Year in Review: Clinical Investigator Perspectives on the Most Relevant New Datasets and Advances in Oncology

EGFR-Mutant Non-Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, April 7, 2026
5:00 PM – 6:00 PM ET

Faculty

Suresh S Ramalingam, MD
Helena Yu, MD

Moderator

Neil Love, MD

RTP Year in Review 2026

Faculty

Suresh S Ramalingam, MD
Executive Director, Winship Cancer Institute
Roberto C Goizueta Chair for Cancer Research
Emory University School of Medicine
Atlanta, Georgia

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Helena Yu, MD
Medical Oncologist
Attending
Memorial Sloan Kettering Cancer Center
New York, New York

Commercial Support

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Dr Love — Disclosures

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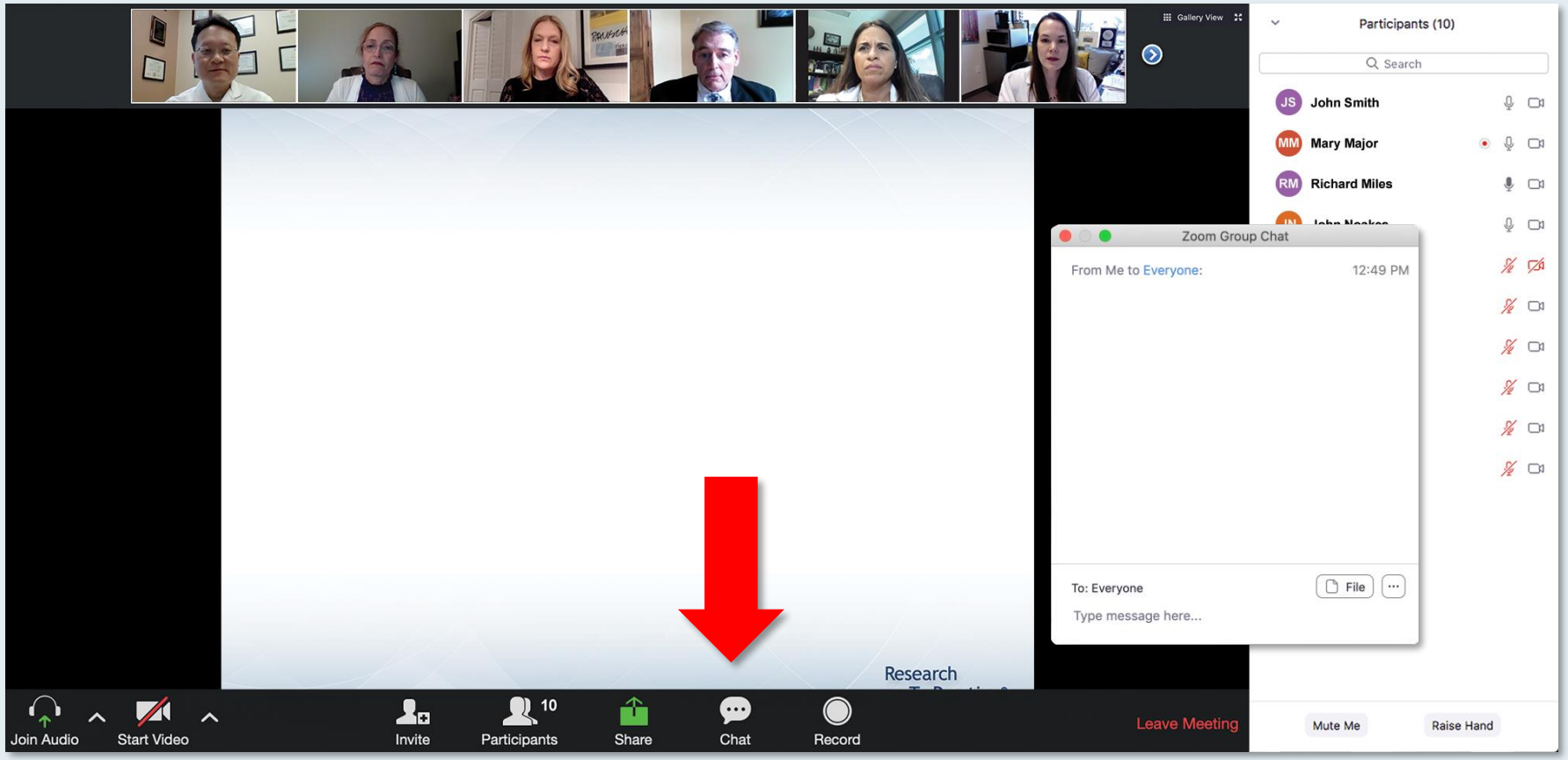

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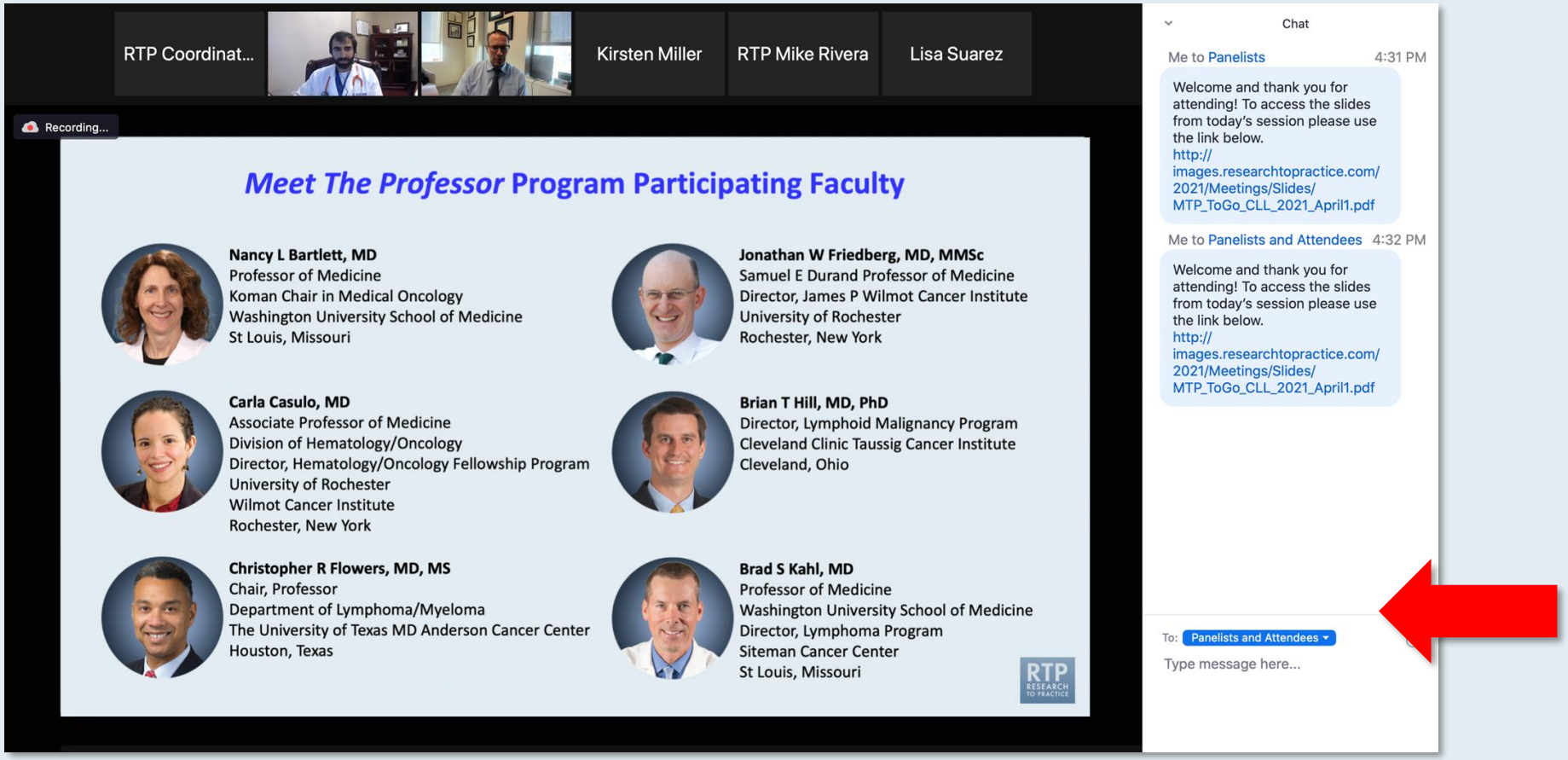

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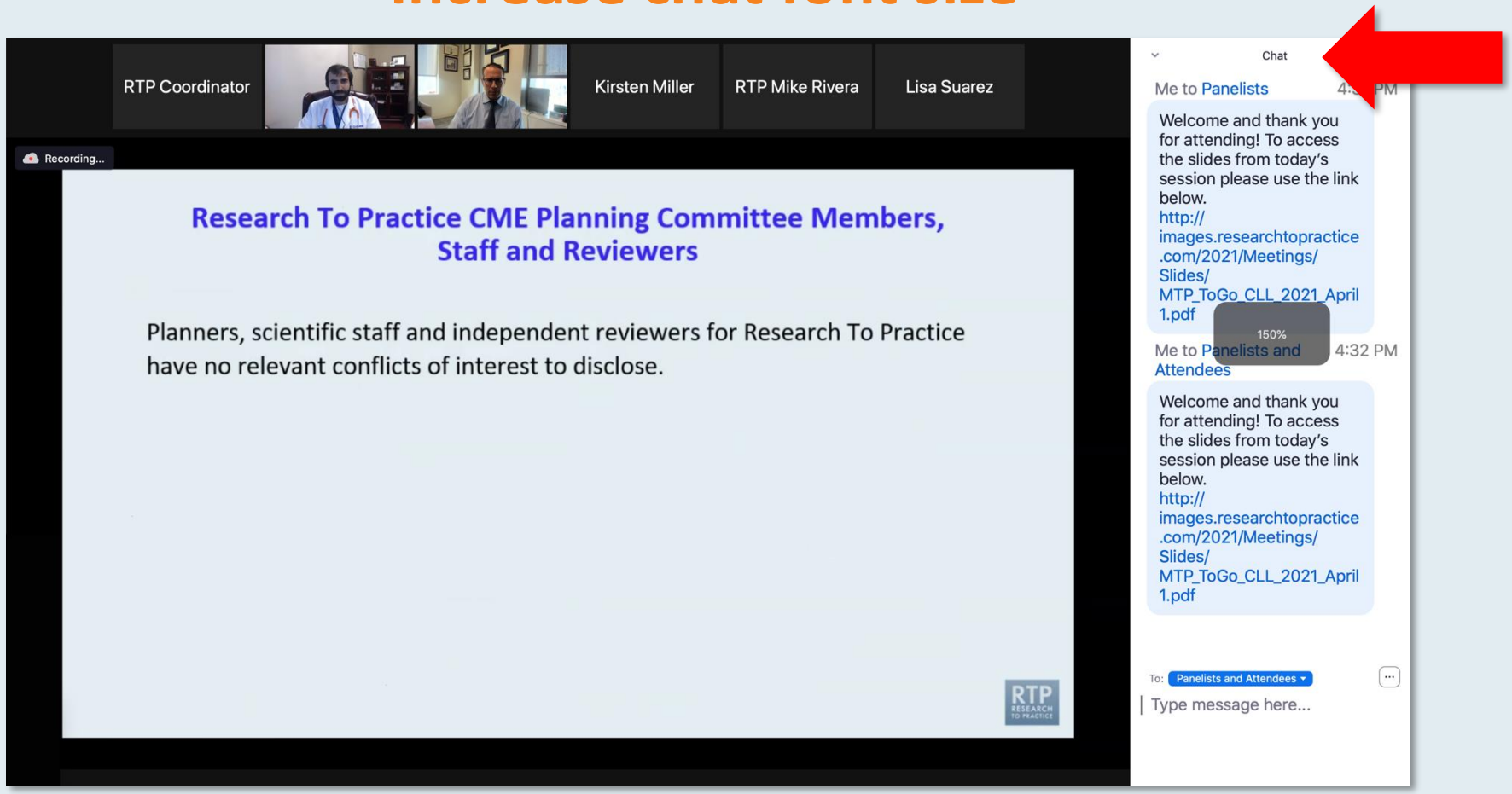

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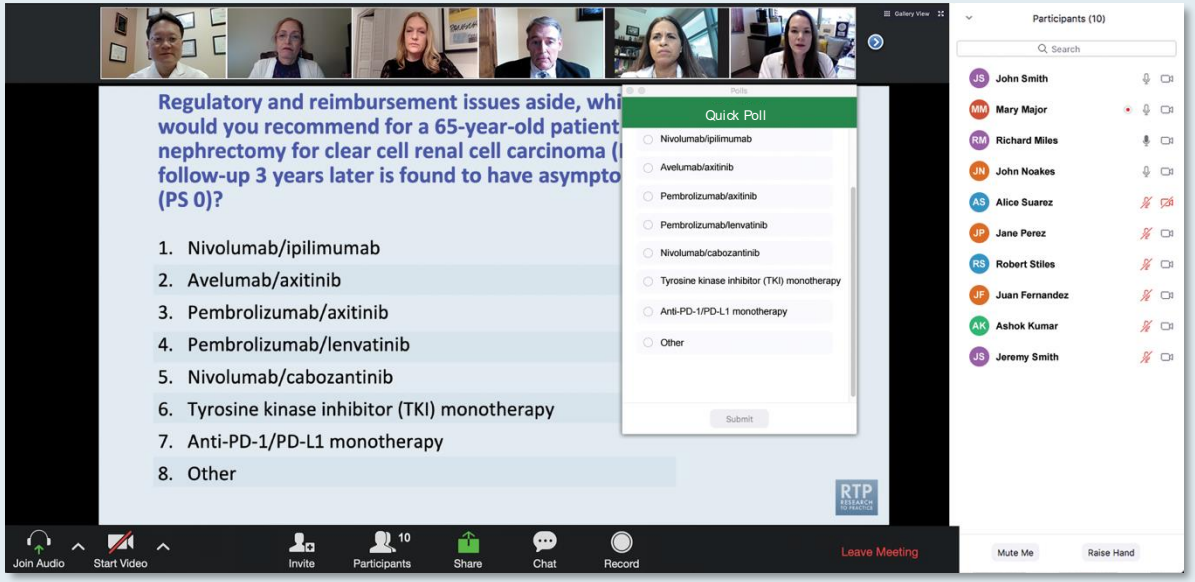

Extensive-Stage Small Cell Lung Cancer — Current Patterns of Care with First-Line and Maintenance Therapy

HOSSEIN BORGHAEI, MD
FOX CHASE CANCER CENTER

ANNE CHIANG, MD, PHD
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INTRODUCTION: Genomics of EGFR (and HER2)

MODULE 1: Metastatic disease

MODULE 2: Localized disease

MODULE 3: EGFR exon 20 insertion mutations

MODULE 4: New agents

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Thank you for joining us!

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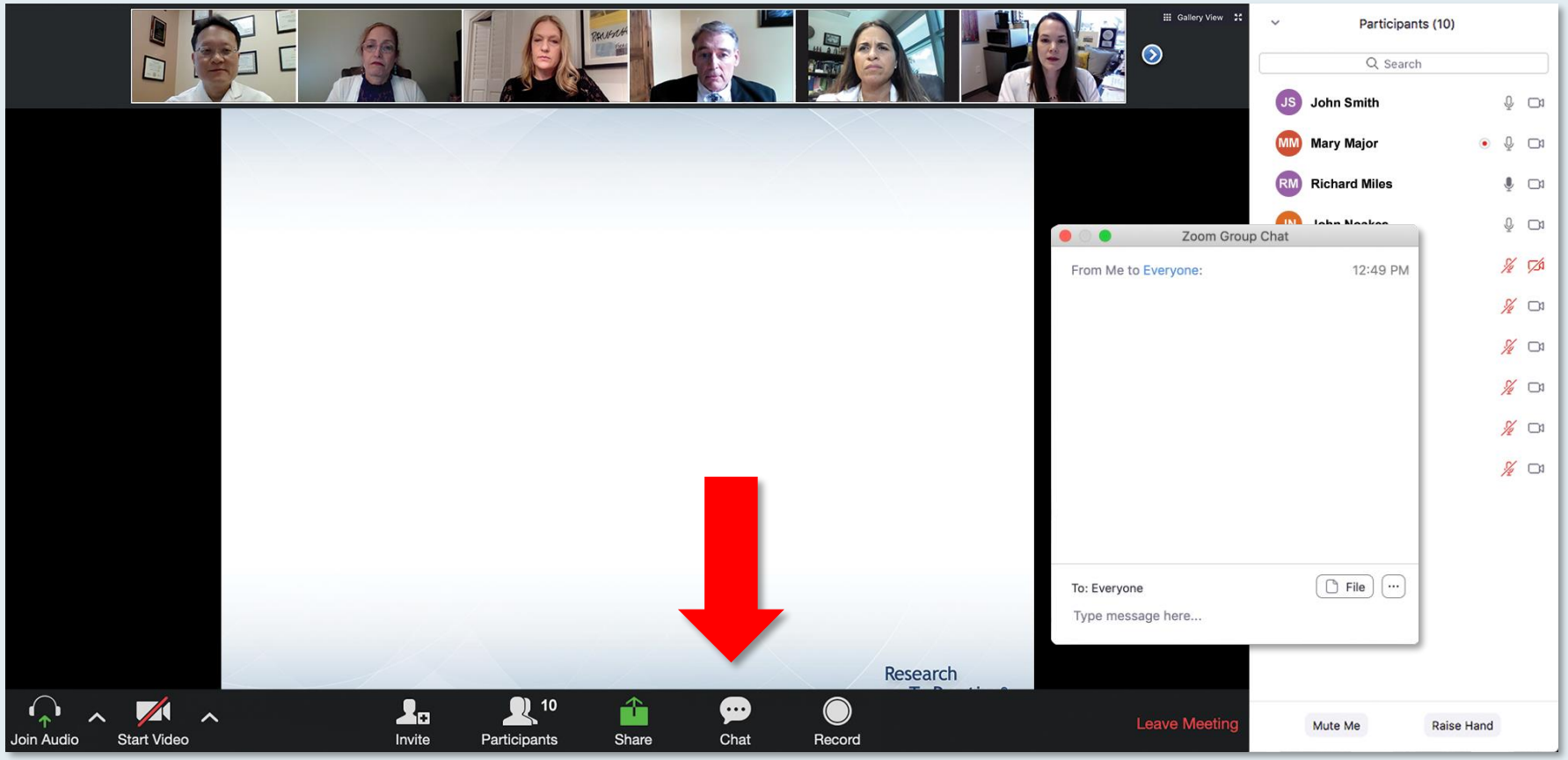

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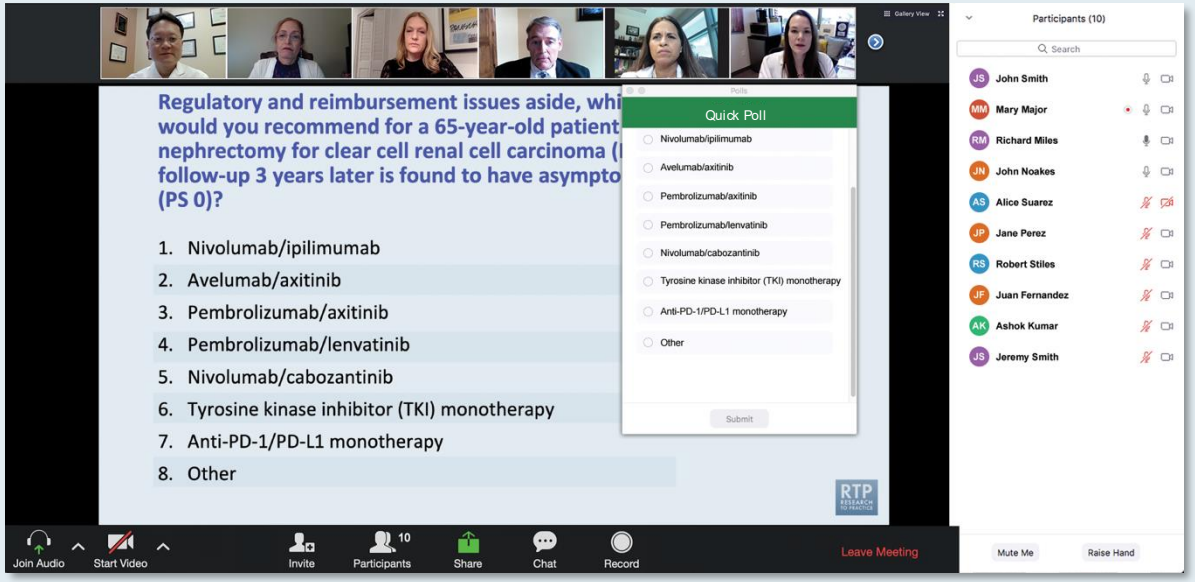

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Year in Review

Management of Metastatic EGFR Mutation-Positive Non-Small Cell Lung Cancer (NSCLC)

Helena Yu, MD

Memorial Sloan Kettering Cancer Center

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Key Datasets

Helena Yu, MD

- Jänne PA et al. Survival with osimertinib plus chemotherapy in EGFR-mutated advanced NSCLC. *N Engl J Med* 2026;394(1):27-38.
- Jänne PA et al. FLAURA2: Exploratory overall survival (OS) analysis in patients (pts) with poorer prognostic factors treated with osimertinib (osi) ± platinum-pemetrexed chemotherapy (CTx) as first-line (1L) treatment (tx) for EGFR-mutated (EGFRm) advanced NSCLC. ESMO 2025;Abstract LBA77.
- Elamin YY et al. NorthStar: A phase II randomized study of osimertinib (OSI) with or without local consolidative therapy (LCT) for metastatic EGFR-mutant non-small cell lung cancer (NSCLC). ESMO 2025;Abstract LBA72.
- Yang JC et al. Overall survival with amivantamab-lazertinib in EGFR-mutated advanced NSCLC. *N Engl J Med* 2025;393(17):1681-93.
- Scott SC et al. PALOMA-2: Subcutaneous amivantamab administered every 4 weeks plus lazertinib in first-line EGFR-mutated advanced NSCLC. WCLC 2025;Abstract MA08.05.
- Alexander M et al. Subcutaneous versus intravenous amivantamab, both in combination with lazertinib, in refractory EGFR-mutated non-small cell lung cancer: Patient satisfaction and resource utilization results from the PALOMA-3 study. *Eur J Cancer* 2025;227:115624.

Key Datasets

Helena Yu, MD (continued)

- Sands J et al. Datopotamab deruxtecan in advanced or metastatic non-small cell lung cancer with actionable genomic alterations: Results from the phase II TROPION-Lung05 study. *J Clin Oncol* 2025;43(10):1254-65.
- Ahn MJ et al. A pooled analysis of datopotamab deruxtecan in patients with EGFR-mutated NSCLC. *J Thorac Oncol* 2025;20(11):1669-82.
- Peled N et al. COMPEL: Osimertinib plus platinum-based chemotherapy in patients with EGFR-mutated advanced NSCLC and progression on first-line osimertinib. *ESMO Open* 2025;10(10):105807.
- Lu S et al. Osimertinib (osi) + datopotamab deruxtecan (Dato-DXd) in patients (pts) with EGFR-mutated (EGFRm) advanced NSCLC (aNSCLC) whose disease progressed on first-line (1L) osi: ORCHARD. ELCC 2025;Abstract 1O.
- Lu S et al. Savolitinib plus osimertinib versus chemotherapy for advanced, EGFR mutation-positive, MET-amplified non-small-cell lung cancer in China (SACHI): Interim analysis of a multicentre, open-label, phase 3 randomised controlled trial. *Lancet* 2026;407(10526):375-87.
- de Marinis F et al. Savolitinib plus osimertinib in epidermal growth factor receptor (EGFR)-mutated advanced non-small cell lung cancer with MET overexpression and/or amplification following disease progression on osimertinib: Primary results from the phase II SAVANNAH study. *Ann Oncol* 2025;36(8):920-33.

Key Datasets

Suresh S Ramalingam, MD

- He J et al. Neoadjuvant osimertinib for resectable EGFR-mutated non-small cell lung cancer. *J Clin Oncol* 2025;43(26):2875-87.
- Blakely C et al. Molecular residual disease (MRD) analysis from NeoADAURA: Neoadjuvant osimertinib ± chemotherapy in resectable EGFRm NSCLC. WLCC 2025;Abstract OA02.02.
- Herbst RS et al. Molecular residual disease analysis of adjuvant osimertinib in resected EGFR-mutated stage IB-IIIA non-small-cell lung cancer. *Nat Med* 2025;31(6):1958-68.
- Ramalingam SR et al. Osimertinib (osi) after definitive chemoradiotherapy (CRT) in patients (pts) with unresectable (UR) stage III EGFR-mutated (EGFRm) non-small cell lung cancer (NSCLC): Updated overall survival (OS) analysis from the LAURA study. ELCC 2025;Abstract LBA4.
- Aperribay EA et al. Molecular residual disease (MRD) analysis from the LAURA study of osimertinib (osi) in unresectable (UR) stage III EGFR-mutated (EGFRm) NSCLC. ESMO 2025;Abstract 1817MO.
- Paz-Ares L et al. Patient-reported outcomes and time to symptomatic progression from PAPILLON: Amivantamab plus chemotherapy vs chemotherapy as first-line treatment of EGFR exon 20 insertion-mutated advanced NSCLC. *Lung Cancer* 2026;213:108788.

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Suresh S Ramalingam, MD (continued)

- Yang JC et al. Phase II dose-randomized study of sunvozertinib in platinum-pretreated non-small cell lung cancer with epidermal growth factor receptor Exon 20 insertion mutations (WU-KONG1B). *J Clin Oncol* 2025;43(29):3198-208.
- Piotrowska Z et al. Zipalertinib in patients with epidermal growth factor receptor exon 20 insertion-positive non-small cell lung cancer previously treated with platinum-based chemotherapy with or without amivantamab. *J Clin Oncol* 2025;43(21):2387-97.
- Piotrowska Z et al. Zipalertinib in NSCLC patients (pts) with EGFR exon 20 insertion (Ex20Ins) mutations who received prior amivantamab. WLCC 2025;Abstract MA08.02.
- Yu HA et al. Activity of zipalertinib against active central nervous system (CNS) metastases in patients with non-small cell lung cancer (NSCLC) harboring EGFR exon 20 insertion (ex20ins)/other uncommon mutations. ESMO 2025;Abstract 1847MO.
- Fang W et al. Sacituzumab tirumotecan in EGFR-TKI-resistant, EGFR-mutated advanced NSCLC. *New Engl J Med* 2026;394(1):13-26.
- Goldman JW et al. Ivonescimab vs placebo plus chemo, phase 3 in patients with EGFR+ NSCLC progressed with 3rd gen EGFR-TKI treatment: HARMONi. WLCC 2025;Abstract PL02.12.

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INTRODUCTION: Genomics of EGFR (and HER2)

MODULE 1: Metastatic disease

MODULE 2: Localized disease

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MODULE 4: New agents

RTP Year in Review 2026

Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

Introduction: Genomics of EGFR (and HER2)

- EGFR L858R; Exon 19; Exon 20 insertion; uncommon mutations

Selpercatinib Delivers Substantial Event-Free Survival Benefit as an Adjuvant Therapy in Localized RET Fusion-Positive Lung Cancer

Press Release: February 16, 2026

"[The manufacturer] announced positive topline results from the Phase 3 LIBRETTO-432 clinical trial of selpercatinib as adjuvant therapy versus placebo. The study met its primary endpoint, demonstrating a highly statistically significant and clinically meaningful improvement in investigator-assessed event-free survival (EFS) in patients with early-stage (II-IIIA) *rearranged during transfection* (RET) fusion-positive non-small cell lung cancer (NSCLC).

Overall survival results trended in favor of selpercatinib, but were immature at the time of this analysis with few events observed. The overall safety profile of selpercatinib in LIBRETTO-432 was generally consistent with previously reported trials in the selpercatinib development program."

https://investor.lilly.com/news-releases/news-release-details/lillys-retevmo-selpercatinib-delivers-substantial-event-free

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MODULE 1: Metastatic disease

- FLAURA2, IPASS studies
- MARIPOSA study: Amivantamab and lazertinib
- PALOMA studies: Subcutaneous amivantamab
  - DVT, pulmonary emboli; prophylactic anticoagulation
- Short-term versus long-term outcomes — tail of the curve?
- COMPEL study: Continuation with chemotherapy of first-line osimertinib — CNS disease, ADCs
- NorthStar study: Local consolidation — RT, surgery
- Datopotamab deruxtecan
  - Exon 20 insertion, uncommon mutations
  - Toxicity: Mucositis, keratitis
  - TROPION-Lung15
- MET inhibitors — after disease progression on osimertinib
  - MET amplified, overexpressed
  - SACHI study: Savolitinib and osimertinib

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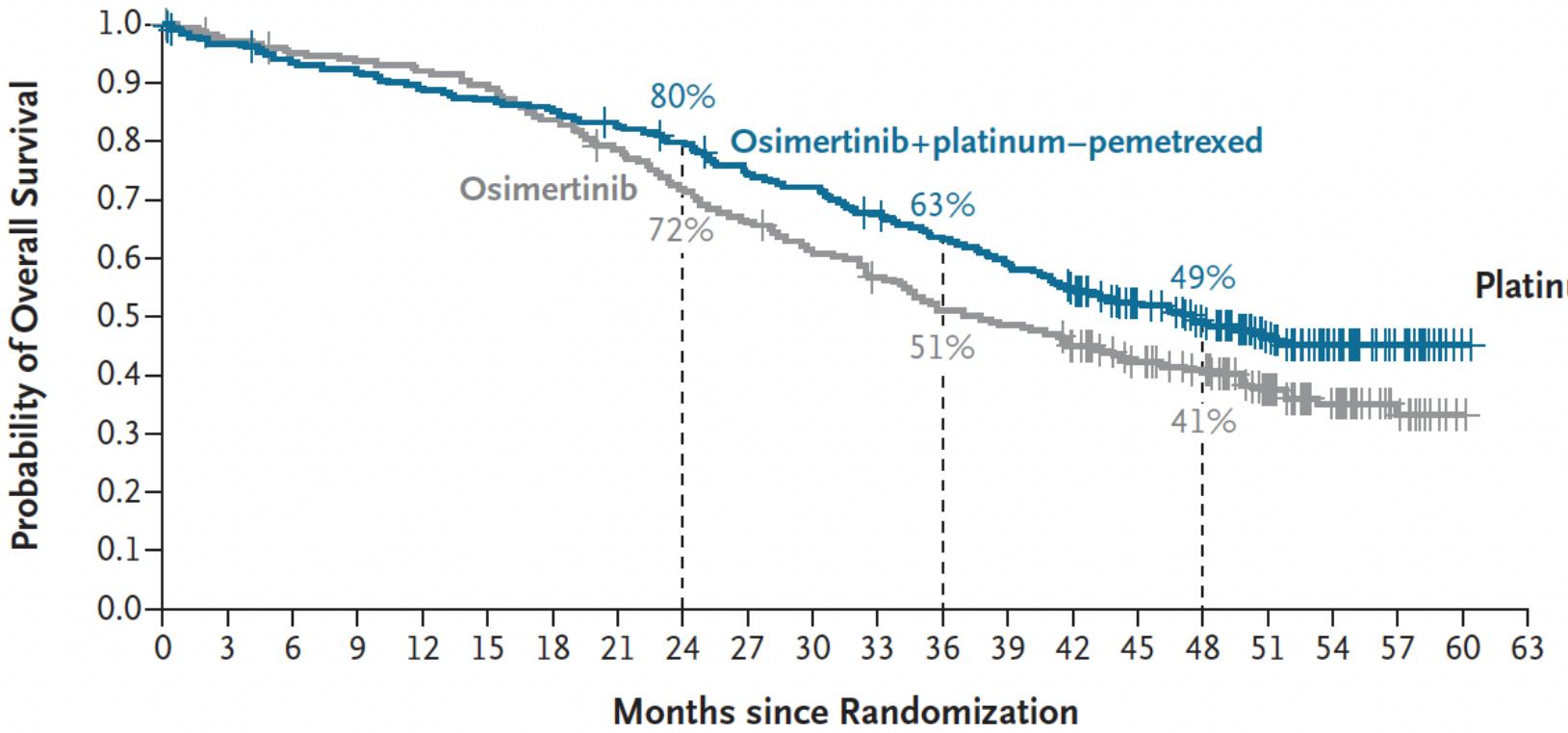
Jänne PA et al. Survival with Osimertinib plus Chemotherapy in EGFR-Mutated Advanced NSCLC. N Engl J Med 2026;394(1):27-38.

FLAURA2 survival

Memorial Sloan Kettering Cancer Center

Courtesy of Helena Yu, MD

FLAURA2 Overall Survival



	Median (95% CI) *mo*
Osimertinib+ Platinum–Pemetrexed	47.5 (41.0–NC)
Osimertinib	37.6 (33.2–43.2)

Hazard ratio for death, 0.77
(95% CI, 0.61–0.96)
P=0.02

No. at Risk

Osimertinib+ platinum–pemetrexed	279	267	258	253	245	240	236	226	218	202	196	183	170	158	143	123	105	71	36	16	1	0
Osimertinib	278	267	260	257	252	245	229	214	195	180	165	152	137	131	118	103	93	61	38	16	1	0

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Yang JC et al. Overall Survival with Amivantamab-Lazertinib in EGFR-Mutated Advanced NSCLC. N Engl J Med 2025;393(17):1681-93.

MARIPOSA - Overall Survival

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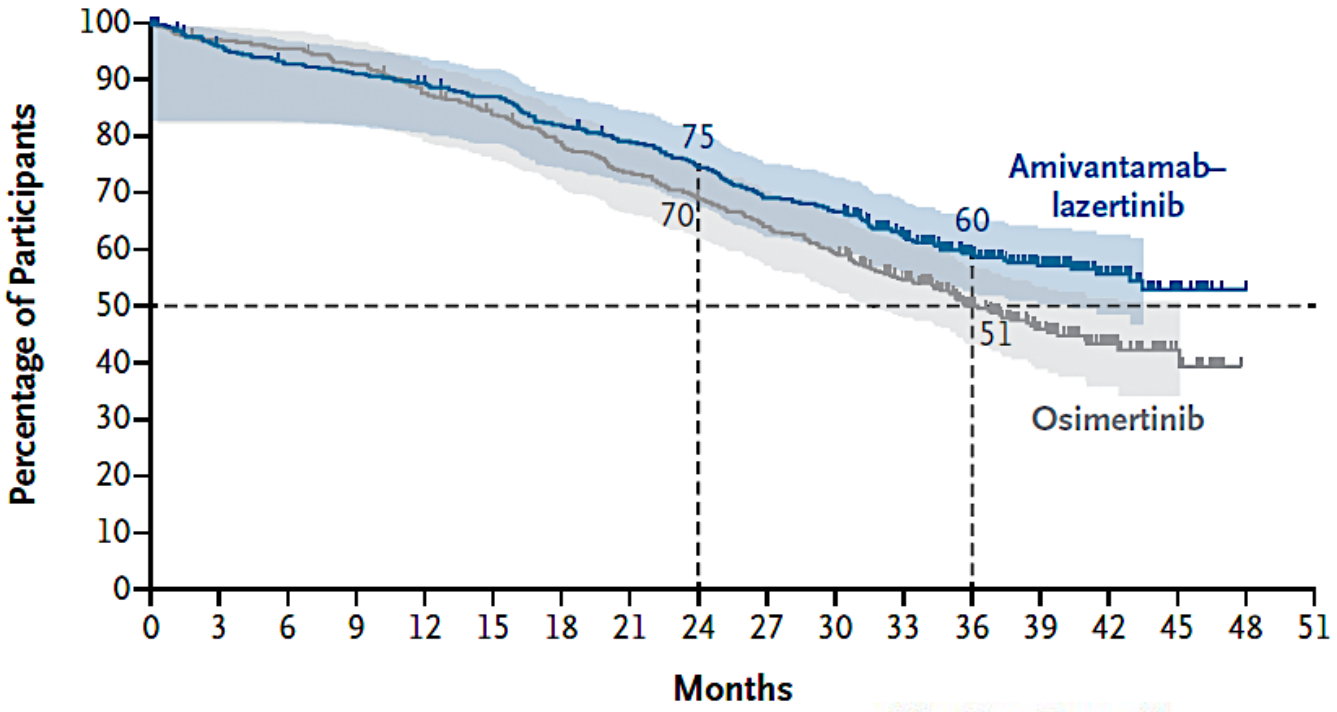
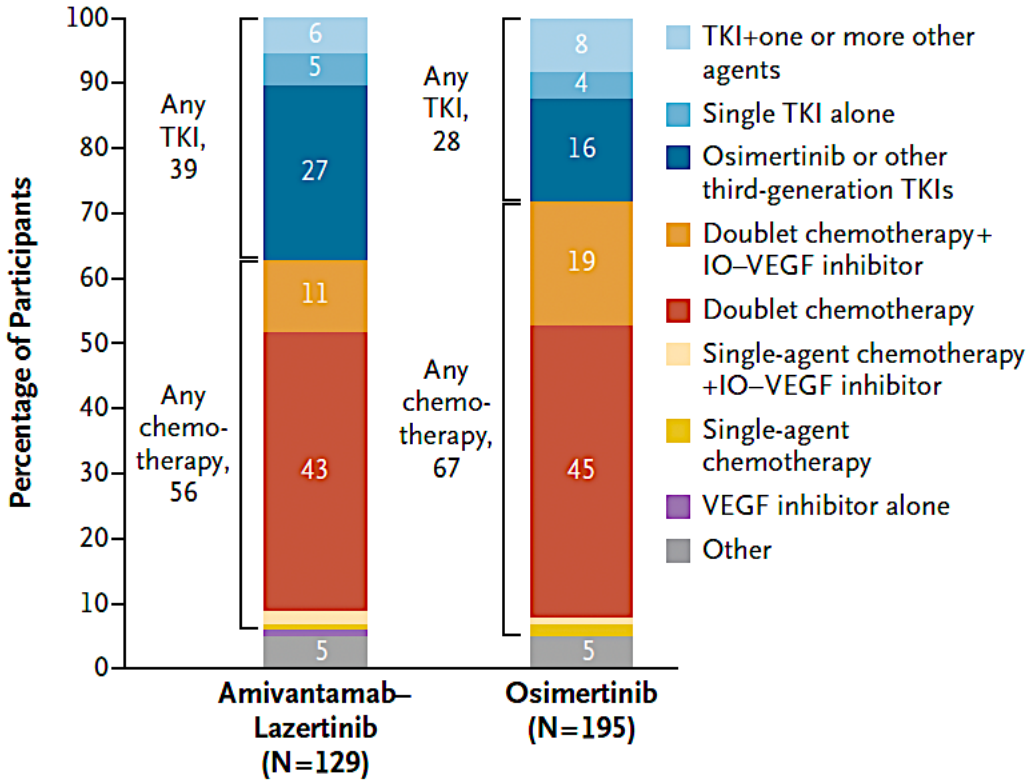
Courtesy of Helena Yu, MD

MARIPOSA - Overall Survival



	Median Overall Survival (95% CI)
	mo
Amivantamab–Lazertinib	NE (42.9–NE)
Osimertinib	36.7 (33.4–41.0)

Hazard ratio for death, 0.75
(95% CI, 0.61–0.92)
P=0.005



- On osimertinib arm, only 3 patients received subsequent amivantamab

Yang JC et al. N Engl J Med 2025;393(17):1681-93.

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Scott SC et al. PALOMA-2: Subcutaneous Amivantamab Administered Every 4 Weeks Plus Lazertinib in First-Line EGFR-Mutated Advanced NSCLC. WCLC 2025;Abstract MA08.05.

Subcutaneous amivantamab

Memorial Sloan Kettering Cancer Center

Courtesy of Helena Yu, MD

Subcutaneous amivantamab

Key eligibility criteria for Cohort 5 (N=77)

- Treatment-naïve, locally advanced or metastatic NSCLC
- Documented *EGFR* Ex19del or L858R mutations
- If brain metastases are present, they must be stable[a]
- ECOG PS score of 0 or 1

Amivantamab SC Q4W + lazertinib

Prophylactic anticoagulation *recommended* for the first 4 months of treatment

Dosing (in 28-day cycles)

Amivantamab SC[b]: Subcutaneous abdominal injection with a Q4W dosing regimen of 1600 mg (2240 mg if ≥80 kg) weekly for the first 4 weeks, and 3520 mg (4640 mg if ≥80 kg) Q4W thereafter

Lazertinib: 240 mg orally daily

Primary endpoint:
- ORR by INV[c]

Secondary endpoints:
- ORR by ICR[c]
- Duration of response
- Time to response
- Clinical benefit rate[d]
- Progression-free survival
- Overall survival
- Safety
- PK

Characteristic, n (%)	Cohort 5 (N=77)
Median age, years (range)	63 (31–80)
Female	52 (68)
Race	
Asian	48 (62)
White	27 (35)
Other[a]	2 (3)
ECOG PS score of 1	52 (68)
History of smoking	25 (32)
Brain metastases	33 (43)
EGFR mutation type[b]	
Exon 19 deletion	46 (60)
L858R	31 (40)
Adenocarcinoma histology	77 (100)

	Prophylactic anticoagulation (n=67)	No prophylactic anticoagulation (n=10)
Any VTE, n (%)	7 (10)	3 (30)
Grade ≥3	0	0
Grade 5	0	0
Any VTE leading to any discontinuation, n (%)	0	0
Grade ≥3 bleeding, n (%)	1 (1)	0

Most common TEAEs (≥20%), n (%)	Cohort 5 (N=77)	
	All grades	Grade ≥3
Associated with EGFR inhibition		
Paronychia	56 (73)	4 (5)
Rash	45 (58)	9 (12)
Dermatitis acneiform	31 (40)	6 (8)
Stomatitis	29 (38)	3 (4)
Pruritus	26 (34)	1 (1)
Diarrhea	22 (29)	2 (3)
Associated with MET inhibition		
Hypoalbuminemia	49 (64)	4 (5)
Peripheral edema	28 (36)	0
Other		
Increased ALT	25 (32)	3 (4)
Increased AST	21 (27)	1 (1)
Dry skin	18 (23)	0

Scott SC et al. WCLC 2025;Abstract MA08.05.

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Peled N et al. COMPEL: Osimertinib plus platinum-based chemotherapy in patients with EGFR-mutated advanced NSCLC and progression on first-line osimertinib. ESMO Open 2025;10(10):105807.

COMPEL study – osimertinib with chemotherapy

Memorial Sloan Kettering Cancer Center

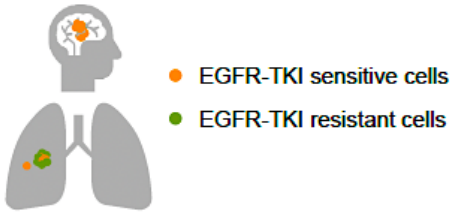
Courtesy of Helena Yu, MD

COMPEL study – osimertinib with chemotherapy

COMPEL: osimertinib plus platinum-based chemotherapy in patients with EGFR-mutated advanced NSCLC and progression on first-line osimertinib

Background

- Some tumor cells may retain sensitivity to EGFR-TKIs following progression on first-line osimertinib (osi), particularly in the central nervous system (CNS)



- COMPEL compared osi + chemotherapy (CTx) versus placebo (PBO) + CTx in patients with EGFR-mutated advanced NSCLC and non-CNS progression on first-line osi

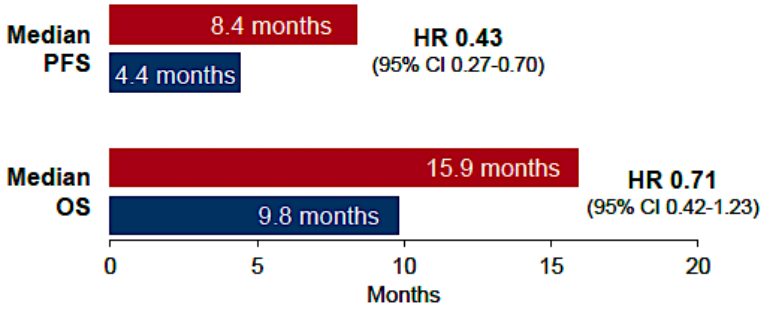
Patients

Randomized 1:1 (n = 98)

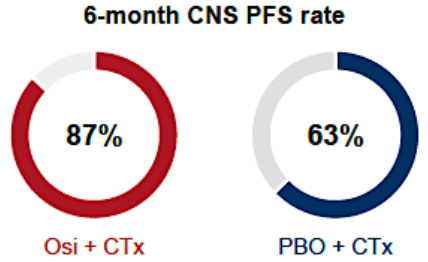
Osi + CTx		PBO + CTx
63 years	Median age	61 years
61%	Female	80%
22%	CNS metastases	24%

Results

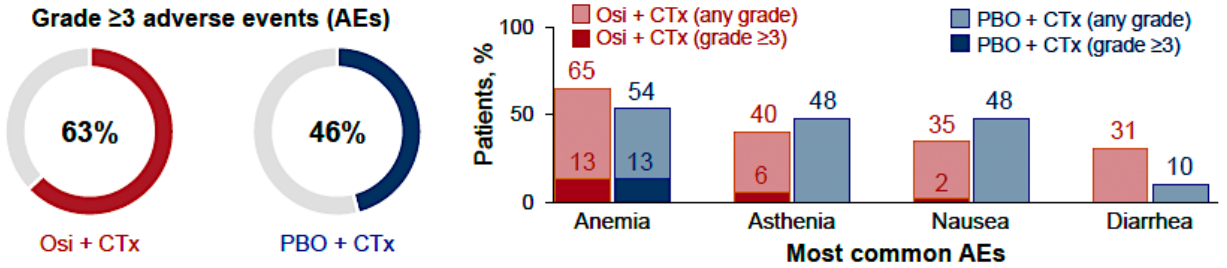
Osi + CTx was associated with improved progression-free survival (PFS) and longer overall survival (OS) versus PBO + CTx (n = 98)



CNS PFS was also longer with osi + CTx versus PBO + CTx in patients without baseline CNS metastases (n = 75)



Safety findings were consistent with the known safety profiles of each drug (n = 96)



CONCLUSION: Osi + CTx was associated with improved PFS and longer OS compared with PBO + CTx in patients with non-CNS progression on first-line osi. These findings support osi as a backbone treatment for EGFR-mutated advanced NSCLC through lines of therapy.

Peled N et al. ESMO Open 2025;10(10):105807.

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Elamin YY et al. NorthStar: A phase II randomized study of osimertinib (OSI) with or without local consolidative therapy (LCT) for metastatic EGFR-mutant non-small cell lung cancer (NSCLC). ESMO 2025;Abstract LBA72.

Local consolidation for EGFR+ NSCLC

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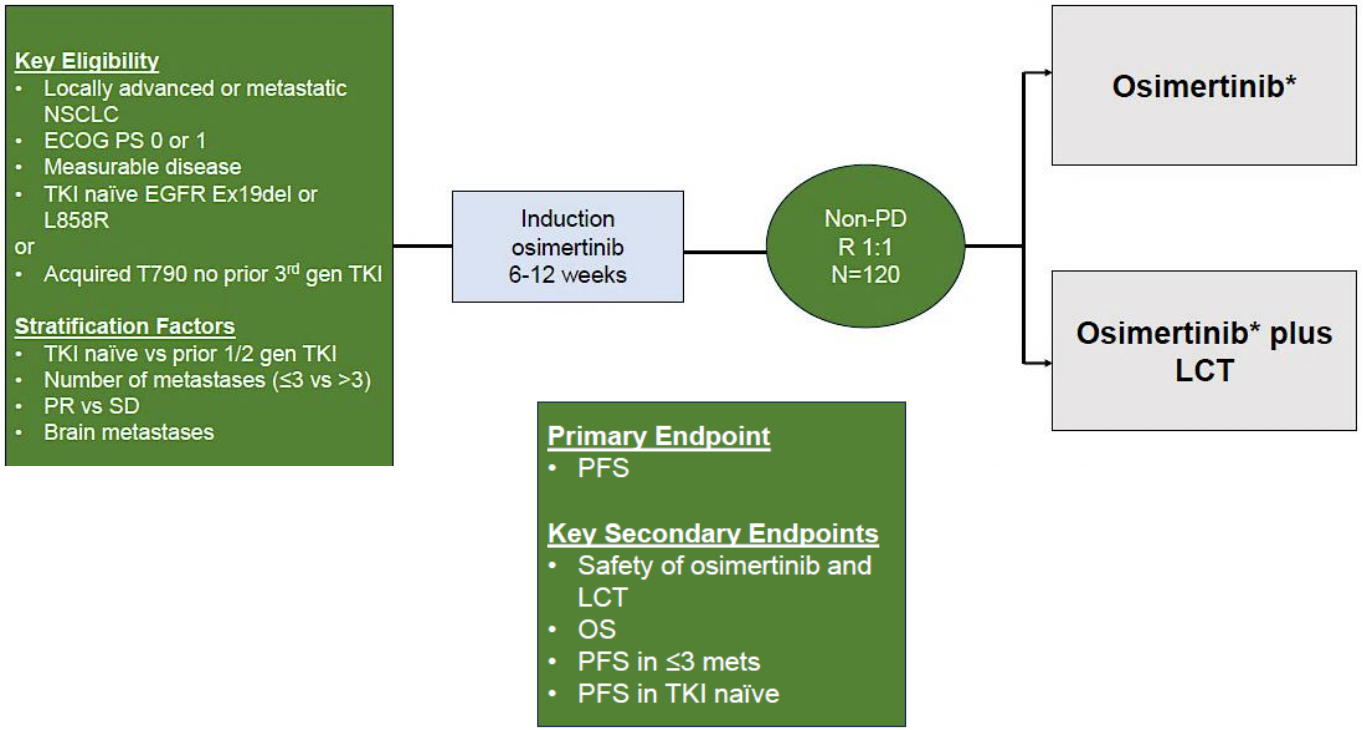
Courtesy of Helena Yu, MD

North Star study – Local consolidation for EGFR+ NSCLC



Characteristics	Osimertinib (n=63)	Osimertinib plus LCT (n=56)
Age, median (range), y	64 (31-82)	66 (40-88)
Women	42 (66.7%)	37 (66.1%)
***EGFR* mutation subtype**		
Ex19del	42 (66.7%)	32 (57.1%)
L858R	18 (28.5%)	22 (39.3%)
T790M (with L858R or Ex19del)	3 (4.8%)	2 (3.6%)
Prior Therapy*		
TKI naïve	60 (95.2%)	54 (96.4%)
1st or 2nd generation TKI	3 (4.8%)	2 (3.6%)
Number of metastases at baseline		
greater than 3	45 (71.4%)	39 (69.6%)
less than or equal 3	18 (28.6%)	17 (30.30%)
Number of metastases at randomization*		
greater than 3	37 (58.7%)	32 (57.1%)
less than or equal 3	26 (41.3%)	24 (42.9%)
Brain metastasis*		
yes	23 (36.5%)	21 (37.5%)
no	40 (63.5%)	35 (62.5%)
Response to induction osimertinib*		
PR	43 (68.3%)	40 (71.4%)
SD	20 (31.7%)	16 (28.6%)

Randomized, multicenter, phase II trial, NCT03410043

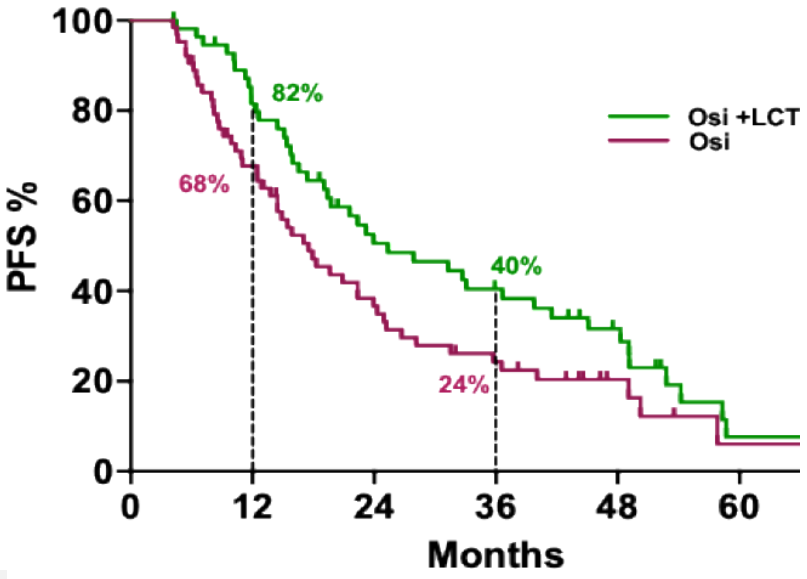
Elamin YY et al. ESMO 2025;Abstract LBA72.

North Star study – Local consolidation for EGFR+ NSCLC

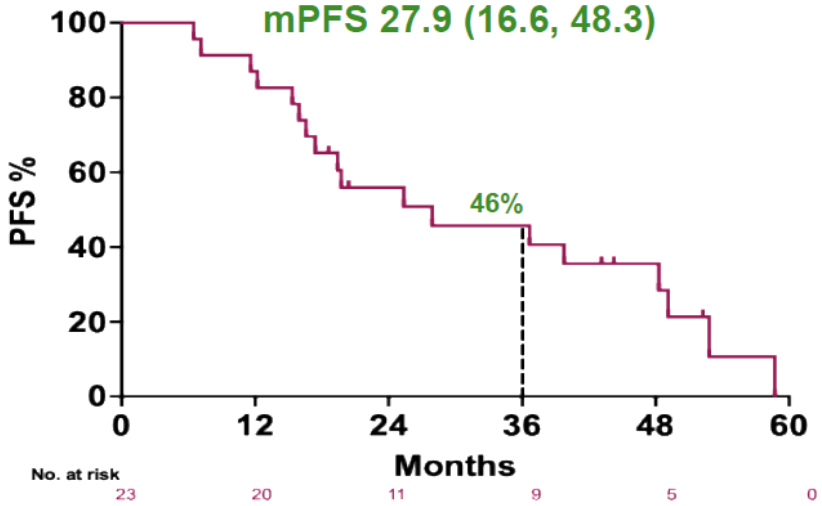
	n (%)
LCT modality n=56	
Radiation	33 (58.9%)
Surgery	17 (32.1%)
Surgery and radiation	6 (9%)
Surgical procedure n=23	
Lobectomy	18 (78.3%)
Lobectomy and wedge resection	1 (4.3%)
Wedge resection	2 (8.7%)
Segmentectomy	1 (4.3%)
Adrenalectomy	1 (4.3%)
Radiation modality n=50, 39 patients	
VMAT or IMRT	28 (56%)
SBRT	15 (30%)
3D conformal or 2D conformal	7 (14%)

Adverse Event	Osimertinib plus LCT (n=56)		
	Grade 1	Grade 2	Grade 3
Pneumonitis	1 (1.8%)	5 (8.9%)	1 (1.8%)
Dyspnea	15 (26.8%)	2 (3.6%)	-
Arterial injury	-	-	1 (1.8%)
Empyema	-	-	1 (1.8%)
Esophagitis	1 (1.8%)	1 (1.8%)	-
Dysphagia	7 (12.5%)	-	-

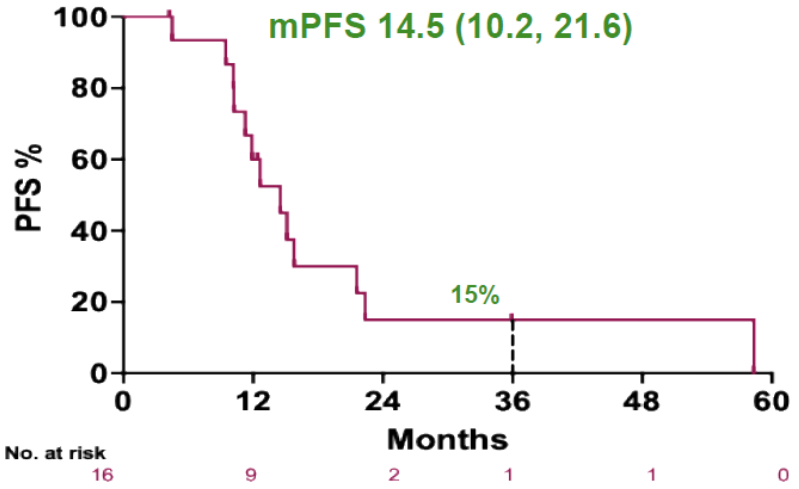
	Osimertinib (n=63)	Osimertinib plus LCT (n=56)
PFS events, n (%)	50 (79.3%)	42 (75%)
Median PFS month 95% CI	17.5 (14.5, 24.3)	25.3 (19.4, 45.0)
HR One-sided 90% CI	0.66 0.50 - 0.87	
P value (1-sided log rank)	0.025	



Complete LCT



Partial LCT



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Sands J et al. Datopotamab Deruxtecan in Advanced or Metastatic Non-Small Cell Lung Cancer With Actionable Genomic Alterations: Results From the Phase II TROPION-Lung05 Study. J Clin Oncol 2025;43(10):1254-65.

Datopotamab deruxtecan - TROPION Lung05

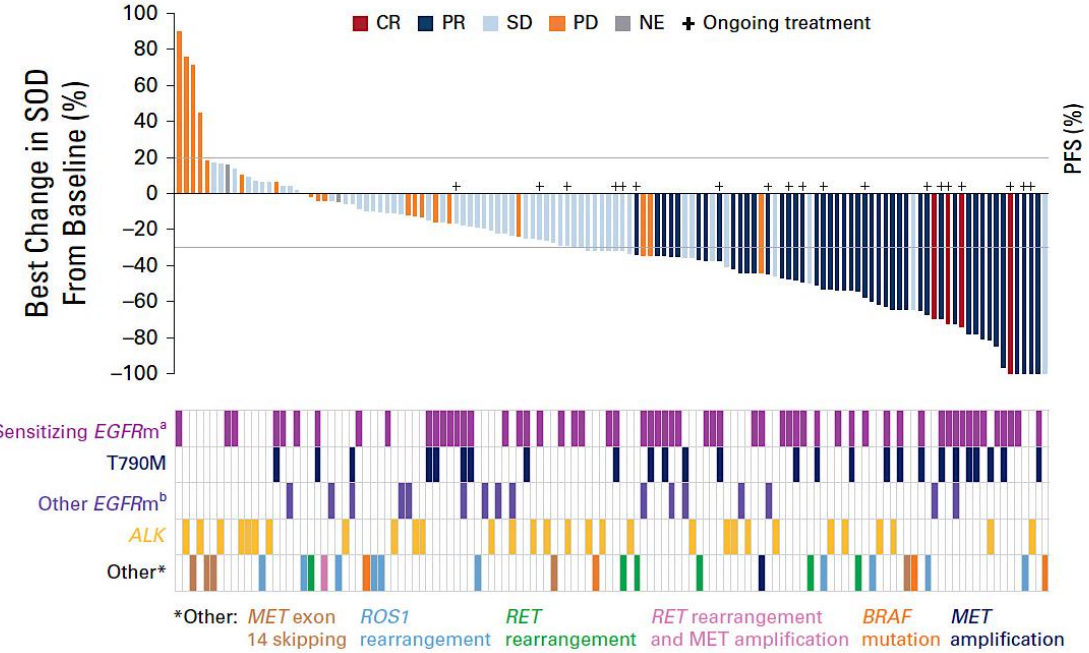
Memorial Sloan Kettering Cancer Center

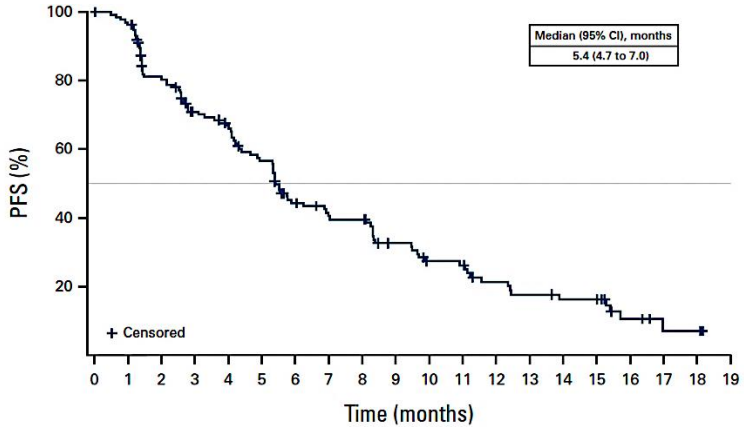
Courtesy of Helena Yu, MD

Datopotamab deruxtecan – TROPION-Lung05

TABLE 1. Baseline Demographics and Disease Characteristics

Patient Characteristic	N = 137
Summary of mutation types,[e] No. (%)	
EGFR	78 (56.9)
Exon 19 deletion	41 (29.9)
Exon 20 T790M	26 (19.0)
Exon 21 L858R	25 (18.2)
Exon 18 G719	5 (3.6)
Exon 21 L861Q	3 (2.2)
Exon 20 insertion	2 (1.5)
ALK rearrangement	34 (24.8)
ROS1 rearrangement	10 (7.3)
RET rearrangement	8 (5.8)
MET exon 14 skipping	5 (3.6)
BRAF mutation	4 (2.9)
MET amplification[f]	3 (2.2)
Prior targeted therapy for advanced/metastatic disease	
Specific for the actionable genomic alteration harbored,[h] No. (%)	137 (100)
Prior cytotoxic systemic therapy,[g] No. (%)	
Platinum-based chemotherapy	137 (100)
Other chemotherapy	136 (99.3)
Anti–PD-1/anti–PD-L1 immunotherapy	49 (35.8)
Other	47 (34.8)
Prior systemic therapies for advanced/metastatic disease	
Median (range)	3 (1-9)
1-2, No. (%)	39 (28.5)
≥3, No. (%)	98 (71.5)





Variable	Overall (N = 137)	*EGFR* Mutations (n = 78)	*ALK* Rearrangements (n = 34)
Confirmed ORR, No. (%)	49 (35.8)	34 (43.6)	8 (23.5)
95% CI[a]	27.8 to 44.4	32.4 to 55.3	10.7 to 41.2
CR, No. (%)	4 (2.9)	4 (5.1)	0
PR, No. (%)	45 (32.8)	30 (38.5)	8 (23.5)
SD, No. (%)	56 (40.9)	27 (34.6)	17 (50.0)
PD, No. (%)	19 (13.9)	10 (12.8)	5 (14.7)

	N = 137, No. (%)			
TRAE	Any Grade	Grade 1	Grade 2	Grade ≥3
Stomatitis (PT)	77 (56.2)	37 (27.0)	27 (19.7)	13 (9.5)
Nausea	75 (54.7)	44 (32.1)	28 (20.4)	3 (2.2)
Alopecia	68 (49.6)	48 (35.0)	19 (13.9)	1 (0.7)
Decreased appetite	28 (20.4)	11 (8.0)	14 (10.2)	3 (2.2)
Fatigue	26 (19.0)	14 (10.2)	10 (7.3)	2 (1.5)
Constipation	21 (15.3)	16 (11.7)	5 (3.6)	0
Rash	19 (13.9)	14 (10.2)	5 (3.6)	0
Vomiting	19 (13.9)	10 (7.3)	8 (5.8)	1 (0.7)
Asthenia	15 (10.9)	8 (5.8)	5 (3.6)	2 (1.5)

Sands J et al. J Clin Oncol 2025;43(10):1254-65.

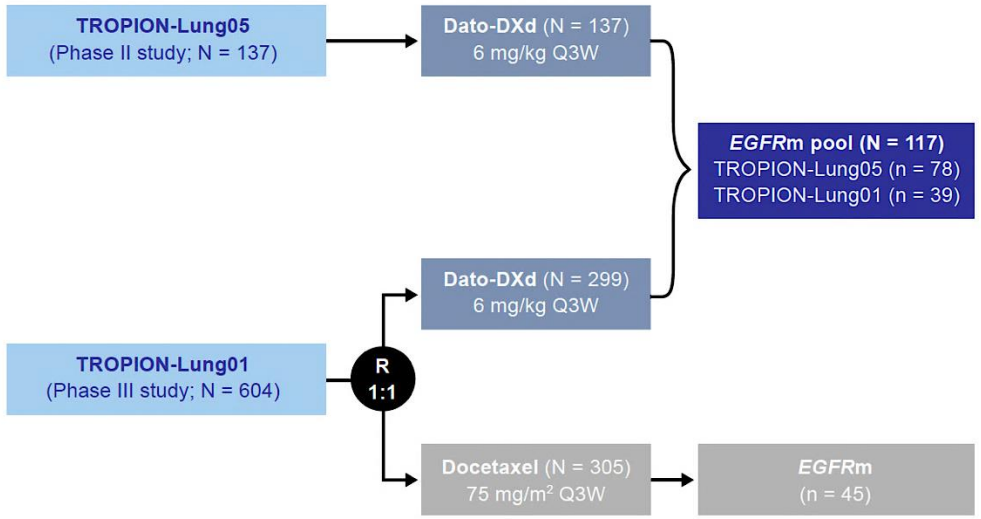
Ahn MJ et al. A Pooled Analysis of Datopotamab Deruxtecan in Patients With EGFR-Mutated NSCLC. J Thorac Oncol 2025;20(11):1669-82.

Pooled analysis of TL01 and TL05

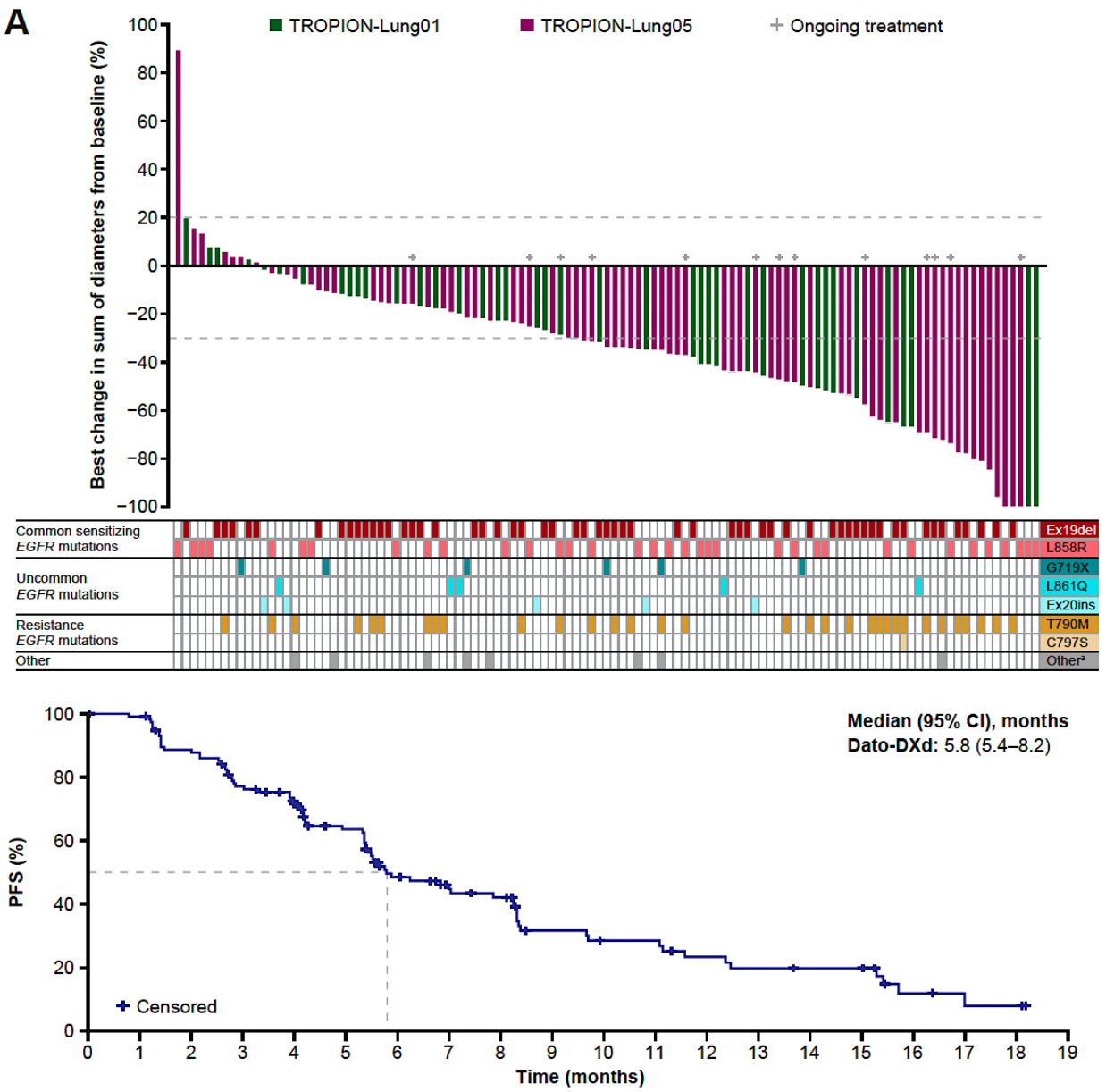
Memorial Sloan Kettering Cancer Center

Courtesy of Helena Yu, MD

Datopotamab deruxtecan – TROPION-Lung01 and Lung05



Characteristic	*EGFR*m Pool (N = 117)
Age, median (range), y	63 (36-81)
Female	73 (62)
Race	
Asian	81 (69)
White	27 (23)
Black or African American	1 (1)
Other or missing	8 (7)
Brain metastases at study entry	36 (31)
Summary of *EGFR* mutation types[b]	
Ex19del	60 (51)
L858R	37 (32)
T790M	32 (27)
G719X	6 (5)
L861G	5 (4)
Ex20ins	5 (4)
Previous lines of systemic therapies for advanced or metastatic disease	
Median (range)	3 (1-5)
1-2	51 (44)
3	36 (31)
≥4	30 (26)



Ahn MJ et al. J Thorac Oncol 2025;20(11):1669-82.

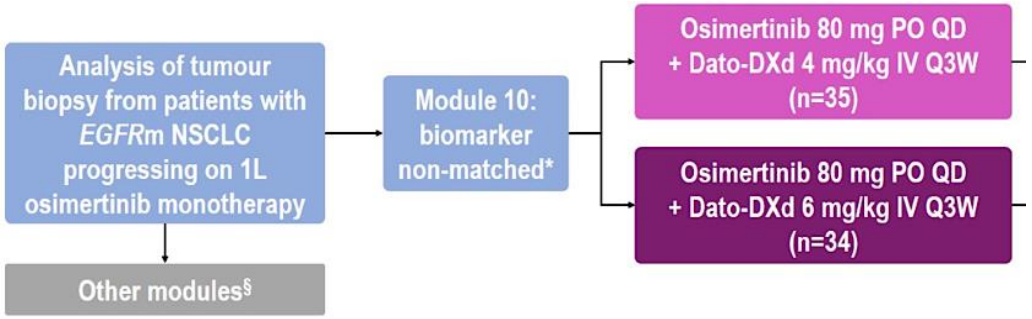
Le X et al. Osimertinib (osi) + datopotamab deruxtecan (Dato-DXd) in patients (pts) with EGFR-mutated (EGFRm) advanced NSCLC (aNSCLC) whose disease progressed on first-line (1L) osi: ORCHARD. ELCC 2025;Abstract 1O.

Datopotamab deruxtecan + osimertinib in the ORCHARD study

Memorial Sloan Kettering Cancer Center

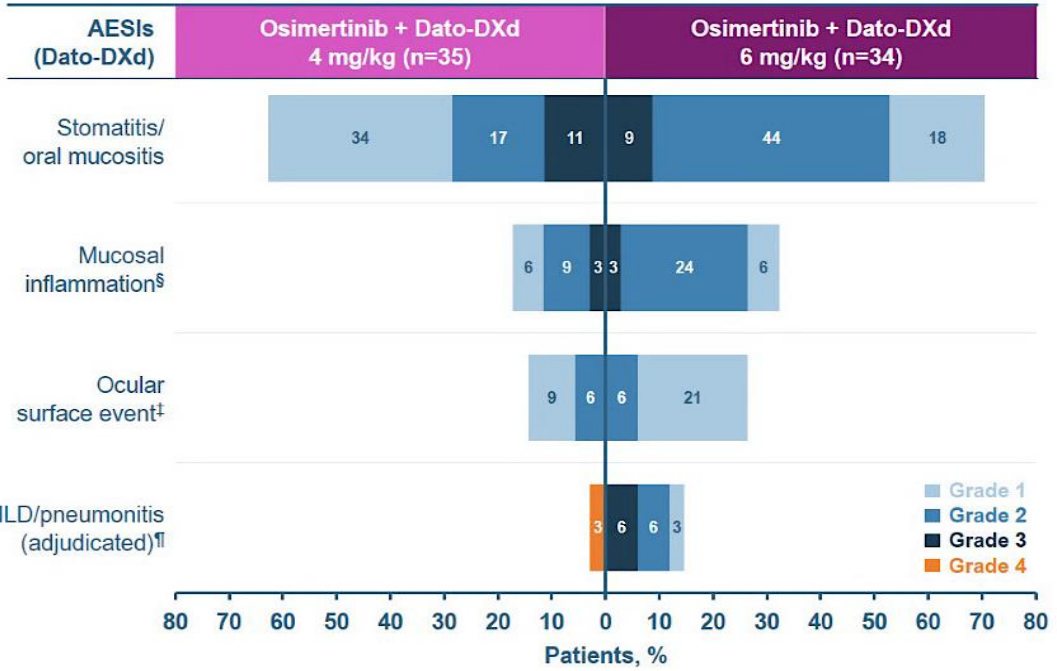
Courtesy of Helena Yu, MD

Datopotamab deruxtecan + osimertinib in ORCHARD



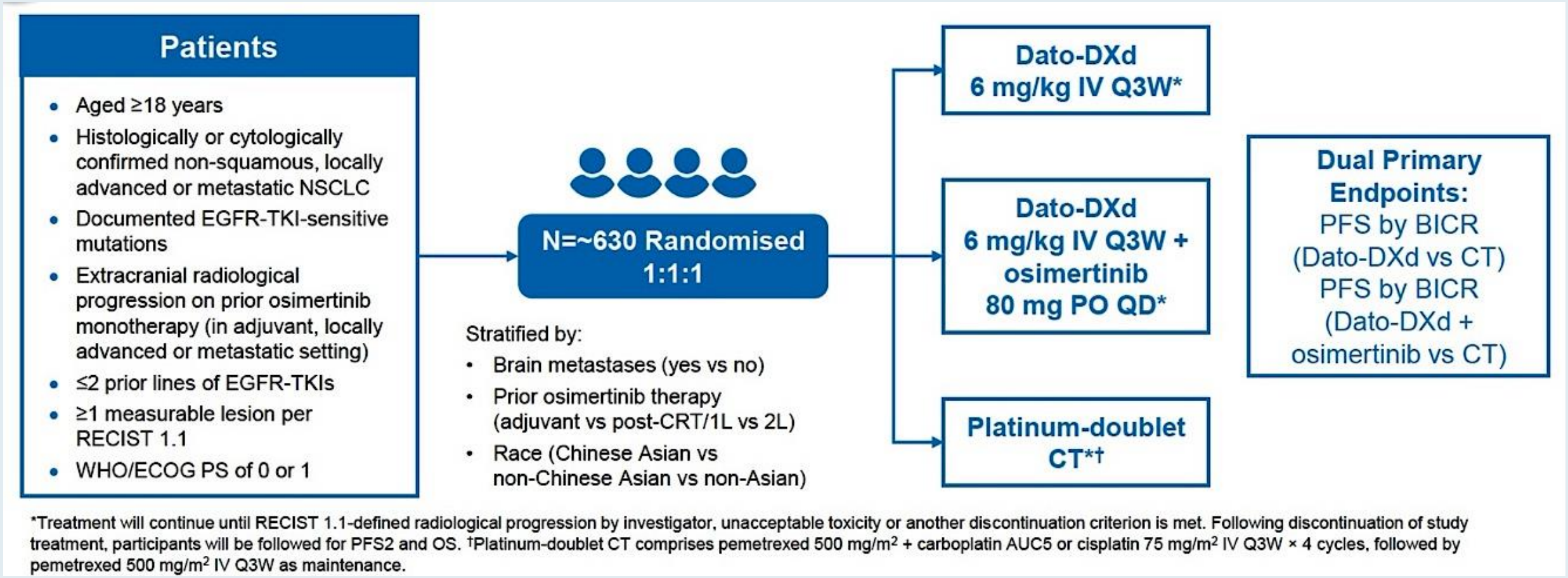
	Osimertinib + Dato-DXd 4 mg/kg (n=35)	Osimertinib + Dato-DXd 6 mg/kg (n=33)
PFS		
mPFS, months (95% CI)	**9.5 (7.2, 9.8)**	**11.7 (8.3, NC)**
6-month rate, % (95% CI)	74 (56, 85)	80 (61, 91)
9-month rate, % (95% CI)	50 (33, 65)	70 (49, 83)
12-month rate, % (95% CI)	21 (9, 35)	39 (21, 57)
ORR, % (80% CI)	**43 (31, 55)**	**36 (25, 49)**
DoR		
mDoR, months (95% CI)*	**6.3 (3.8, 8.2)**	**20.5 (6.2, NC)**
6-month rate, % (95% CI)	60 (32, 80)	92 (54, 99)
9-month rate, % (95% CI)	15 (2, 38)	64 (30, 85)
Median time to onset of response, months (Q1, Q3)	**2.7 (1.5, 4.1)**	**1.4 (1.2, 2.1)**
Median duration of follow-up, months	13.4	13.8
OS events, n (%)	16 (46)	9 (27)

	Osimertinib + Dato-DXd 4 mg/kg (n=35)	Osimertinib + Dato-DXd 6 mg/kg (n=34)
Treatment-related AE, n (%)	34 (97)	33 (97)
Grade ≥3	12 (34)	19 (56)
Grade ≥3 possibly related to osimertinib only	2 (6)	0
Grade ≥3 possibly related to Dato-DXd only	5 (14)	12 (35)
Any Grade ≥3 AE, n (%)	17 (49)	25 (74)
Dose reduction, n (%)		
AE leading to osimertinib dose reduction	6 (17)	0
AE leading to Dato-DXd dose reduction	8 (23)	20 (59)
Dose interruption, n (%)		
AE leading to osimertinib dose interruption	15 (43)	12 (35)
AE leading to Dato-DXd dose interruption	16 (46)	22 (65)
Discontinuation, n (%)		
AE leading to osimertinib discontinuation	6 (17)	8 (24)
AE leading to Dato-DXd discontinuation	6 (17)	9 (26)



Le X et al. ELCC 2025;Abstract 1O.

Phase III TROPION-Lung15 Study Design



*Treatment will continue until RECIST 1.1-defined radiological progression by investigator, unacceptable toxicity or another discontinuation criterion is met. Following discontinuation of study treatment, participants will be followed for PFS2 and OS. †Platinum-doublet CT comprises pemetrexed 500 mg/m^2 + carboplatin AUC5 or cisplatin 75 mg/m^2 IV Q3W × 4 cycles, followed by pemetrexed 500 mg/m^2 IV Q3W as maintenance.

Enrollment started October 2024 | Enrollment is ongoing

Nadal E et al. ELCC 2025;Abstract 124TiP.

Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 1: Metastatic disease

- FLAURA2, IPASS studies
- MARIPOSA study: Amivantamab and lazertinib
- PALOMA studies: Subcutaneous amivantamab
  - DVT, pulmonary emboli; prophylactic anticoagulation
- Short-term versus long-term outcomes — tail of the curve?
- COMPEL study: Continuation with chemotherapy of first-line osimertinib — CNS disease, ADCs
- NorthStar study: Local consolidation — RT, surgery
- Datopotamab deruxtecan
  - Exon 20 insertion, uncommon mutations
  - Toxicity: Mucositis, keratitis
  - TROPION-Lung15
- MET inhibitors — after disease progression on osimertinib
  - MET amplified, overexpressed
  - SACHI study: Savolitinib and osimertinib

de Marinis F et al. Savolitinib plus osimertinib in epidermal growth factor receptor (EGFR)-mutated advanced non-small cell lung cancer with MET overexpression and/or amplification following disease progression on osimertinib: Primary results from the phase II SAVANNAH study. Ann Oncol 2025;36(8):920-33.

SAVANNAH study - Savolitinib + osimertinib

Memorial Sloan Kettering Cancer Center

Courtesy of Helena Yu, MD

SAVANNAH study- Savolitinib + osimertinib

Table 1. Demographic and clinical characteristics of patients at baseline in the primary efficacy population

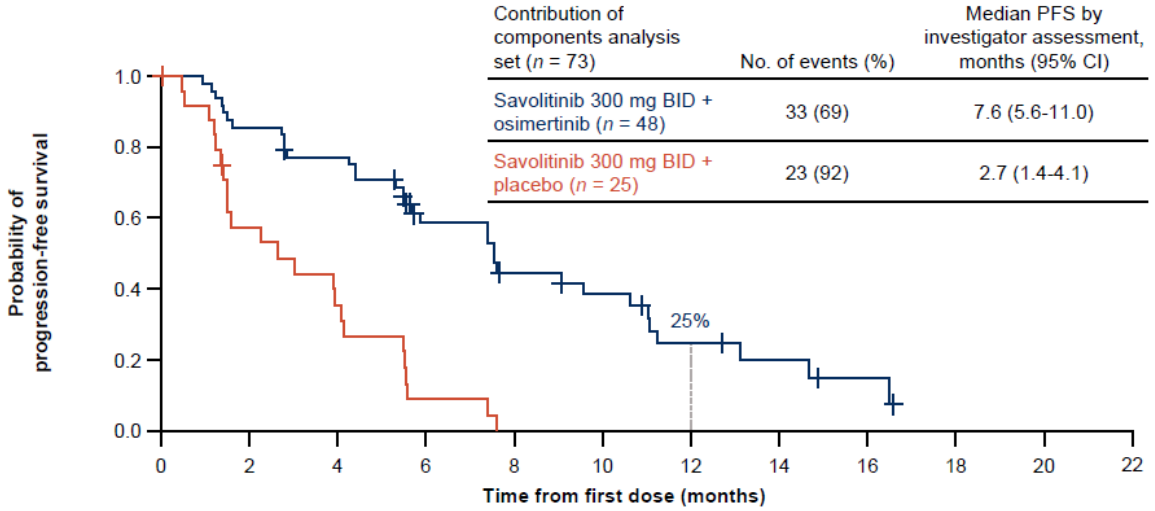
Characteristics	Savolitinib 300 mg b.i.d. + osimertinib 80 mg o.d. (primary efficacy population) *n* = 80
Sex, *n* (%)	
Female	56 (70.0)
Male	24 (30.0)
Age, years	
Median (range)	66.0 (29-83)
Category, *n* (%)	
<65	39 (48.8)
≥65	41 (51.3)
Race, *n* (%)	
Asian	21 (26.3)
White	57 (71.3)
Other	2 (2.5)
ECOG performance status, *n* (%)	
0	32 (40.0)
1	48 (60.0)
2	0
Smoking status (any), *n* (%)	
Current or former	38 (47.5)
Never	42 (52.5)
EGFR mutation type, (%)[a]	
Exon 19 deletion	48 (60.0)
L858R mutation	30 (37.5)
Other[b]	7 (8.8)
Brain metastases at study entry, *n* (%)	31 (38.8)
Prior lines of therapy (any), *n* (%)	
1	80 (100)
≥2	0 (0)
Previous osimertinib line of therapy, *n* (%)	
Osimertinib as the first-line therapy	80 (100)[c]
Osimertinib as the second-line therapy or later	0 (0)
MET overexpression and/or amplification status	
MET IHC3+/≥90% and/or FISH10+	100
MET IHC3+/≥90%[d]	75
MET FISH10+[d]	70

Table 2. Key efficacy endpoint data (primary efficacy population)

Endpoint	Savolitinib 300 mg b.i.d. + osimertinib 80 mg o.d. (primary efficacy population) *n* = 80	
	Investigator assessment	BICR assessment
Confirmed ORR (Clopper–Pearson 95% CI) (%)	56.3 (44.7 to 67.3)[a]	55.0 (43.5 to 66.2)[a]
Best objective response, *n* (%)		
Complete response	1 (1.3)	1 (1.3)
Partial response	44 (55.0)	43 (53.8)
Stable disease	22 (27.5)	29 (36.3)
Progressive disease	13 (16.3)	6 (7.5)
Not evaluable	0 (0)	1 (1.3)
Time to onset of response in patients with response (weeks)		
Median (interquartile range)	6.14 (6.00-6.71)	6.00 (5.71-6.64)
Duration of response in patients with response (months)		
Median (95% CI)	7.1 (5.6-9.6)	9.9 (6.0-13.7)
Progression-free survival (months)		
Events, *n* (%)	65 (81.3)	49 (61.3)
Median (95% CI)	7.4 (5.5-7.6)[b]	7.5 (6.4-11.3)[c]

MET cut-offs initially MET IHC 3+/≥50% and/or FISH5+ (≥5 MET gene copies, MET/CEP7≥2) and increased to MET IHC3+/≥90% and FISH10+ after a preliminary analysis.

With lower cutoff, the mPFS was 2.8mo and ORR 9%



de Marinis F et al. Ann Oncol 2025;36(8):920-33.

Lu S et al. Savolitinib plus osimertinib versus chemotherapy for advanced, EGFR mutation-positive, MET-amplified non-small-cell lung cancer in China (SACHI): Interim analysis of a multicentre, open-label, phase 3 randomised controlled trial. Lancet 2026;407(10526):375-87.

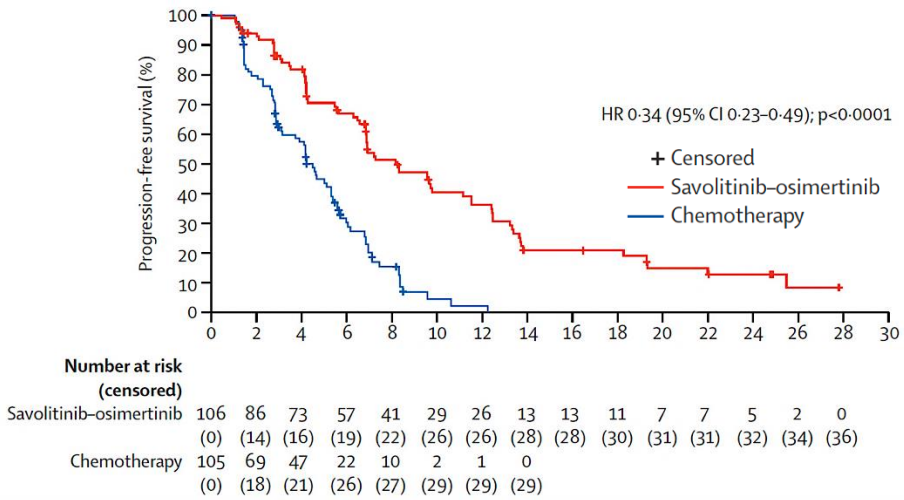
SACHI study - Savolitinib + osimertinib

Memorial Sloan Kettering Cancer Center

Courtesy of Helena Yu, MD

SACHI study- Savolitinib + osimertinib

	Savolitinib–osimertinib (n=106)	Chemotherapy (n=105)
Age, years	59·4 (54·3–65·8)	61·9 (56·3–69·1)
Sex		
Male	44 (42%)	50 (48%)
Female	62 (58%)	55 (52%)
Race		
Asian	106 (100%)	105 (100%)
Time from diagnosis to randomisation, months	17·2 (10·4–30·9)	14·7 (9·9–24·5)
Type of EGFR mutation		
Exon 19 deletion	40 (38%)	40 (38%)
L858R	55 (52%)	53 (50%)
Other†	11 (10%)	12 (11%)
MET amplification detected by central laboratory	106 (100%)	105 (100%)
Brain metastasis		
Yes	39 (37%)	41 (39%)
No	67 (63%)	64 (61%)
Liver metastasis		
Yes	11 (10%)	15 (14%)
No	95 (90%)	90 (86%)
Previous first-line EGFR TKI	106 (100%)	105 (100%)
First generation or second generation	69 (65%)	68 (65%)
Icotinib	28/69 (41%)	33/68 (49%)
Gefitinib	20/69 (29%)	17/68 (25%)
Afatinib	14/69 (20%)	11/68 (16%)
Dacomitinib	5/69 (7%)	7/68 (10%)
Erlotinib	3/69 (4%)	0
Third generation	37 (35%)	37 (35%)
Osimertinib	23/37 (62%)	29/37 (78%)
Aumolertinib	9/37 (24%)	5/37 (14%)
Furmonertinib	2/37 (5%)	3/37 (8%)
Rezivertinib	3/37 (8%)	0



	Intention-to-treat population		
	Savolitinib–osimertinib (n=106)	Chemotherapy (n=105)	HR (95% CI)
Primary endpoint			
Progression-free survival (INV), months	8·2 (6·9–11·2)	4·5 (3·0–5·4)	0·34 (0·23–0·49)
Progression-free survival rate at 6 months	67% (56–76)	32% (22–42)	..

	Assessed by investigator				
	Savolitinib–osimertinib (n=37)	Chemotherapy (n=37)	HR (95% CI)	OR (95% CI)	p value
Progression-free survival, months	6·9 (4·2–9·7)	3·0 (2·7–4·6)	0·32 (0·18–0·57)	..	<0·0001
Progression-free survival rate at 6 months	59% (41–74)	18% (7–33)	..	..	..
Objective response rate	23 (62%, 45–78)	10 (27%, 14–44)	..	4·46 (1·50–13·31)	0·0025
Disease control rate	31 (84%, 68–94)	24 (65%, 47–80)	..	2·86 (0·84–10·36)	0·062
Duration of response, months	8·2 (5·3–12·4)	3·0 (0·9–4·1)	..	..	..
Time to response, months	1·4 (1·4–1·4)	1·4 (1·2–1·5)	..	..	..

MET amplification definition: MET copy number ≥5, MET to CEP7 ratio ≥2 after 1st/2nd gen EGFR TKI or MET copy number ≥10 after 3rd gen EGFR TKI

Lu S et al. Lancet 2026;407(10526):375-87.

Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 2: Localized disease

- Adjuvant osimertinib (ADAURA trial): ctDNA — 3 years duration?
- NeoADAURA trial: Neoadjuvant osimertinib — with chemotherapy
  - Current role: N2+, Stage IIIA?

- Surgically unresectable disease — chemotherapy, radiation therapy
  - LAURA trial
    - Indefinite osimertinib: survival results
    - MRD findings (current role?)
  - NEOLA trial: osimertinib before and after chemoradiation

Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

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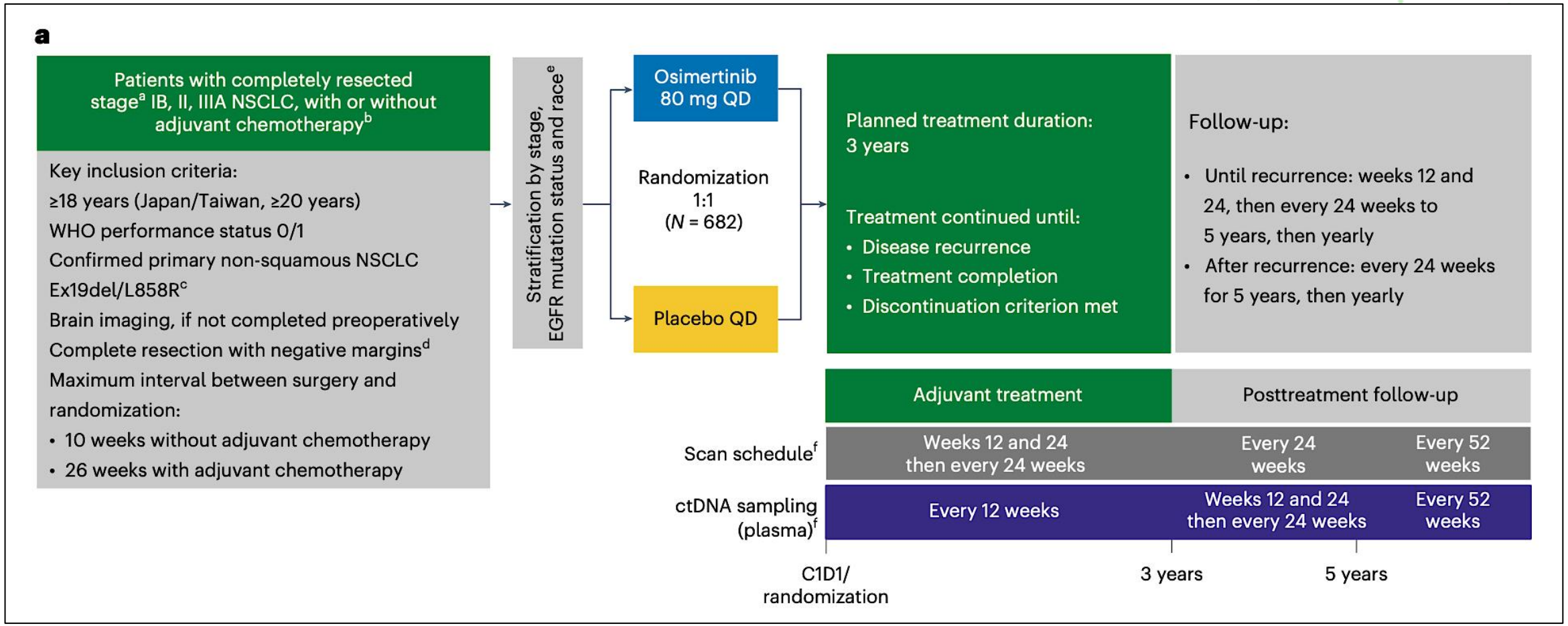
MRD Analysis in ADAURA Trial



Herbst R et al, Nat Med, 2025.

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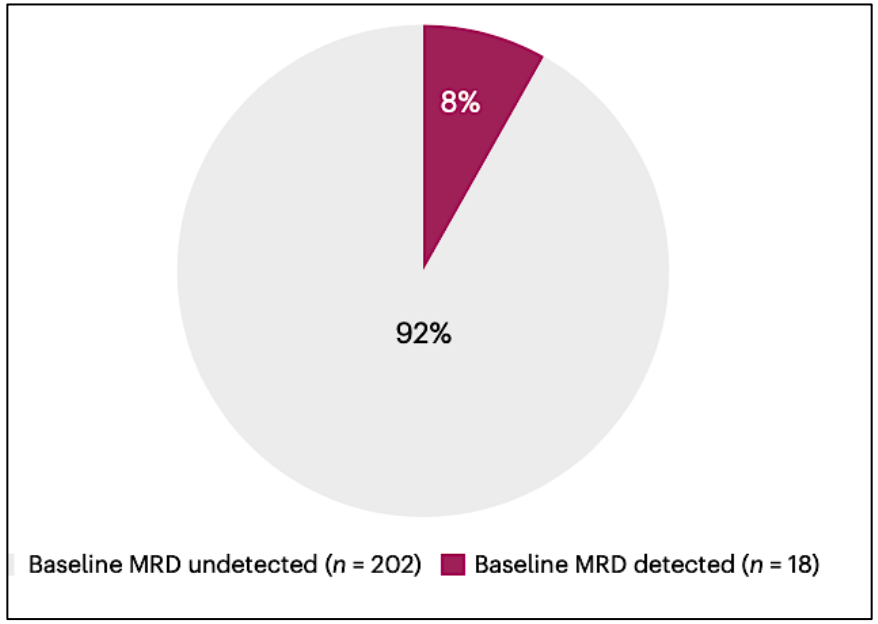
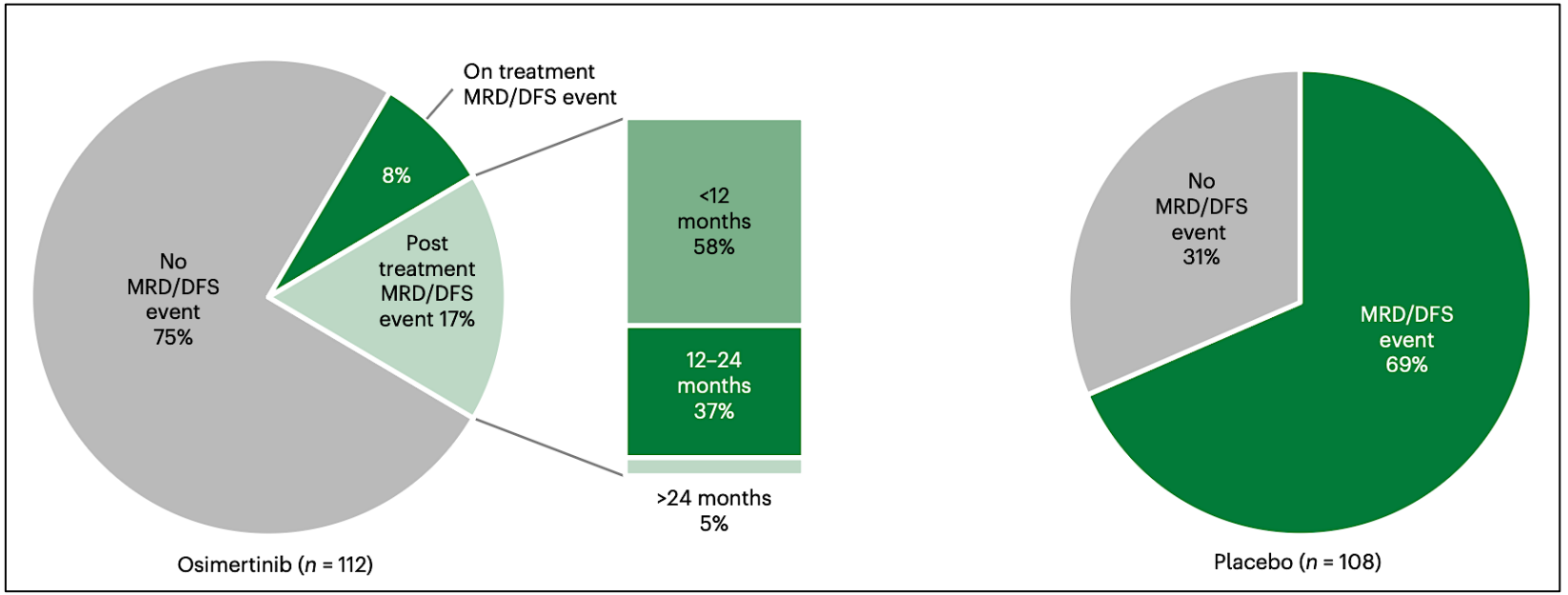
MRD Status at Baseline and with Therapy





Herbst R et al, Nat Med, 2025.

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Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

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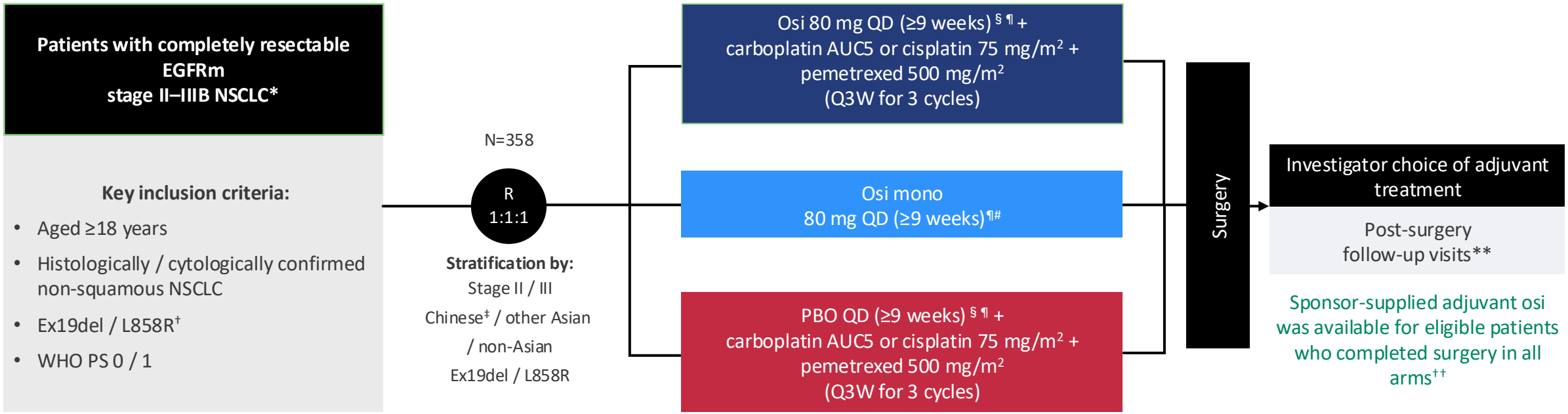
    - Indefinite osimertinib: survival results
    - MRD findings (current role?)
  - NEOLA trial: osimertinib before and after chemoradiation

NeoADAURA



Endpoints:

- **Primary: major pathological response (MPR; by blinded central pathology review)**
- Secondary: event-free survival, pathological complete response, nodal downstaging and safety

Chaft J et al, ASCO 2025.

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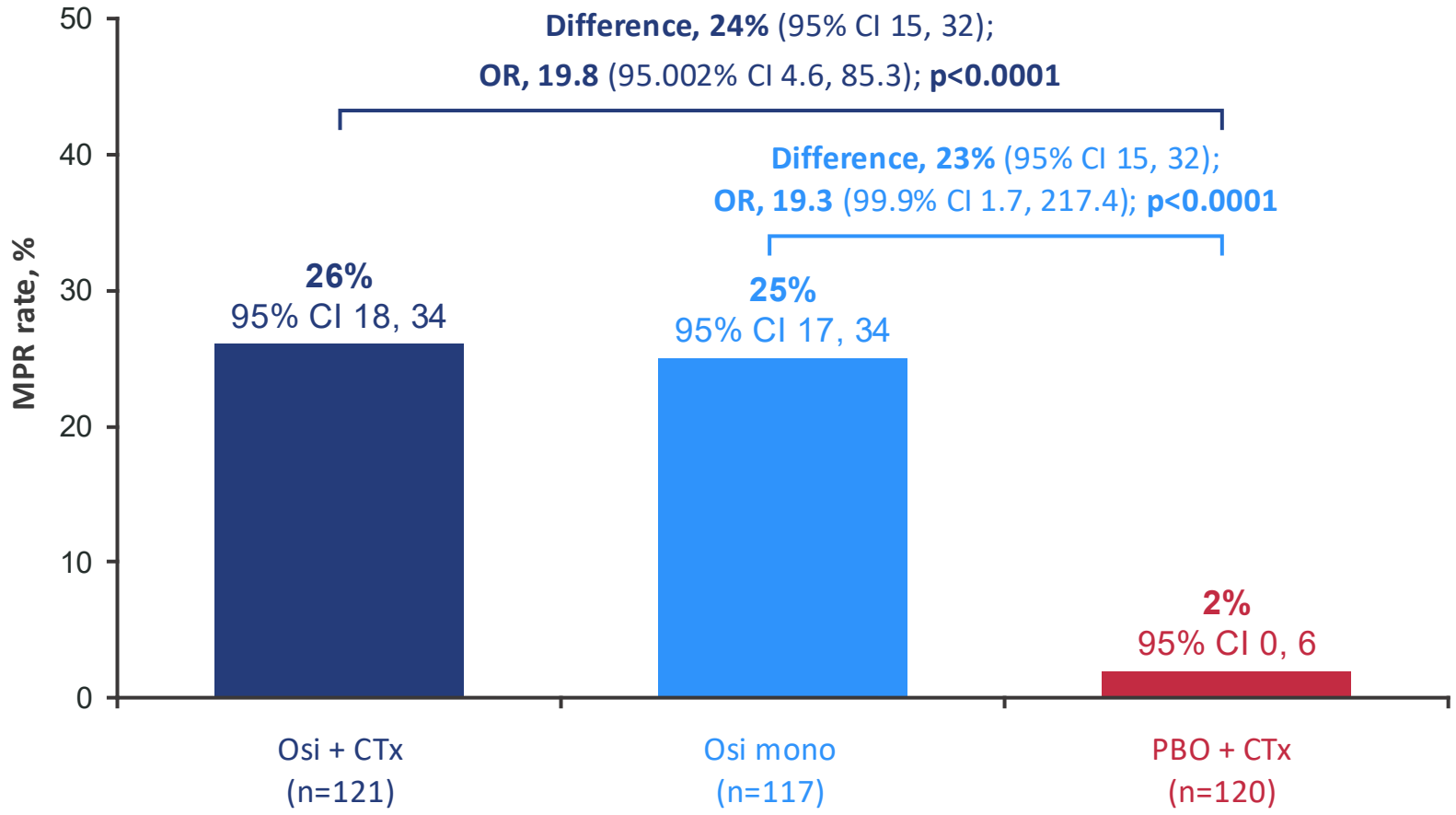
MPR

The MPR rate was statistically significantly higher with both osi-containing regimens



Chaft J et al, ASCO 2025.

CI, confidence interval; CTx, chemotherapy; EGFR, epidermal growth factor receptor; Ex19del, Exon 19 deletion; IASLC, International Association for the Study of Lung Cancer; mono, monotherapy; MPR, major pathological response; OR, odds ratio; osi, osimertinib; PBO, placebo

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Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 2: **Localized disease**

- Adjuvant osimertinib (ADAURA trial): ctDNA — 3 years duration?
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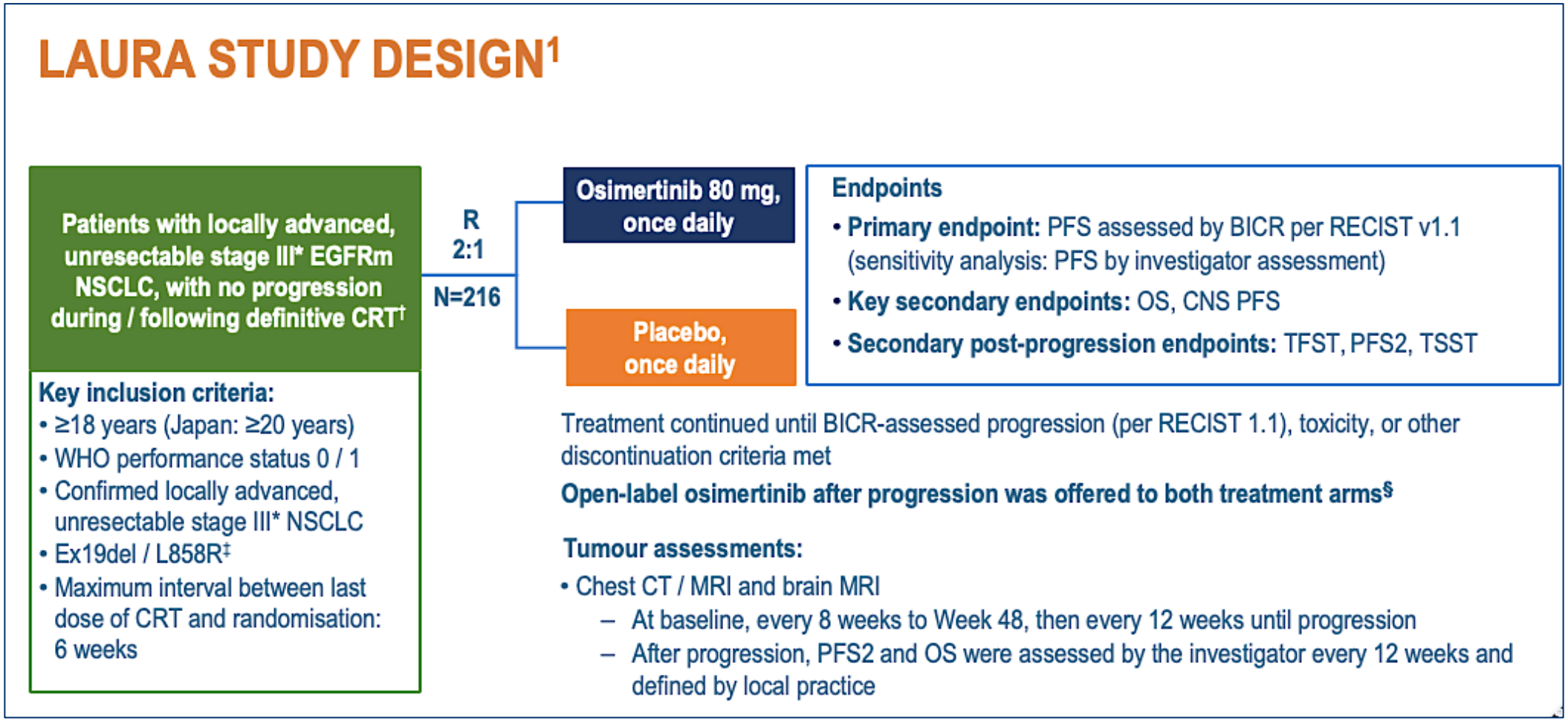
    - Indefinite osimertinib: survival results
    - MRD findings (current role?)
  - NEOLA trial: osimertinib before and after chemoradiation

LAURA: updated overall survival results



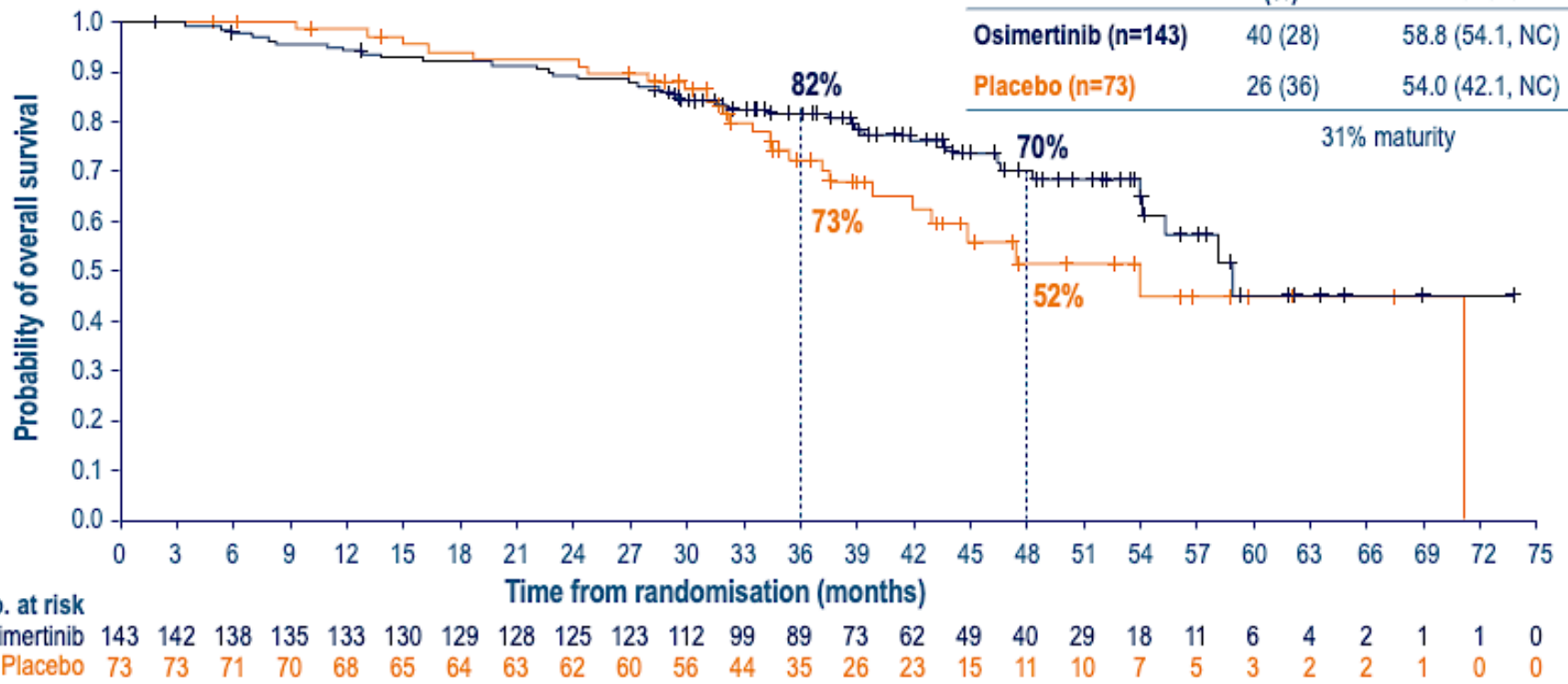
Ramalingam S et al, ELCC 2025.

EMORY HEALTHCARE

Updated DCO

IMPROVED TREND TOWARDS OS BENEFIT SEEN WITH OSIMERTINIB AT UPDATED ANALYSIS

	No. of events (%)	Median (95% CI), months	HR (95% CI) Log-rank p-value
Osimertinib (n=143)	40 (28)	58.8 (54.1, NC)	0.67 (0.40, 1.14) p=0.140
Placebo (n=73)	26 (36)	54.0 (42.1, NC)	



- 55/69 (80%) patients who discontinued study treatment in the placebo group received subsequent treatment with a 3rd-gen EGFR-TKI*

Ramalingam S et al, ELCC 2025.

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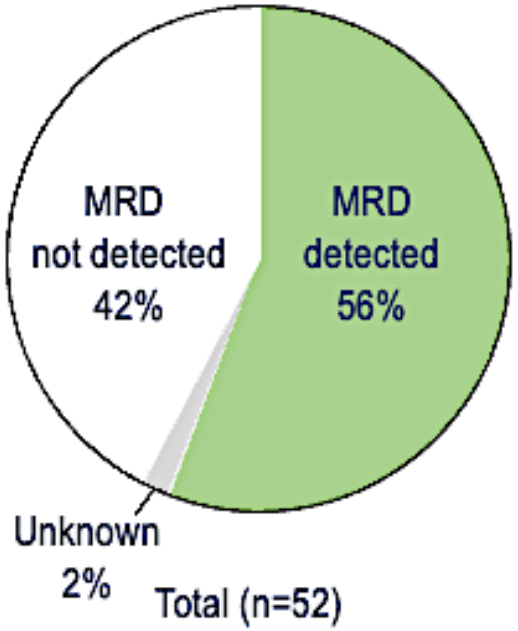
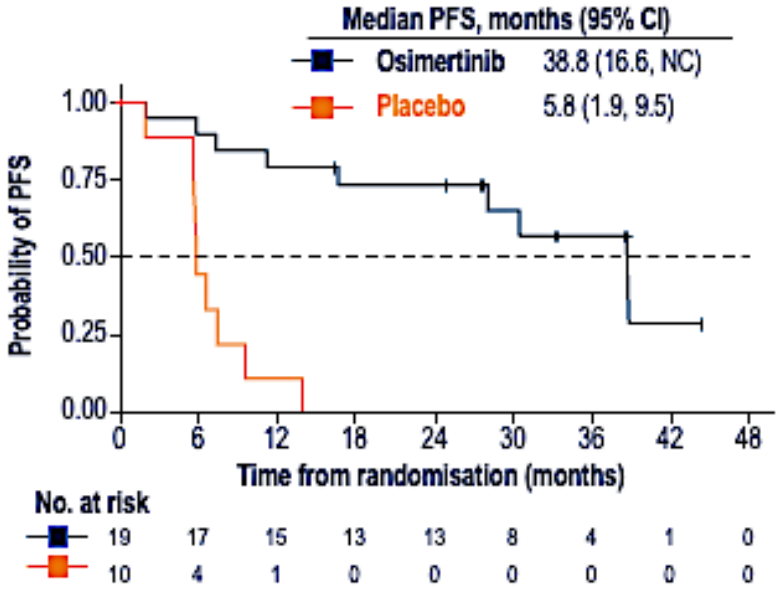
LAURA: Results by MRD Status

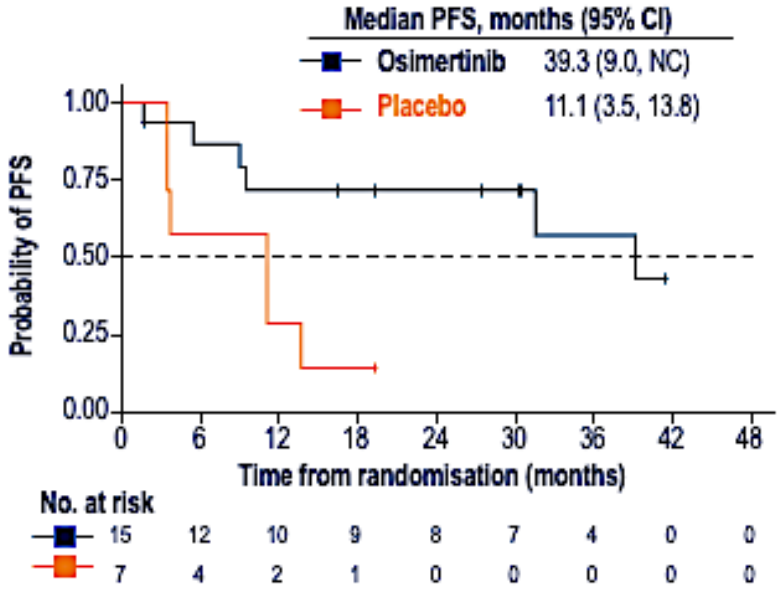
Post-CRT (randomisation) MRD status



MRD detected post-CRT (randomisation)*†



MRD not detected post-CRT (randomisation)*†



Arriola L et al, ESMO 2025.

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Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 3: EGFR exon 20 insertion mutations

- First-line amivantamab/chemotherapy: PAPILLON trial
- Sunvozertinib
  - WU-KONG1B trial
  - Press release Phase III trial
- Zipalertinib

Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 3: EGFR exon 20 insertion mutations

- First-line amivantamab/chemotherapy: PAPILLON trial
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EGFR Exon 20 Insertion Mutation: PAPILLON Study

- Chemotherapy with amivantamab improves PFS
- Median PFS improved from 6.7 m to 11.4 m
- Approved by FDA for 1st line therapy
- Report on patient reported outcomes by Paz-Ares L et al, Lung Cancer, 2025.
  - Physical functioning and global health status were maintained in both arms
  - 77% of patients remained free of symptomatic progression with chemo-Ami compared at 60% with chemo at 12 months

Zhou C et al, NEJM, 2023; Paz-Ares L et al, Lung Cancer, 2025.

EMORY HEALTHCARE

Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 3: **EGFR exon 20 insertion mutations**

- First-line amivantamab/chemotherapy: PAPILLON trial
- Sunvozertinib
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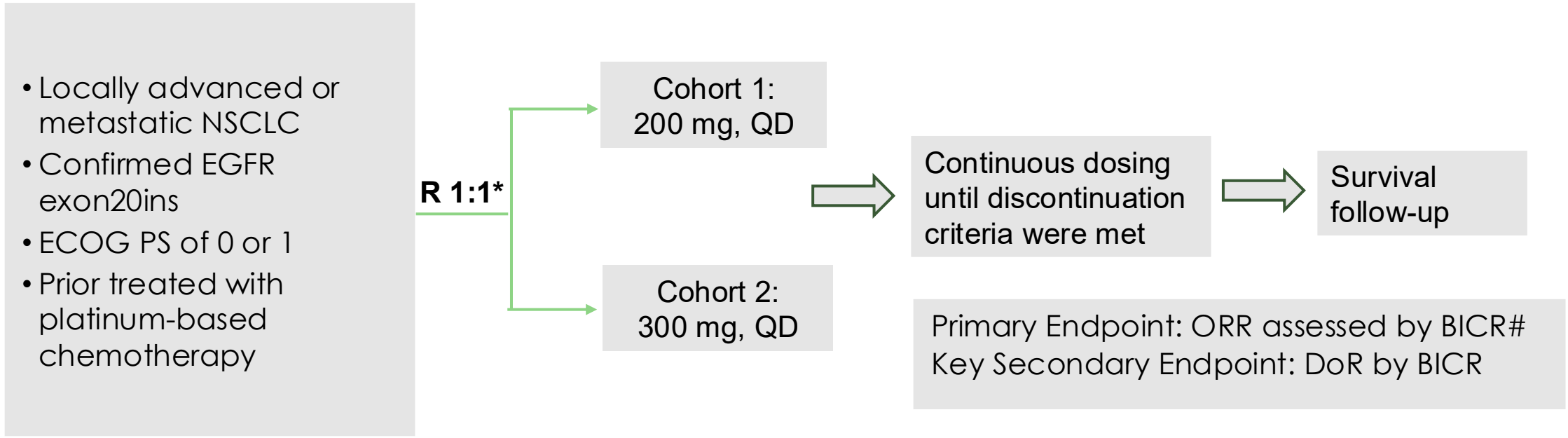
  - Press release Phase III trial
- Zipalertinib

Sunvozertinib for EGFR Exon 20 Mutant NSCLC: WU-KONG1B

- Sunvozertinib (DZD9008) is a rationally designed, potent, selective and irreversible EGFR inhibitor targeting EGFR exon 20 insertion mutations (exon20ins).



Yang J et al, ASCO 2025

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Sunvozertinib: Summary of Anti-tumor Efficacy

Tumor Response Per BICR		200 mg (N = 85)	300 mg (N = 89)
Confirmed ORR		46%	47%
Disease Control Rate		89%	92%
Median DoR		11.1 m	13.8 m
Median PFS		8.4 m	7.7 m
Subgroup Analysis of Confirmed ORR			
Prior Amivantamab Treatment	With	25%	42%
	Without	49%	48%
Baseline Brain Metastasis	With	29%	52%
	Without	57%	46%

The most common TRAEs with grade ≥3 included **diarrhea, blood CPK increase** and **anemia**, generally did not lead to treatment discontinuation or dose reduction.

Yang J et al, ASCO 2024; Yang J et al, JCO 2025

EMORY HEALTHCARE

Positive Top-Line Phase III Results from the WU-KONG28 Study of Sunvozertinib as First-Line Treatment for NSCLC with EGFR Exon 20 Insertion Mutations

Press Release: March 21, 2026

"[The manufacturer] today announced that its multinational Phase 3 WU-KONG28 study evaluating sunvozertinib monotherapy as first-line treatment in non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations (exon20ins) met its primary endpoint with positive topline results.

WU-KONG28 is a multinational, open-label, randomized confirmatory phase 3 study evaluating sunvozertinib versus platinum-based chemotherapy as first-line treatment in advanced NSCLC patients with EGFR exon20ins. ... The primary endpoint is progression-free survival (PFS) assessed by blinded independent central review (BICR). Topline results demonstrated that sunvozertinib significantly improved PFS compared to platinum-based doublet chemotherapy, with meaningful clinical benefit. Detailed data from the primary analysis will be submitted for presentation at an upcoming international scientific congress."

https://www.dizalpharma.com/news/detail?id=109&search=&currentPage=1

Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 3: **EGFR exon 20 insertion mutations**

- First-line amivantamab/chemotherapy: PAPILLON trial
- Sunvozertinib
  - WU-KONG1B trial
  - Press release Phase III trial
- Zipalertinib

Zipalertinib: REZILIENT1 Phase 2b study

- REZILIENT1 is a phase 1/2, open-label, multicenter trial (NCT04036682)

Key eligibility criteria
- Age ≥18 years
- Locally advanced or metastatic NSCLC
- Documented EGFR exon 20 insertion
- ECOG PS 0 or 1
- Stable/asymptomatic CNS metastases allowed

Zipalertinib
100 mg PO BID

Prior platinum-based chemotherapy without prior ex20ins-targeted therapy

Prior platinum-based chemotherapy with prior amivantamab ± other ex20ins-targeted therapy

Primary endpoint:
- **ORR and DOR as assessed by blinded ICR per RECIST v1.1**

Secondary endpoints:
- ORR and DOR by investigator
- DCR
- CBR
- PFS by ICR and investigator
- OS
- Antitumor activity in patients with CNS disease
- Safety

- Safety analysis population: all patients who received ≥1 dose of zipalertinib 100 mg BID (N=244)
- Primary efficacy population: all patients who received ≥1 dose of zipalertinib 100 mg BID with ~8 months of minimum follow-up before data cutoff (December 10, 2024) (N=176)
- Patients were assigned to a cohort based on previous therapy (ie, platinum-based chemotherapy only or amivantamab)

BID, twice daily; CBR, clinical benefit rate; CNS, central nervous system; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; ex20ins, exon 20 insertions; ICR, independent central review; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PO, orally; RECIST, Response Evaluation Criteria in Solid Tumors.

Yu H et al, ASCO 2025.

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Zipalertinib Efficacy

Outcome	Primary efficacy population (N=176)	Platinum-based chemotherapy without ex20ins-targeted therapy (n=125)	Prior amivantamab ± other ex20ins-target therapy (n=51)[a]
Confirmed ORR	35%	40%	24%
Median DOR	8.8 m	8.8 m	8.5 m

Any-grade TRAEs reported in ≥10% of patients, No. (%)	Any grade	Grade 3
Paronychia	94 (38.5)	0
Rash	74 (30.3)	6 (2.5)
Dermatitis acneiform	60 (24.6)	1 (0.4)
Dry skin	60 (24.6)	0
Diarrhea	53 (21.7)	5 (2.0)
Stomatitis	49 (20.1)	4 (1.6)
Anemia	48 (19.7)	17 (7.0)

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Yu H et al, ASCO 2025.

Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 4: New Agents

- Ivonescimab: HARMONi Phase III trial — Ivonescimab/chemotherapy
- Sacituzumab tirumotecan: OptiTROP-Lung04 study

Year in Review:
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HARMONi Phase 3 Trial

Key Eligibility Criteria

Locally advanced or metastatic NSCLC:

- EGFR sensitizing mutation+
- Progressed on 3rd gen EGFR-TKI
- ECOG 0 or 1
- Any PD-L1 expression

Stratification factor by geographic region:

- Brain metastases (yes or no)

R 1:1

N=438

Ivonescimab + Chemotherapy (N = 219)

Placebo + Chemotherapy (N = 219)

Ivonescimab: 20 mg/kg Q3W

Chemotherapy:

- Carboplatin: AUC5 Q3W x 4 cycles (21 day/cycle)
- Pemetrexed: 500 mg/m^2 Q3W

Endpoints:

Primary

- OS, PFS by IRRC per RECIST 1.1

Secondary

- ORR by IRRC, DoR, safety and tolerability

Planned Efficacy Analyses

- PFS primary (at ~231 events) & OS interim analyses
- OS final analysis (at ~261 events)

FPI: Jan 2022 (overall)
LPI Asia: Nov 2022
LPI NA & EU (and overall): Oct 2024

DoR=duration of response; ECOG=eastern cooperative oncology group; EGFR= Epidermal growth factor receptor; EU=Europe; FPI=first patient in; IRRC= independent radiology review committee; LPI=last patient in; mets=metastases; NA=North America; ORR=overall response rate; OS=overall survival; NSCLC=non-small cell lung cancer; TKI=tyrosine kinase inhibitor; PD-L1= programmed cell death ligand; PFS=progression-free survival; Q3W=every 3 weeks; RECIST=response evaluation criteria in solid tumors.

Note: Positive outcomes were reported from the single-region (Asia) study HARMONi-A, with PFS as the primary endpoint.

Goldman J et al, WCLC 2025.

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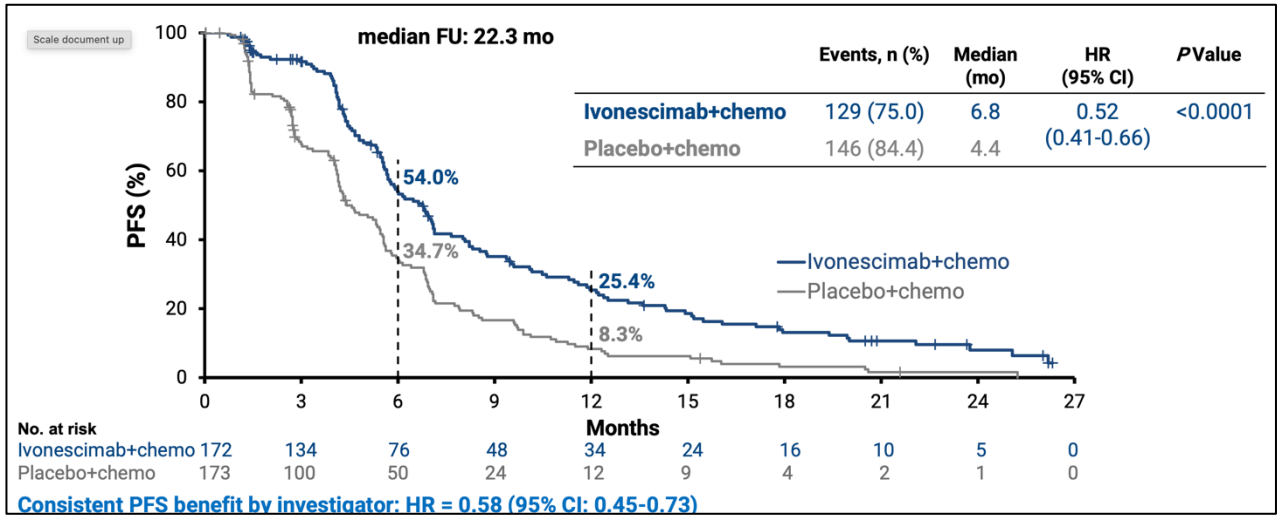
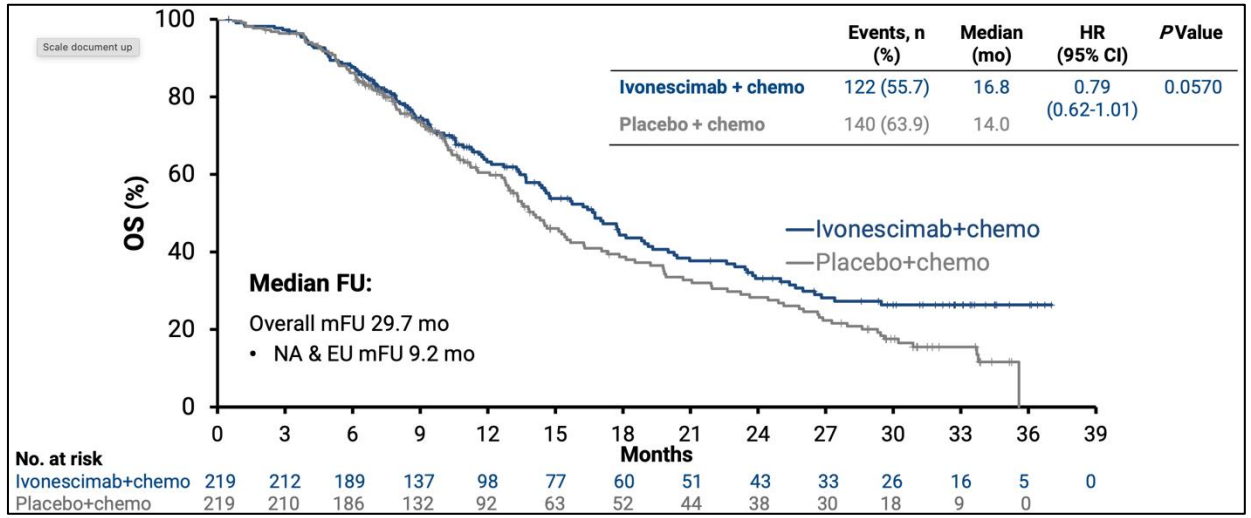
HARMONi: PFS & OS





Goldman J et al, WCLC 2025.

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Year in Review:
EGFR-Mutant Non-Small Cell Lung Cancer

MODULE 4: **New Agents**

- Ivonescimab: HARMONi Phase III trial — Ivonescimab/chemotherapy
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OptiTROP-Lung04 Study Design

Randomized, multicenter, open-label, phase 3 trial (NCT05870319)

Stratification factors:

1. Prior EGFR-TKI therapy
   (**3rd gen TKI in 1st line** *vs* **in 2nd line** *vs* **no 3rd gen TKI**)
2. Brain metastases (**yes** *vs* **no**)

Statistical considerations:

- Hierarchical testing was conducted for PFS by BICR and OS.
- Pre-specified interim analysis for OS:
  at approximately 50% maturity,
  or 24 months after the first patient randomized.

*Tumor response was assessed using RECIST version 1.1.

BICR, blinded independent central review; OS, overall survival; ORR, objective response rate; DOR, duration of response; DCR, disease control rate; R, randomization; RECIST, Response Evaluation Criteria in Solid Tumors; IA, interim analysis; ECOG, Eastern Cooperative Oncology Group.

Limited to patients of age < 75 yrs

Fang W et al, NEJM, 2025; Zhang et al. ASCO 2025.

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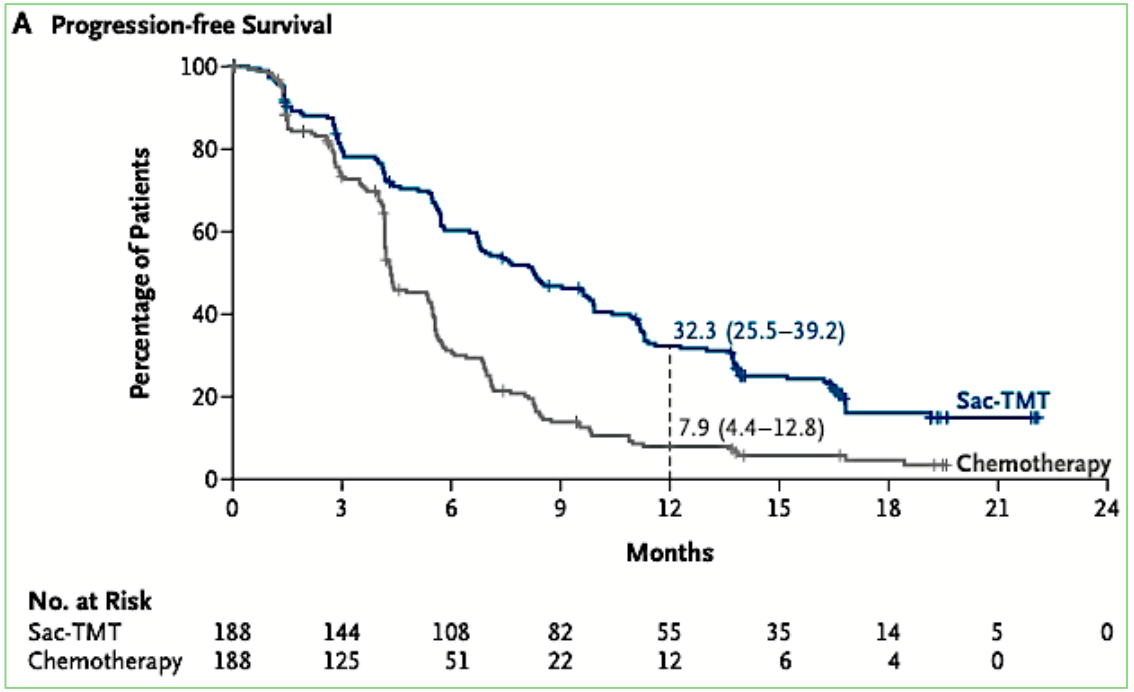
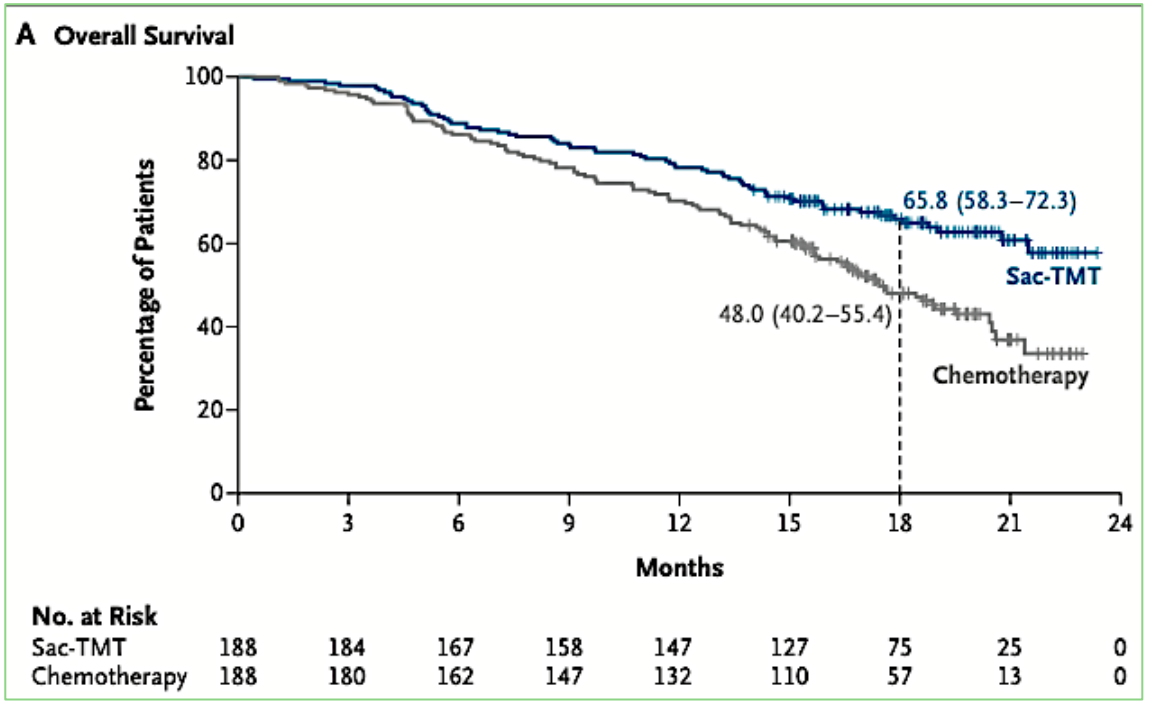
Optitrop-Lung04 trial



HR: 0.49; 8.3m vs. 4.3m



HR: 0.6; NE vs 17.4m

Salient AE with Sac-TMT:
Stomatitis; 64% (Gr 1 22%, Gr 2 37% & Gr 3 5%)

Fang W et al, NEJM, 2025.

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An Independent CME Symposium Series During the 2026 Society of Gynecologic Oncology (SGO) Annual Meeting on Women's Cancer®

HER2-Positive Gynecologic Cancers

Saturday, April 11, 2026

12:45 PM – 2:15 PM AST

Ovarian Cancer

Sunday, April 12, 2026

1:30 PM – 3:00 PM AST

Immunotherapy for Endometrial Cancer

Saturday, April 11, 2026

12:45 PM – 2:15 PM AST

Antibody-Drug Conjugates in Gynecologic Cancers

Sunday, April 12, 2026

1:30 PM – 3:00 PM AST

RTP RESEARCH TO PRACTICE

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RTP Year in Review 2026