

- EFS by BICR

### Secondary endpoints

- pCR<sup>e</sup> by BIPR
- MPR<sup>e</sup> by BIPR
- OS
- Safety

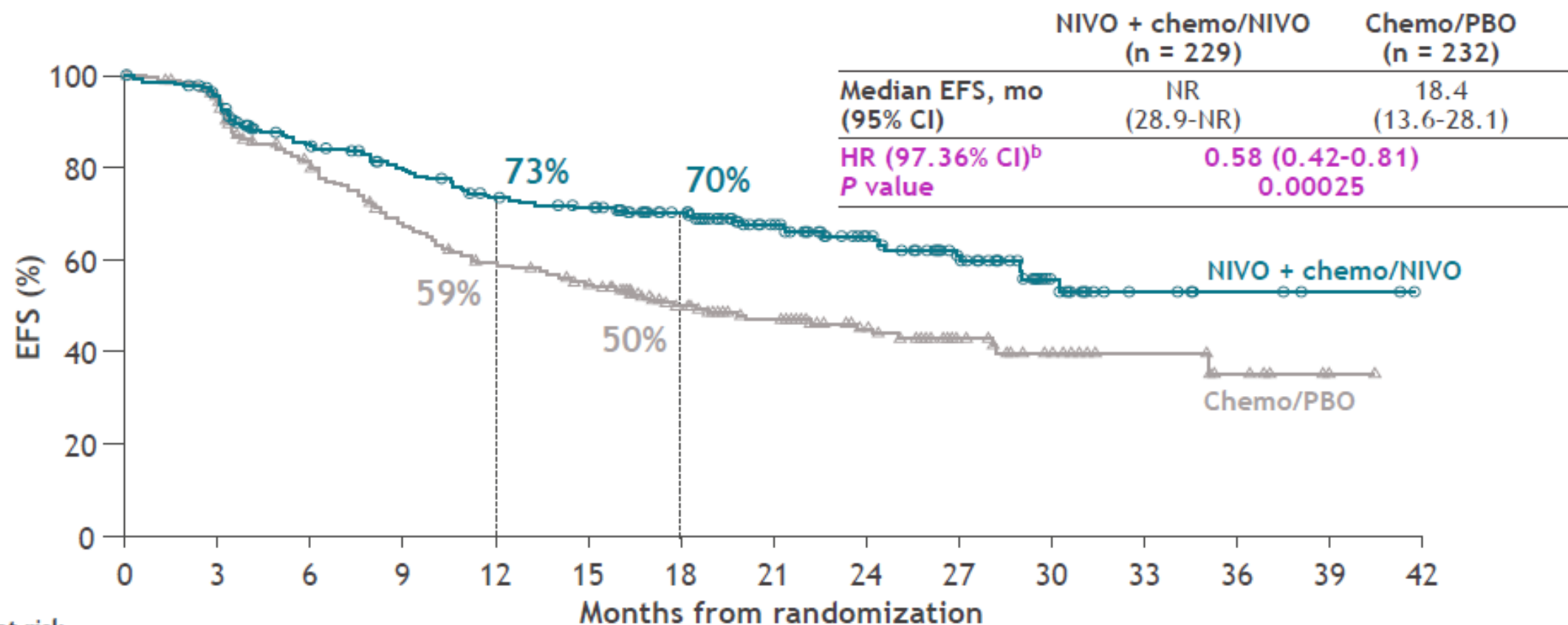
### Exploratory analyses

- EFS by pCR/MPR
- EFS by adjuvant treatment

Database lock date: September 6, 2023.

<sup>a</sup>NCT04025879. <sup>b</sup>*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. <sup>c</sup>Determined by the PD-L1 IHC 28-8 pharmDx assay (Dako). <sup>d</sup>NSQ: cisplatin + pemetrexed, carboplatin + pemetrexed, or carboplatin + paclitaxel; SQ: cisplatin + docetaxel or carboplatin + paclitaxel. <sup>e</sup>Assessed per immune-related pathologic response criteria. <sup>f</sup>BICR, blinded independent central review; BIPR, blinded independent pathological review. 1. Cottrell TR, et al. *Ann Oncol* 2018;29:1853-1860.

# Primary endpoint: EFS<sup>a</sup> per BICR with neoadjuvant NIVO + chemo/adjuvant NIVO vs chemo/PBO



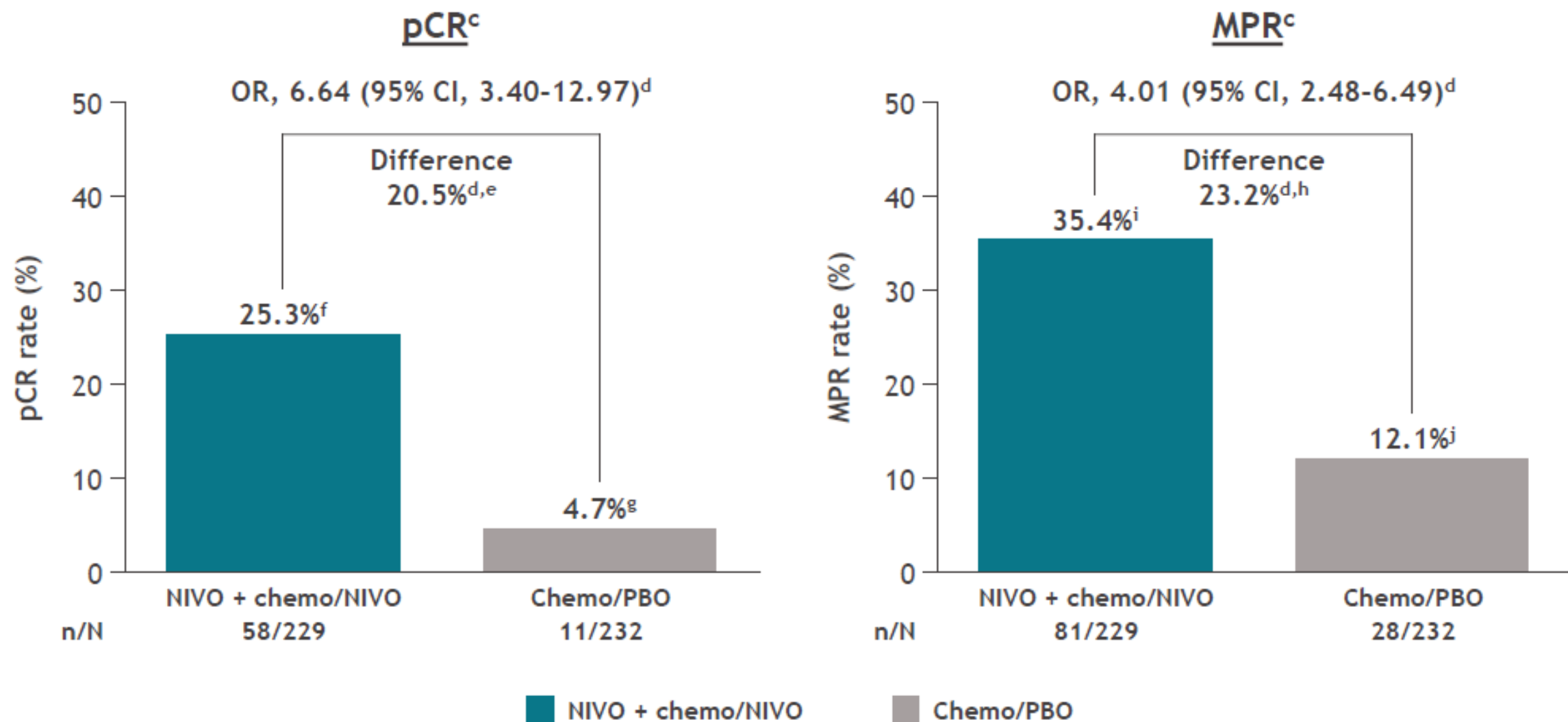
| No. at risk       | 0   | 3   | 6   | 9   | 12  | 15  | 18  | 21 | 24 | 27 | 30 | 33 | 36 | 39 | 42 |
|-------------------|-----|-----|-----|-----|-----|-----|-----|----|----|----|----|----|----|----|----|
| NIVO + chemo/NIVO | 229 | 208 | 173 | 157 | 141 | 134 | 115 | 89 | 69 | 46 | 20 | 7  | 4  | 2  | 0  |
| Chemo/PBO         | 232 | 204 | 165 | 138 | 118 | 106 | 78  | 59 | 44 | 29 | 19 | 10 | 6  | 1  | 0  |

- EFS per investigator assessment, NIVO + chemo/NIVO vs chemo/PBO: HR, 0.56; 95% CI, 0.41-0.76

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

<sup>a</sup>Time from randomization to any disease progression precluding surgery, abandoned surgery due to unresectability or disease progression, disease progression/recurrence after surgery, progression in patients without surgery, or death due to any cause. Patients who received subsequent therapy were censored at the last evaluable tumor assessment on or prior to the date of subsequent therapy. <sup>b</sup>Unstratified HR (95% CI), 0.59 (0.44-0.79).

# pCR<sup>a</sup> and MPR<sup>b</sup> per BIPR



<sup>a</sup>0% residual viable tumor cells post-surgery in both primary tumor (lung) and sampled lymph nodes per immune-related pathologic response criteria. <sup>b</sup>≤ 10% residual viable tumor cells post-surgery in both primary tumor (lung) and sampled lymph nodes per immune-related pathologic response criteria. <sup>c</sup>Patients who did not undergo surgery or received alternative anti-cancer treatment prior to surgery were classified as non-responders. <sup>d</sup>Calculated using the stratified Cochran-Mantel-Haenszel method. <sup>e</sup>95% CI: <sup>f</sup>14.3-26.6; <sup>g</sup>19.8-31.5; <sup>h</sup>2.4-8.3; <sup>i</sup>15.8-30.6; <sup>j</sup>9.2-41.9; <sup>k</sup>8.2-17.0. BIPR, blinded independent pathological review.



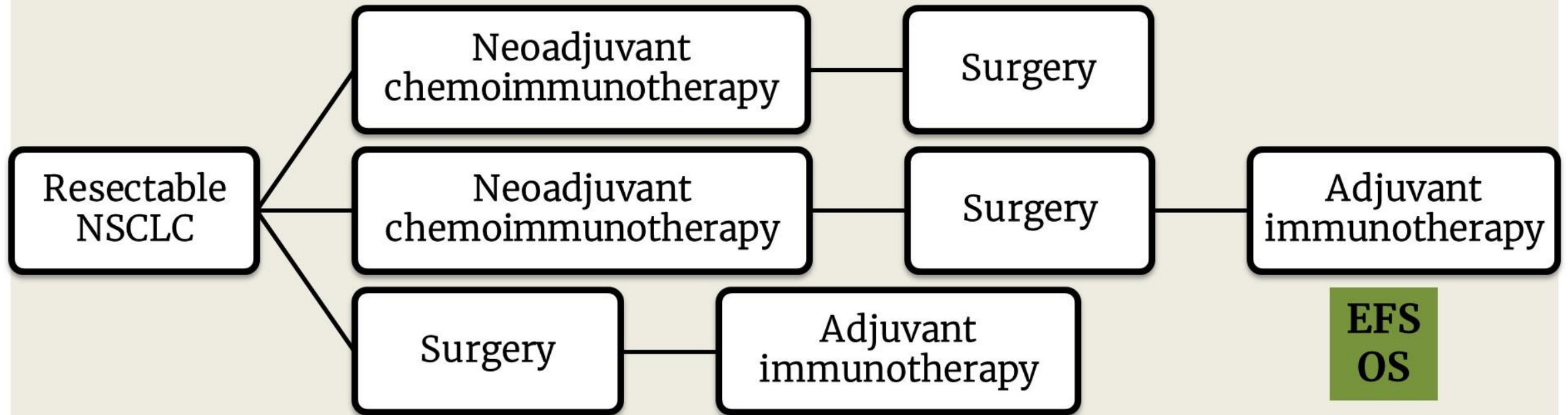
# What are we doing now ?



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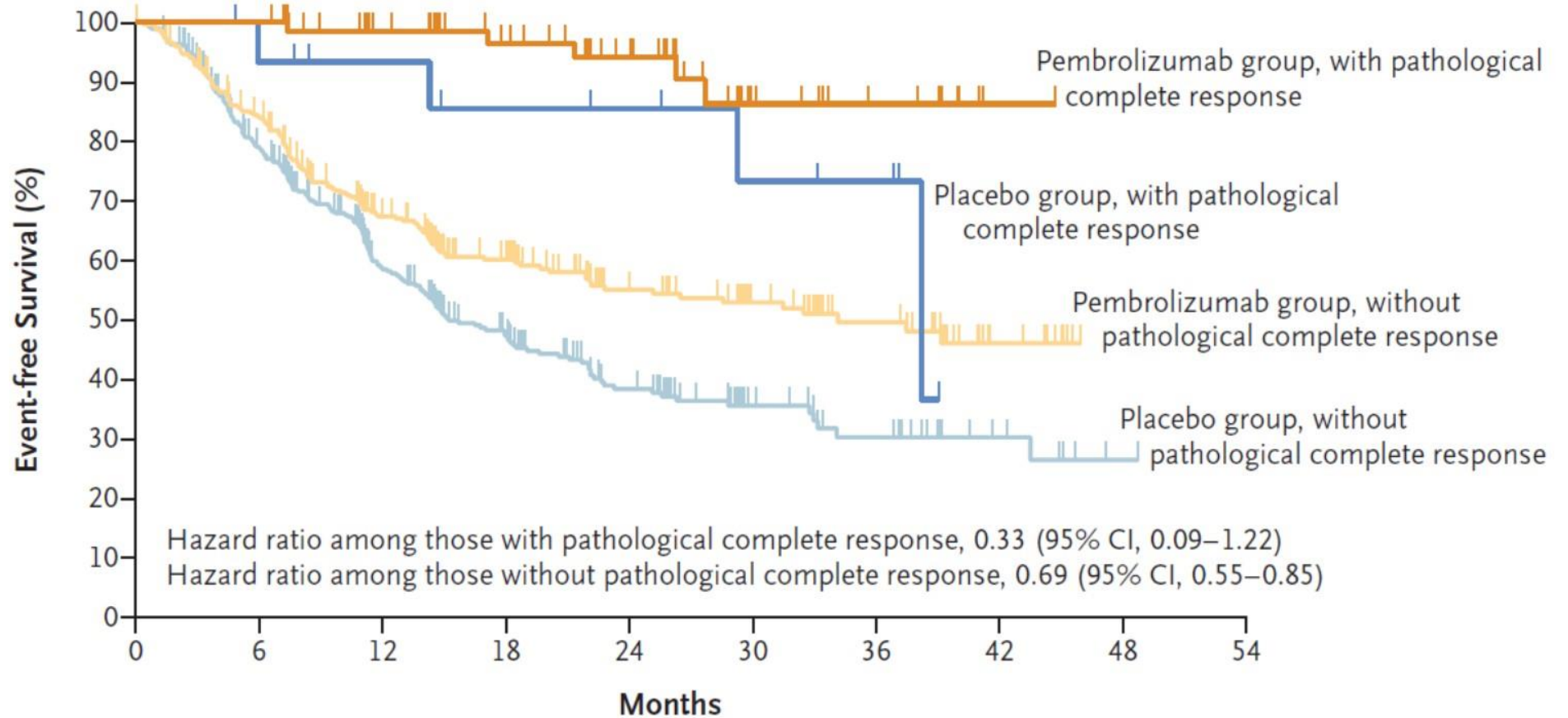
# Potential Pragmatic Three-Arm Trial



# Can We Use Pathologic Complete Response to Guide Decisions on Adjuvant Therapy?



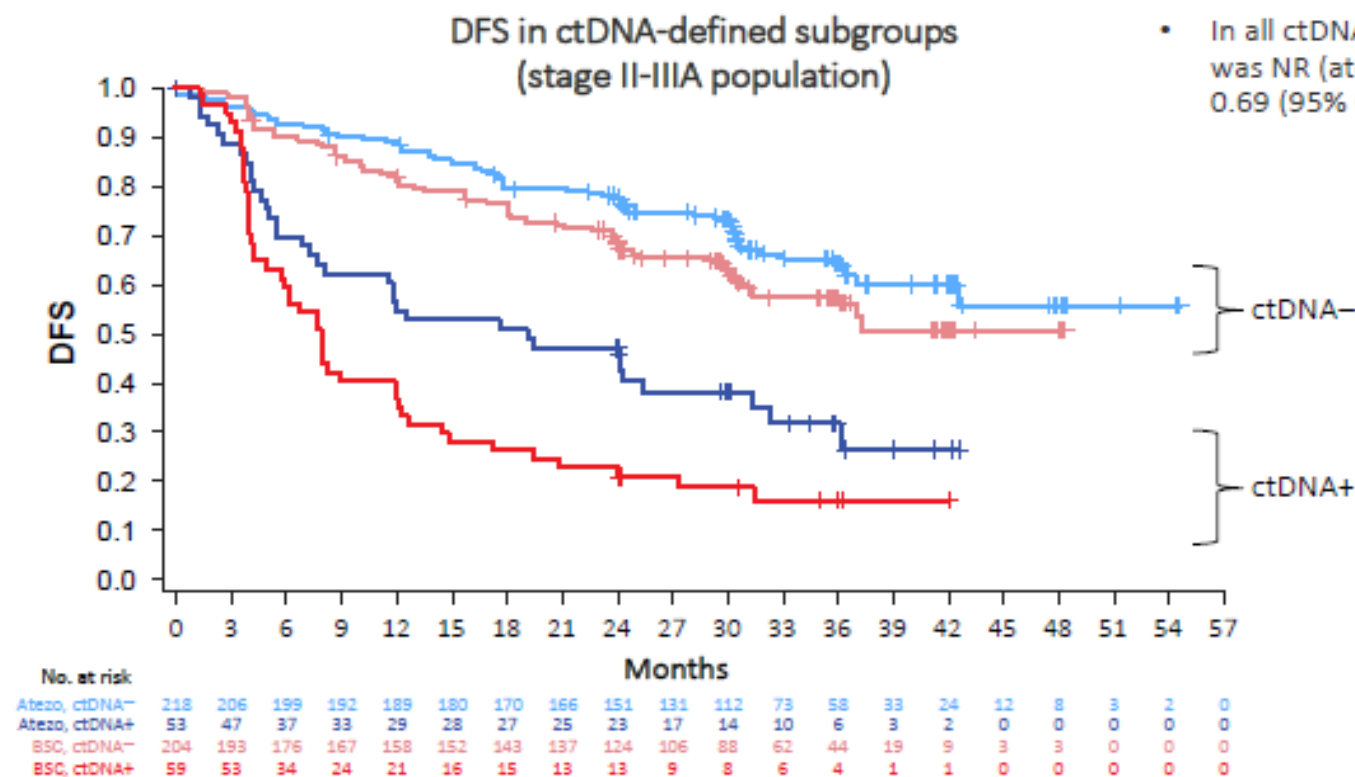
Event-free Survival According to Pathological Complete Response



N Engl J Med 2023;389:491-503.  
DOI: 10.1056/NEJMoa2302983



# IMpower010 ctDNA MRD Analysis



- In all ctDNA-evaluable stage II-IIIa patients, mDFS was NR (atezo) vs 31.4 months (BSC), with an HR of 0.69 (95% CI: 0.53, 0.89)

|                    |                   |                |
|--------------------|-------------------|----------------|
| ctDNA <sup>-</sup> | Atezo<br>(n=218)  | BSC<br>(n=204) |
| mDFS, mo           | NR                | NR             |
| HR (95% CI)        | 0.72 (0.52, 1.00) |                |
| ctDNA <sup>+</sup> | Atezo<br>(n=53)   | BSC<br>(n=59)  |
| mDFS, mo           | 19.1              | 7.9            |
| HR (95% CI)        | 0.61 (0.39, 0.94) |                |

Benefit of consolidation immunotherapy is strongest in ctDNA-positive patients



Thanks



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