Lung Cancer UPDATES
ESMO HIGHLIGHTS
17 - 21 OCTUBRE 2025
Berlin, Germany

GECP lung cancer research

HIGHLIGHTS ESMO 2025:
CPNM ESTADIO LOCALMENTE AVANZADO

REYES BERNABÉ

HOSPITAL VIRGEN DEL ROCIO

CONFLICTOS DE INTERÉS

- Consultant or Advisory Role: Astra Zeneca, MSD, Pierre Fabre, BMS, Roche, Pfizer, Daichi, Pharmamar
- Research Funding: Roche
- Speaking: Astra Zeneca, Amgen, Roche, BMS,

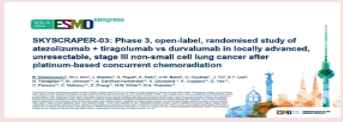
AGENDA

Neoadjuvant durvalumab (D) + chemotherapy (CT) followed by either surgery (Sx) and adjuvant D or CRT and consolidation D in patients (pts) with resectable or borderline resectable stage IIB–IIIB NSCLC: Interim analysis (IA) of the phase II MDT-BRIDGE study

Martin Reck (Grosshansdorf, Germany)

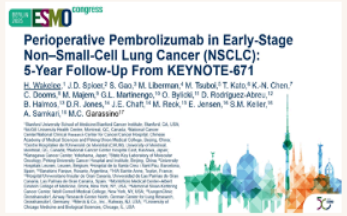
Surgery versus radiotherapy after induction therapy with serplulimab combined with chemotherapy for unresectable stage IIIB-IIIC non-small cell lung cancer: A randomized controlled, open-label, phase II trial

Suyu Wang (Shanghai, China)



SKYSCRAPER-03: Phase III, open-label, randomised study of atezolizumab (atezo) + tiragolumab (tira) vs durvalumab (durva) in locally advanced, unresectable, stage III non-small cell lung cancer (NSCLC) after platinum-based concurrent chemoradiation (cCRT)

Rafal Dziadziuszko (Gdansk, Poland)



Perioperative pembrolizumab in early-stage non-small- cell lung cancer (NSCLC): 5-year follow-up from KEYNOTE- 671

Heather Wakelee (Stanford, United States of America)

Molecular residual disease (MRD) analysis from the LAURA study of osimertinib (osi) in unresectable (UR) stage III EGFR-mutated (EGFRm) NSCLC

Edurne Arriola Aperribay (Barcelona, Spain)

Neoadjuvant durvalumab (D) + chemotherapy (CT) followed by either surgery (Sx) and adjuvant D or CRT and consolidation D in patients (pts) with resectable or borderline resectable stage IIB–IIIB NSCLC: Interim analysis (IA) of the phase II MDT-BRIDGE study

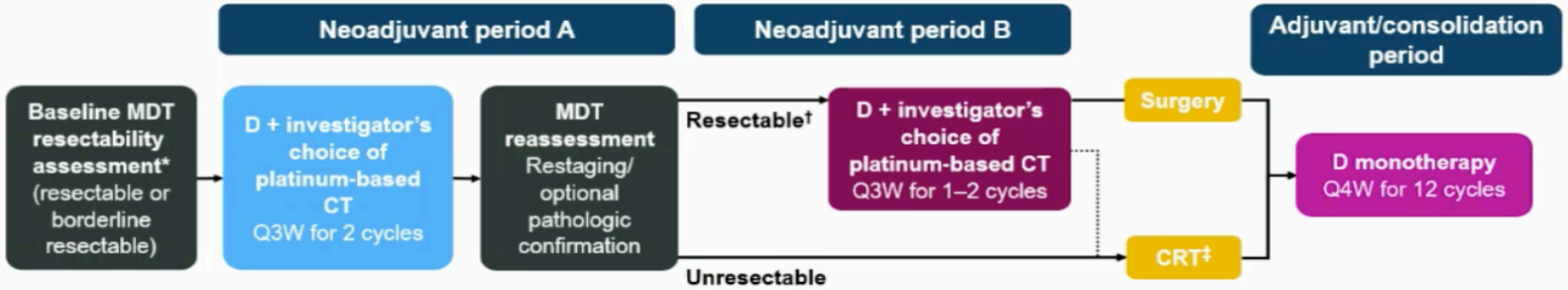
Martin Reck (Grosshansdorf, Germany)

MDT-BRIDGE study design[1]

Global, phase 2, non-randomized study (NCT05925530)

Key inclusion criteria and study requirements

- Aged ≥18 years
- Previously untreated and pathologically confirmed, resectable or borderline resectable, stage IIB–IIIB NSCLC (per AJCC 8th edition[2])
- *EGFR*/*ALK*wt (per local test)
- WHO/ECOG PS 0–1
- At least 1 target lesion not previously irradiated
- Pre-operative RT not allowed



Primary endpoint

- Resection rate, defined as proportion of all patients who underwent definitive surgery

Secondary endpoints

- Resection rate in patients deemed resectable/borderline resectable at baseline
- Surgical outcomes in patients who underwent surgery
- ORR in patients deemed resectable/unresectable at reassessment
- pCR in patients deemed resectable at reassessment
- Safety

- This planned interim analysis (DCO 8 May 2025) was conducted in the subset with sufficient follow-up, defined as patients who have had the opportunity to be followed up for 6 months or undergo definitive surgery, including patients who discontinued the study for any reason or died (**efficacy subset, N=84**)
- Safety was analysed in all patients who had received ≥1 dose of study treatment at the time of the DCO (**safety population, N=131**)

*MDT comprised of a medical oncologist/pulmonary oncologist, thoracic surgeon, radiation oncologist, and pathologist at a minimum; resectable/borderline resectable status determined per MDT decision based on baseline available assessments. †Patients who were deemed eligible for surgery at MDT evaluation but then deemed unresectable/progressed locally at the pre-surgery assessments entered the unresectable cohort. ‡Five fractions/week for ~6 weeks (± 3 days) (total 60 Gy ± 10%). AJCC, American Joint Committee on Cancer; DCO, data cutoff; ECOG, Eastern Cooperative Oncology Group; ORR, objective response rate; PS, performance status; QXW, once every X weeks; RT, radiotherapy; WHO, World Health Organization; wt, wild-type.

1. Reck M, et al. *Clin Lung Cancer*. 2024;25(6):587–93.e3; 2. Amin MB, et al. *AJCC Cancer Staging Manual*. 8th ed. New York, NY: Springer International Publishing; 2017.

Patient characteristics at baseline (efficacy subset*)

Baseline patient characteristics were generally balanced between the cohorts

Characteristic		All patients (N=84)	Baseline resectable cohort (n=56)	Baseline borderline resectable cohort (n=28)
Age	Median (range), years	66.0 (46–82)	66.0 (46–80)	66.0 (48–82)
	≥75 years, n (%)	10 (11.9)	7 (12.5)	3 (10.7)
Sex, n (%)	Female	36 (42.9)	26 (46.4)	10 (35.7)
	Male	48 (57.1)	30 (53.6)	18 (64.3)
Race, n (%)	Asian	1 (1.2)	1 (1.8)	0 (0)
	White	62 (73.8)	38 (67.9)	24 (85.7)
	Missing	21 (25.0)	17 (30.4)	4 (14.3)
Region, n (%)	Europe	75 (89.3)	50 (89.3)	25 (89.3)
	North America	9 (10.7)	6 (10.7)	3 (10.7)
ECOG PS, n (%)	0	57 (67.9)	39 (69.6)	18 (64.3)
	1	27 (32.1)	17 (30.4)	10 (35.7)
Smoking status, n (%)	Current	20 (23.8)	13 (23.2)	7 (25.0)
	Former	61 (72.6)	41 (73.2)	20 (71.4)
	Never	3 (3.6)	2 (3.6)	1 (3.6)

Disease characteristics at baseline (efficacy subset*)

A greater proportion in the borderline resectable cohort had Stage IIIB disease and T4 primary tumours

Characteristic, n (%)		All patients (N=84)	Baseline resectable cohort (n=56)	Baseline borderline resectable cohort (n=28)
Histology	Squamous	32 (38.2)	21 (37.5)	11 (39.3)
	Non-squamous	51 (60.7)	34 (60.7)	17 (60.7)
	Other	1 (1.2)	1 (1.8)	0
Disease stage	IIB	13 (15.5)	8 (14.3)	5 (17.9)
	IIIA	52 (61.9)	37 (66.1)	15 (53.6)
	IIIB	19 (22.6)	11 (19.6)	8 (28.6)
TNM classification (primary tumour)	T1	10 (12.0)	7 (12.5)	3 (10.7)
	T2	13 (15.5)	11 (19.6)	2 (7.1)
	T3	31 (36.9)	24 (42.9)	7 (25.0)
	T4	29 (34.5)	14 (25.0)	15 (53.6)
TNM classification (regional lymph nodes)	N0	30 (35.7)	17 (30.4)	13 (46.4)
	N1	15 (17.9)	11 (19.6)	4 (14.3)
	N2	39 (46.4)	28 (50.0)	11 (39.3)

DCO 8 May 2025

*Patients who have had the opportunity to be followed up for 6 months or underg

Treatment exposure during neoadjuvant period (efficacy subset*)

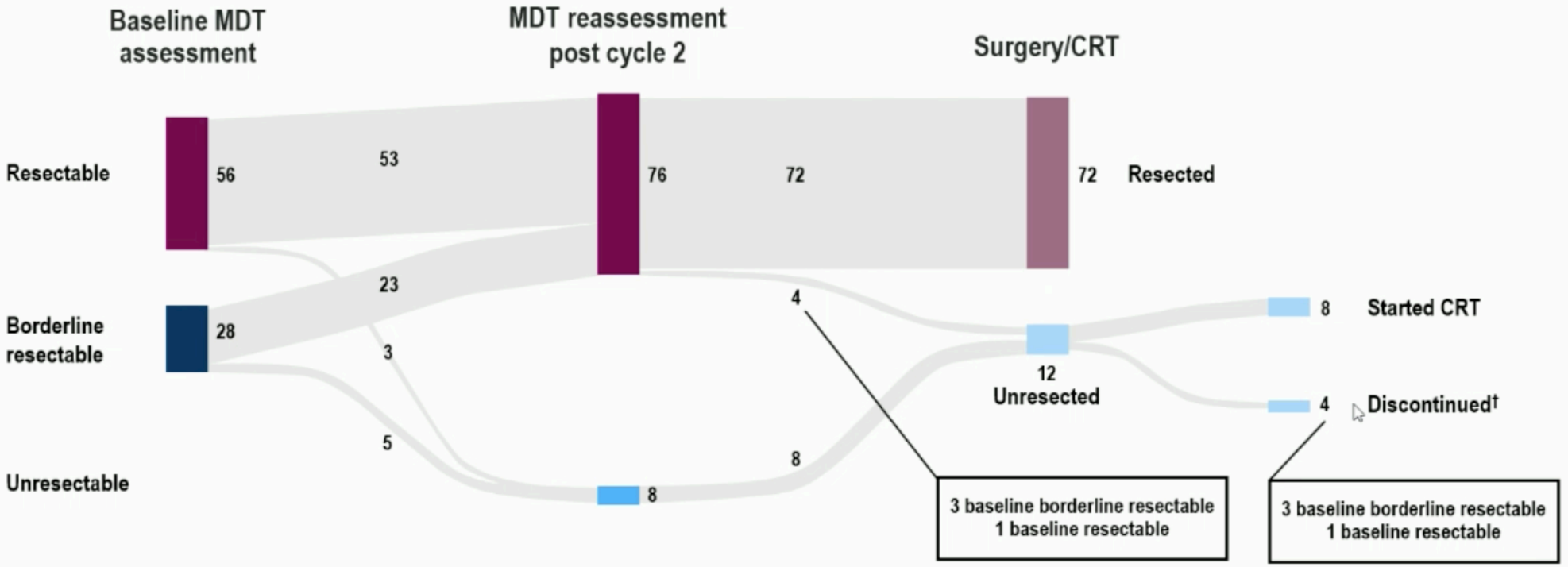
All patients received ≥2 cycles of neoadjuvant durvalumab and 32% received 4 cycles

Exposure, n (%)		All patients (N=84)	Baseline resectable cohort (n=56)	Baseline borderline resectable cohort (n=28)
Number of neoadjuvant durvalumab cycles received	≥2	84 (100)	56 (100)	28 (100)
	≥3	76 (90.5)	53 (94.6)	23 (82.1)
	4	27 (32.1)	20 (35.7)	7 (25.0)
Chemotherapy backbone	Cisplatin	8 (9.5)	4 (7.1)	4 (14.3)
	Carboplatin	76 (90.5)	52 (92.9)	24 (85.7)

dy for any reason or died.

Change in resectability and local treatment received (efficacy subset*)

Most patients deemed borderline resectable at baseline were reassessed as resectable after 2 cycles



95.2% had either surgery or CRT after neoadjuvant D + CT

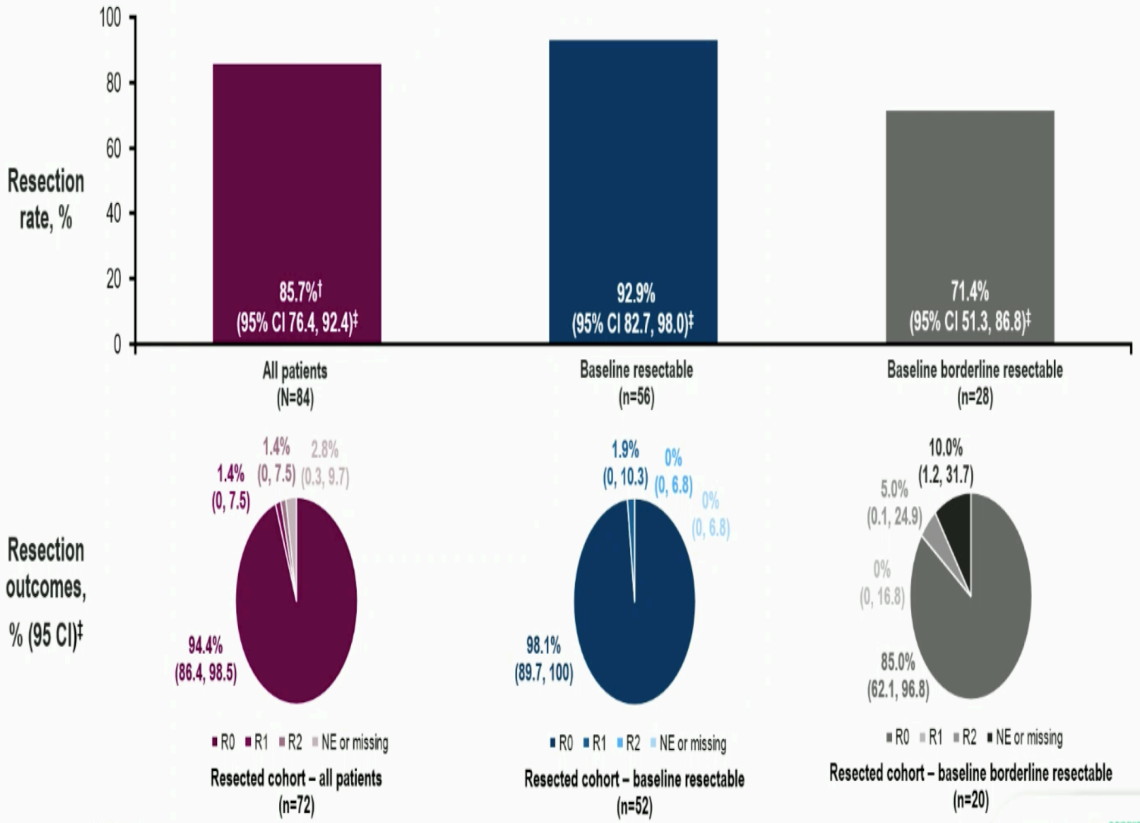
DCO 8 May 2025

*Patients who have had the opportunity to be followed up for 6 months or undergo definitive surgery, including patients who discontinued the study for any reason or died.

†AE, n=1; disease progression, n=1; patient decision, n=1; other, n=1. AE, adverse event.

Resection rates and outcomes (efficacy subset*)

The overall resection rate was 85.7% and the majority of patients had R0 resection

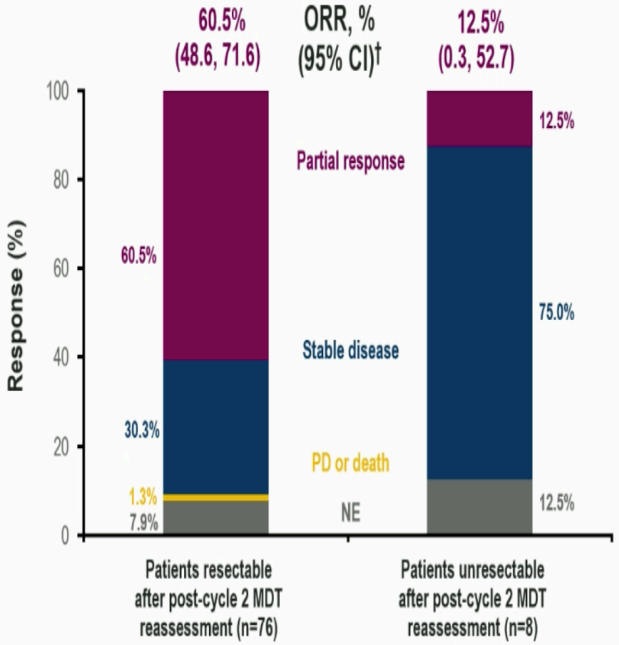


DCO 8 May 2025

*Patients who have had the opportunity to be followed up for 6 months or undergo definitive surgery, including patients who discontinued the study for any reason or died. †One patient did not complete surgical resection as intended due to the absence of a primary tumour in the lung parenchyma; only lymph nodes were removed. ‡95% CIs calculated using the Clopper-Pearson exact method. CI, confidence interval; NE, non-evaluable.

ORR* pre-surgery/pre-CRT (efficacy subset†)

In patients deemed resectable at reassessment, 60.5% had objective responses after completion of neoadjuvant treatment



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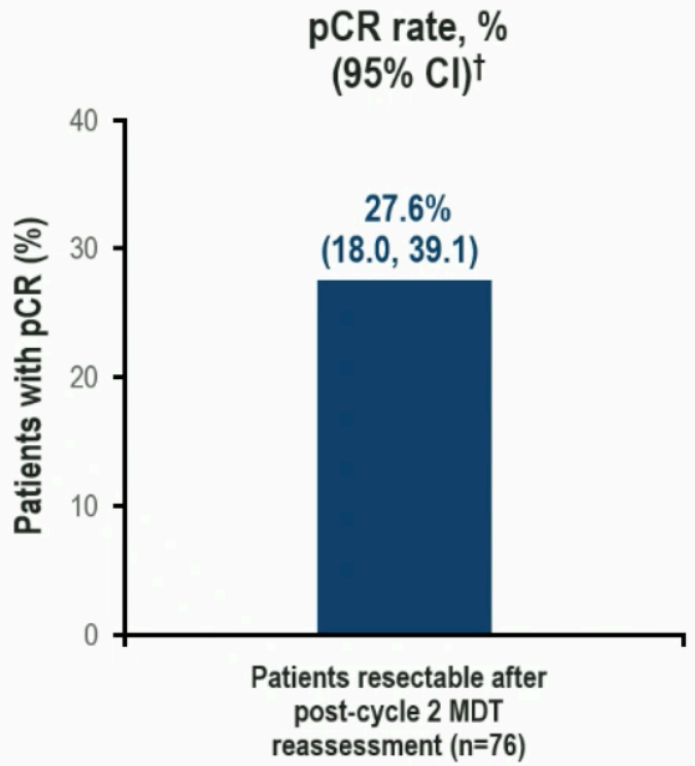
*ORR was defined as the proportion of patients who have unconfirmed complete or partial response, pre-surgery/pre-CRT as assessed by the investigator per RECIST v1.1. Baseline scan for deriving ORR was the screening scan. †Patients who have had the opportunity to be followed up for 6 months or undergo definitive surgery, including patients who discontinued the study for any reason or died. ‡95% CIs calculated using the Clopper-Pearson exact method. PD, progressive disease; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1.

pCR rate (efficacy subset*)

27.6% of patients deemed resectable at reassessment achieved pCR



Characteristic, n (%)		Patients with pCR (n=21)
Resectability at baseline	Resectable	17 (81.0)
	Borderline resectable	4 (19.0)
Stage at baseline	IIB	4 (19.0)
	IIIA	13 (61.9)
	IIIB	4 (19.0)
Histology	Squamous	11 (52.4)
	Non-squamous	10 (47.6)
Chemotherapy backbone	Cisplatin	1 (4.8)
	Carboplatin	20 (95.2)
Surgery received	Lobectomy	18 (85.7)
	Pneumonectomy	2 (9.5)
	Bilobectomy	1 (4.8)

DCO 8 May 2025

*Patients who have had the opportunity to be followed up for 6 months or undergo definitive surgery, including patients who discontinued the study for any reason or died.

†95% CIs calculated using the Clopper-Pearson exact method. pCR, pathological complete response.

Disposition in resected and unresected cohorts (efficacy subset*)

The majority of patients who had surgery or CRT went on to receive adjuvant or consolidation durvalumab

n (%)	Resected cohort (n=72)
Completed surgery	
Yes	71 (98.6)
No†	1 (1.4)
Started adjuvant durvalumab	
Yes	53 (73.6)
No	19 (26.4)
Discontinued adjuvant durvalumab prematurely	
AE	1 (1.4)
Other	1 (1.4)
Ongoing adjuvant durvalumab at DCO	51 (70.8)

n (%)	Unresected cohort (n=12)
Started CRT	
Yes	8 (66.7)
No	4 (33.3)
AE	1 (8.3)
Disease progression	1 (8.3)
Patient decision	1 (8.3)
Other	1 (8.3)
Completed CRT	8 (66.7)
Started consolidation durvalumab	
Yes	7 (58.3)
No	1 (8.3)
Disease progression	1 (8.3)
Discontinued consolidation durvalumab prematurely	
AE	1 (8.3)
Ongoing consolidation at DCO	6 (50.0)

DCO 8 May 2025

*Patients who have had the opportunity to be followed up for 6 months or undergo definitive surgery, including patients who discontinued the study for any reason or died;

†One patient did not complete surgical resection as intended due to the absence of a primary tumour in the lung parenchyma; only lymph nodes were removed.

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Surgery versus radiotherapy after induction therapy with serplulimab combined with chemotherapy for unresectable stage IIIB-IIIC non-small cell lung cancer: a randomized controlled, open-label, phase 2 trial

Suyu Wang, Dongliang Bian, Qiji Guo, Zhida Huang, Yifei Zhou, Shiqi Hu, Tao Ge, Shuangyi Li, Yue Liu, Lele Zhang, Huansha Yu, Jie Yang, Peng Zhang

Presenter: Suyu Wang
Principal investigator: Peng Zhang

Department of Thoracic Surgery, Shanghai Pulmonary Hospital, School of Medicine, Tongji University, Shanghai, China

20 October 2025

ESMO EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY

GECP lung cancer research

LungMate-013 Study Schema

Serplulimab is a recombinant humanized anti-PD-1 monoclonal antibody.

Key eligibility criteria

- Aged ≥18 years
- Histologically or cytologically confirmed unresectable stage IIIB-IIIC (AJCC 8th edition) NSCLC*
- ECOG performance status of 0 or 1
- No known EGFR21 L858R/19 DEL or ALK rearrangement

Induction therapy

Serplulimab (4.5mg/kg)+ platinum-doublet chemotherapy, on day 1, Q3W, for 4 cycles

Resectable

Disease downstaging to stage IIIA or lower stage and resectable

R 1:1

- Surgery
- Radiotherapy

Stratification factors: Histological type; N stage after induction therapy

Unresectable

Disease of stage IIIB or higher stage or unresectable

→ Treated by MDT

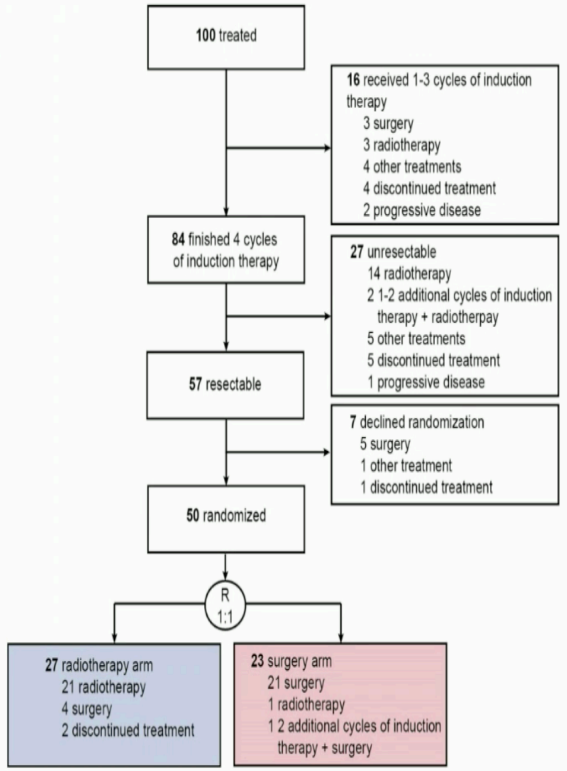
*Unresectable NSCLC was deemed unresectable initially evaluated by multidisciplinary clinical team in our trial.
#Adenocarcinoma: carboplatin AUC 5 and pemetrexed 500 mg/m² on day 1; Squamous cell carcinoma or other NSCLCs: carboplatin AUC 5 on day 1 and nab-paclitaxel 260 mg/m² on day 1(or liposomal paclitaxel 135 mg/m² on day 1).

Primary endpoint: Event-free-survival (EFS)

Second endpoints: EFS-from-randomization (EFS-FR) and OS-from-randomization (OS-FR) in randomized population; objective response rate (ORR) after induction therapy; major pathological response (MPR) in the surgery population; overall survival (OS); resectable conversion rate; R0 resection rate; safety; Health-Related Quality of Life (HRQoL).

Patient Characteristics and Disposition

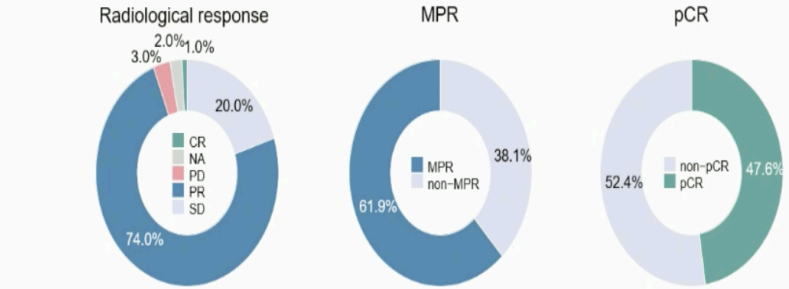
Variables	Overall N = 100	Radiotherapy N = 27	Surgery N = 23
Age, years, median (IQR)	64 (59-69)	65 (58.5-69)	59 (55.5-69.5)
Gender, n (%)			
Male	96 (96.0)	26 (96.3)	22 (95.7)
Female	4 (4.0)	1 (3.7)	1 (4.3)
Smoking history, n (%)			
No	8 (8.0)	2 (7.4)	1 (4.3)
Yes	92 (92.0)	25 (92.6)	22 (95.7)
Stage, n (%)			
IIIB	66 (66.0)	18 (66.7)	16 (69.6)
IIIC	34 (34.0)	9 (33.3)	7 (30.4)
PD-L1(E1L3N), n (%)			
<1	33 (33.0)	7 (25.9)	6 (26.1)
1-49	20 (20.0)	6 (22.2)	4 (17.4)
≥50	8 (8.0)	4 (14.8)	3 (13.0)
Unknown	39 (39.0)	10 (37.0)	10 (43.5)
Histological type, n (%)			
Squamous cell carcinoma	70 (70.0)	19 (70.4)	17 (73.9)
Adenocarcinoma	16 (16.0)	4 (14.8)	2 (8.7)
Other NSCLCs	14 (14.0)	4 (14.8)	4 (17.4)

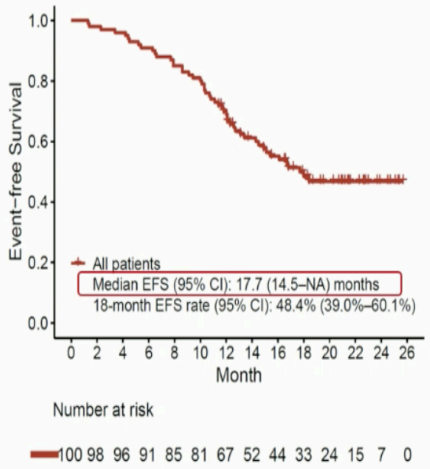


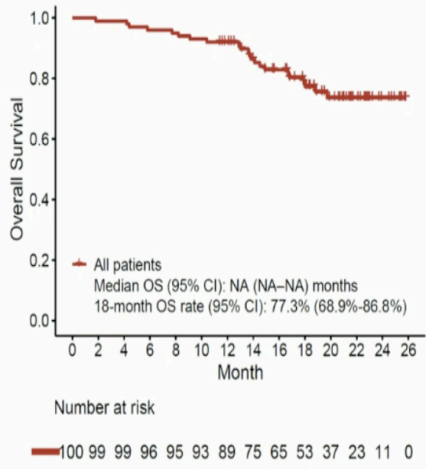
Efficacy in 100 enrolled pts (data cutoff April 2025)

Radiological response in 98 evaluable pts and pathological response in 21 per-protocol pts in surgery arm

EFS/OS for 100 enrolled pts (median follow-up time: 20.3 months)



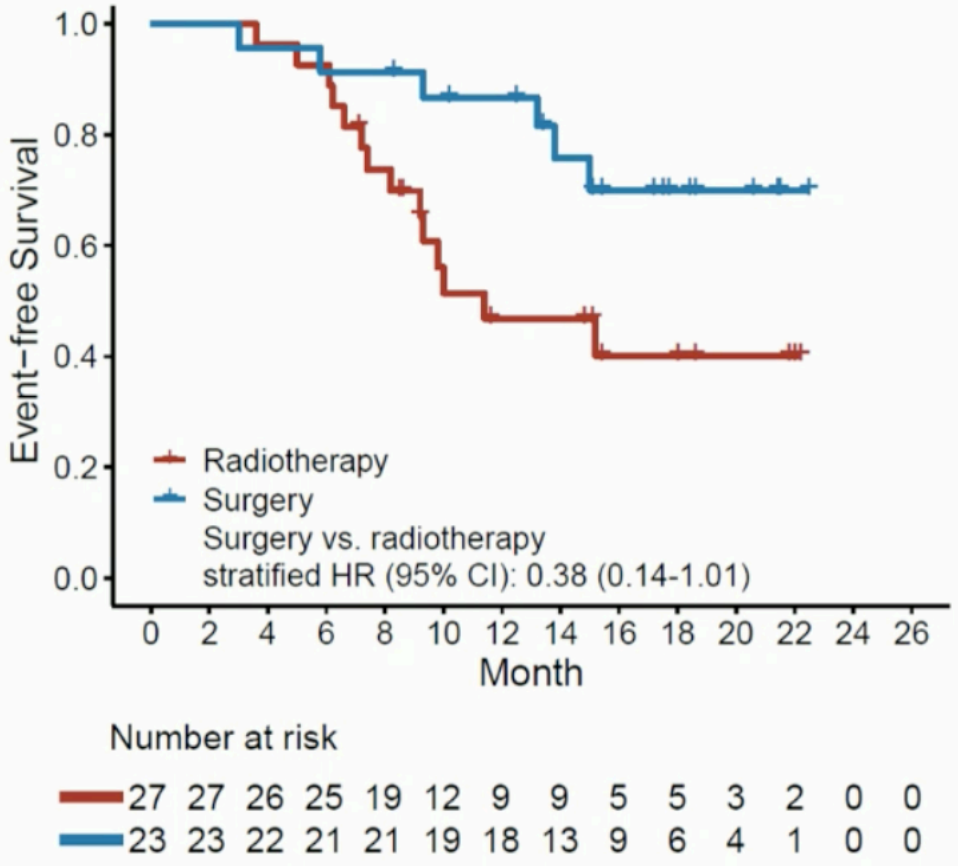




Suyu Wang M.D.

EFS for 50 randomized pts (data cutoff April 2025)

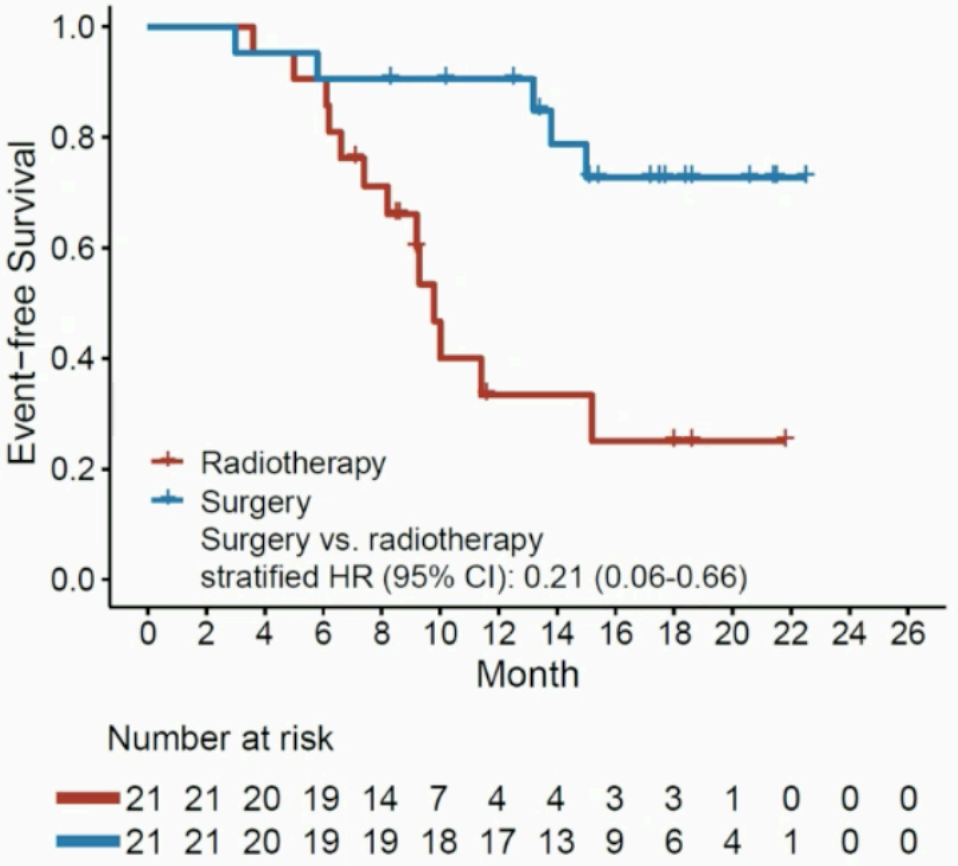
EFS from randomization for 50 intention-to-treat pts



Number at risk

Radiotherapy	27	27	26	25	19	12	9	9	5	5	3	2	0	0
Surgery	23	23	22	21	21	19	18	13	9	6	4	1	0	0

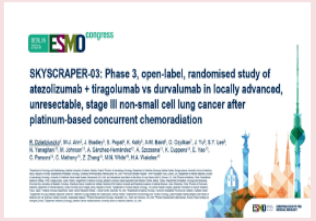
EFS from randomization for 42 per-protocol pts



Number at risk

Radiotherapy	21	21	20	19	14	7	4	4	3	3	1	0	0	0
Surgery	21	21	20	19	19	18	17	13	9	6	4	1	0	0

Suyu Wang M.D.



SKYSCRAPER-03: Phase III, open-label, randomised study of atezolizumab (atezo) + tiragolumab (tira) vs durvalumab (durva) in locally advanced, unresectable, stage III non-small cell lung cancer (NSCLC) after platinum-based concurrent chemoradiation (cCRT)

Rafal Dziadziuszko (Gdansk, Poland)

SKYSCRAPER-03: a phase 3, open-label, randomised study

Open-label treatment
13 x 28-day cycles

Key eligibility criteria
- Newly diagnosed, unresectable, stage III NSCLC without progression after definitive platinum-based cCRT (≥2 cycles)
- Known PD-L1 status*
- ECOG PS 0 or 1
- EGFR/ALK positive excluded

R 1:1 — 1–42 days post-cCRT

- **Tiragolumab** 840 mg IV Q4W + **atezolizumab** 1680 mg IV Q4W
- **Durvalumab** 10 mg/kg IV Q2W or 1500 mg IV Q4W†

Type I error 0.05 (two-sided) hierarchical testing

Primary endpoint: IRF-PFS for tiragolumab + atezolizumab vs durvalumab in **PD-L1+ (TC ≥1%)**

Statistical significance reached

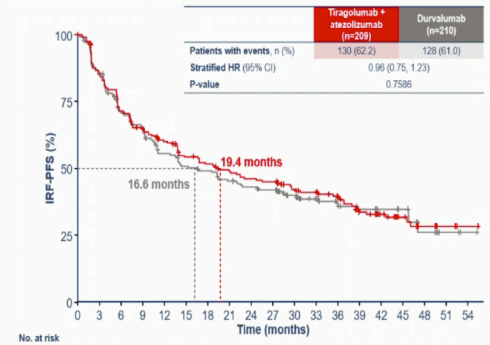
Primary endpoint: IRF-PFS for tiragolumab + atezolizumab vs durvalumab in **PD-L1 all-comers**

Stratification factors
- ECOG PS (0 vs 1)
- PD-L1 status* (<1% vs ≥1%)
- Staging (IIIA vs IIIB or IIIC)
- Histology (squamous vs non-squamous)

Endpoints
- **Primary**: IRF-PFS in PD-L1+ (TC ≥1%) and PD-L1 all-comers
- **Secondary**: OS‡, INV-PFS, DOR, ORR, TTDM, PRO, safety

IRF-PFS and OS in PD-L1+ (TC ≥1%)

Primary endpoint: PFS



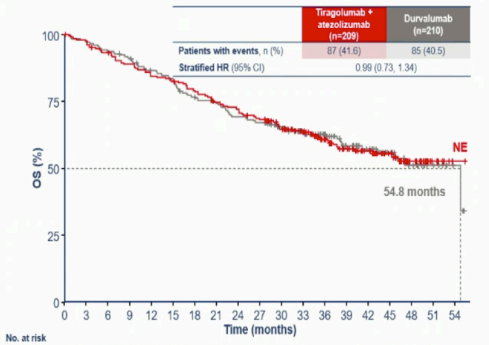
	Tiragolumab + atezolizumab (n=209)	Durvalumab (n=210)
Patients with events, n (%)	130 (62.2)	128 (61.0)
Stratified HR (95% CI)	0.96 (0.75, 1.23)	
P-value	0.7586	

No. at risk

Tira + atezo	209	173	145	130	116	102	96	89	84	82	72	68	58	40	30	20	11	4	1						
Durva	210	180	143	130	105	95	90	82	77	73	57	48	38	23	20	15	7	3	1						

	Tiragolumab + atezolizumab (n=209)	Durvalumab (n=210)
Median PFS, months (95% CI)	19.4 (13.8, 29.5)	16.6 (11.1, 22.8)
12-month event free rate (%)	60.0	55.4
24-month event free rate (%)	46.1	42.9

Secondary endpoint: OS



	Tiragolumab + atezolizumab (n=209)	Durvalumab (n=210)
Patients with events, n (%)	87 (41.6)	85 (40.5)
Stratified HR (95% CI)	0.99 (0.73, 1.34)	

No. at risk

Tira + atezo	209	203	192	182	174	169	161	151	146	137	123	110	89	72	59	41	24	7	1						
Durva	210	204	196	190	177	171	156	148	138	134	117	100	83	60	51	29	19	9	3						

	Tiragolumab + atezolizumab (n=209)	Durvalumab (n=210)
Median OS, months (95% CI)	NE (40.0, NE)	54.8 (41.2, NE)
12-month event free rate (%)	84.9	86.5
24-month event free rate (%)	72.2	69.2

Data cutoff: 27 May 2025

Minimum follow-up: 27.3 months; median follow-up: 33.0 months

Atezo, atezolizumab; CI, confidence interval; Durva, durvalumab; HR, hazard ratio; NE, not evaluable; Tira, tiragolumab

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Perioperative Pembrolizumab in Early-Stage Non–Small-Cell Lung Cancer (NSCLC): 5-Year Follow-Up From KEYNOTE-671

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GECP lung cancer research

KEYNOTE-671 Study Design

Randomized, Double-Blind, Phase 3 Trial

Key Eligibility Criteria

- Pathologically confirmed, resectable stage II, IIIA, or IIIB (N2) NSCLC per AJCC v8
- No prior therapy
- Able to undergo surgery
- Provision of tumor sample for PD-L1 evaluation[a]
- ECOG PS 0 or 1

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Pembrolizumab 200 mg IV Q3W + Cisplatin and Gemcitabine[b] or Cisplatin and Pemetrexed[c] for up to 4 cycles → Surgery[d] → **Pembrolizumab 200 mg IV Q3W for up to 13 cycles**

Placebo IV Q3W + Cisplatin and Gemcitabine[b] or Cisplatin and Pemetrexed[c] for up to 4 cycles → Surgery[d] → **Placebo IV Q3W for up to 13 cycles**

Stratification Factors

- Disease stage (II vs III)
- PD-L1 TPS[a] (<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

Demographics and Baseline Clinical Characteristics

	Pembro Arm (n = 397)	Placebo Arm (n = 400)		Pembro Arm (n = 397)	Placebo Arm (n = 400)
Age, median (range), y	63.0 (26–83)	64.0 (35–81)	Clinical disease stage		
Male	279 (70.3)	284 (71.0)	II	118 (29.7)	121 (30.3)
Race			III	279 (70.3)	279 (69.8)
Asian	124 (31.2)	125 (31.3)	Clinical node stage		
Black or African American	6 (1.5)	10 (2.5)	N0	148 (37.3)	142 (35.5)
White	250 (63.0)	239 (59.8)	N1	82 (20.7)	73 (18.3)
Missing	13 (3.3)	16 (4.0)	N2	166 (41.8)	185 (46.3)
Other	4 (1.0)	10 (2.5)	NX	1 (0.3)	0
Geographic region			PD-L1 TPS		
East Asia	123 (31.0)	121 (30.3)	≥50%	132 (33.2)	134 (33.5)
Not east Asia	274 (69.0)	279 (69.8)	1%–49%	127 (32.0)	115 (28.8)
ECOG PS 1	144 (36.3)	154 (38.5)	<1%	138 (34.8)	151 (37.8)
Current/former smoker	343 (86.4)	353 (88.3)	Known *EGFR* mutation[a]	14 (3.5)	19 (4.8)
Nonsquamous histology	226 (56.9)	227 (56.8)	Known *ALK* translocation[b]	12 (3.0)	9 (2.3)

Data are n (%) unless otherwise indicated.
[a]*EGFR* status was unknown in 272 participants (68.5%) in the pembro arm and 257 (64.3%) in the placebo arm.
[b]*ALK* status was unknown in 281 participants (70.8%) in the pembro arm and 259 (64.8%) in the placebo arm.
Median time from randomization to data cutoff was 60.4 (range, 42.6–85.8) months.
Data cutoff date: July 3, 2025.

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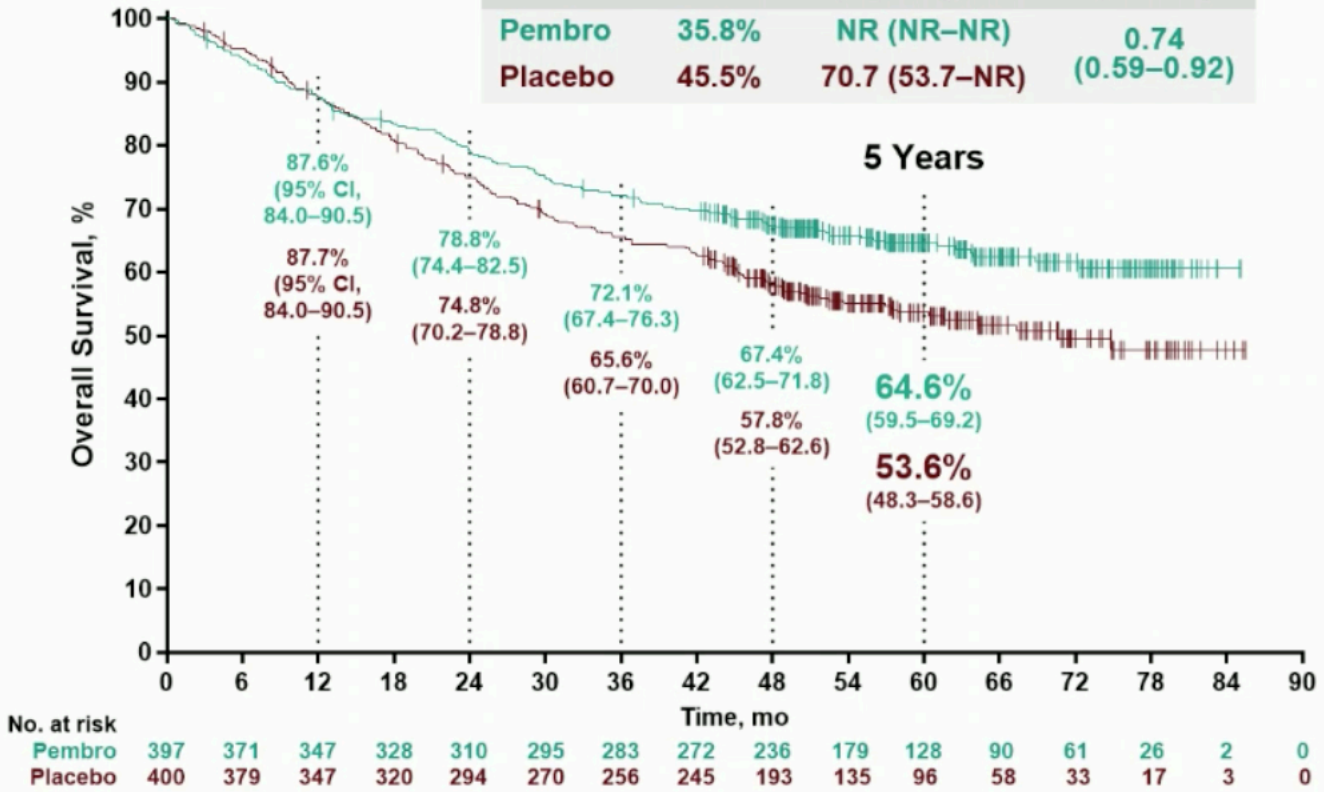
5-Year Update of Overall Survival

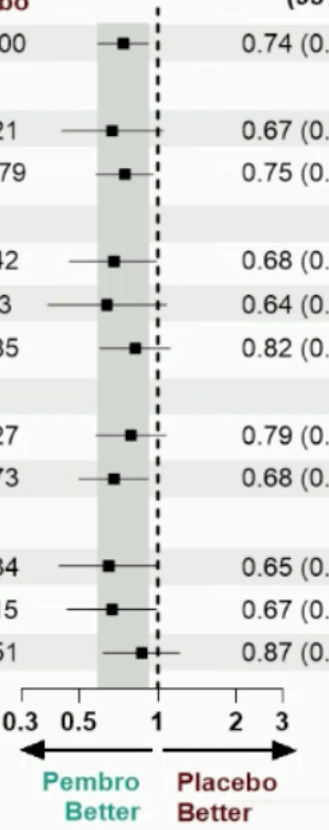
Overall Population

	Pts w/ Event	Median (95% CI), mo	HR (95% CI)
Pembro	35.8%	NR (NR–NR)	0.74 (0.59–0.92)
Placebo	45.5%	70.7 (53.7–NR)	



Key Subgroups

Subgroup	Events/participants Pembro	Events/participants Placebo	Hazard Ratio (95% CI)
Overall	142/397	182/400	0.74 (0.59–0.92)
Disease stage			
II	32/118	47/121	0.67 (0.43–1.05)
III	110/279	135/279	0.75 (0.58–0.96)
Nodal status			
N0	46/148	61/142	0.68 (0.46–0.99)
N1	24/82	32/73	0.64 (0.38–1.08)
N2	71/166	89/185	0.82 (0.60–1.12)
Histology			
Nonsquamous	72/226	86/227	0.79 (0.58–1.08)
Squamous	70/171	96/173	0.68 (0.50–0.92)
PD-L1 TPS			
≥50%	34/132	48/134	0.65 (0.42–1.00)
1%–49%	45/127	56/115	0.67 (0.45–0.99)
<1%	63/138	78/151	0.87 (0.62–1.21)



Median time from randomization to data cutoff was 60.4 (range, 42.6–85.8) months.
Data cutoff date: July 3, 2025.

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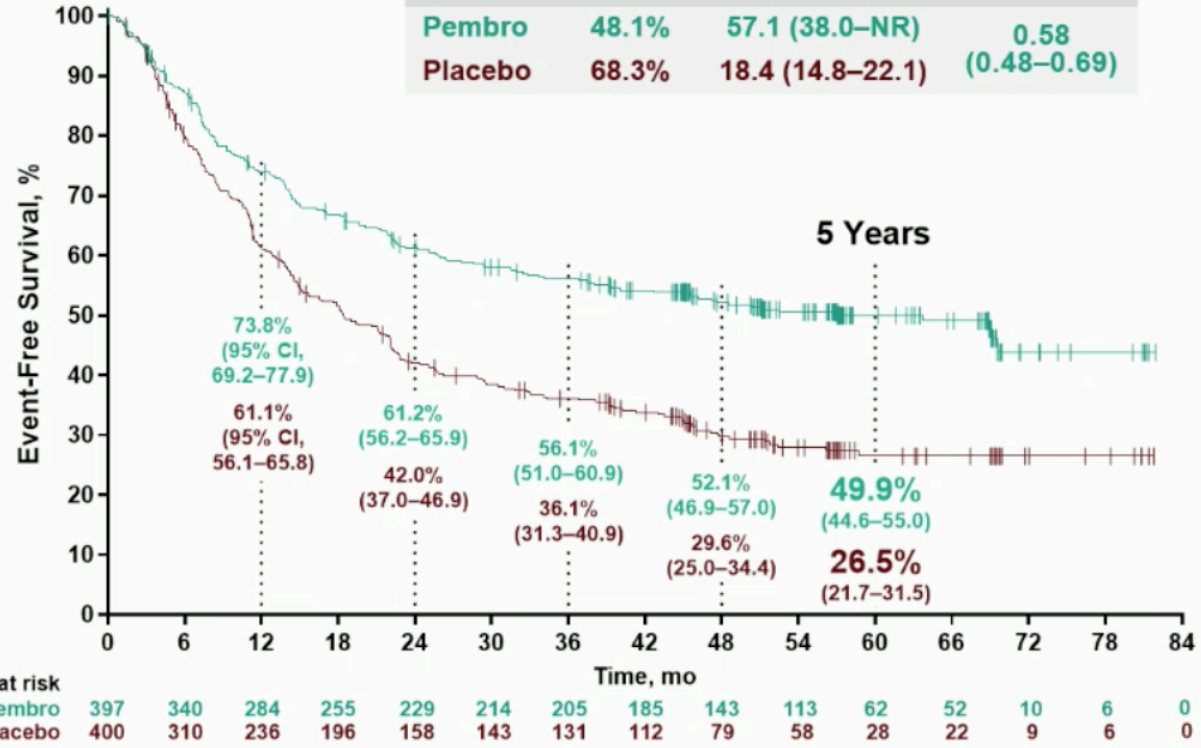
5-Year Update of Event-Free Survival[a]

Overall Population

	Pts w/ Event	Median (95% CI), mo	HR (95% CI)
Pembro	48.1%	57.1 (38.0–NR)	0.58 (0.48–0.69)
Placebo	68.3%	18.4 (14.8–22.1)	

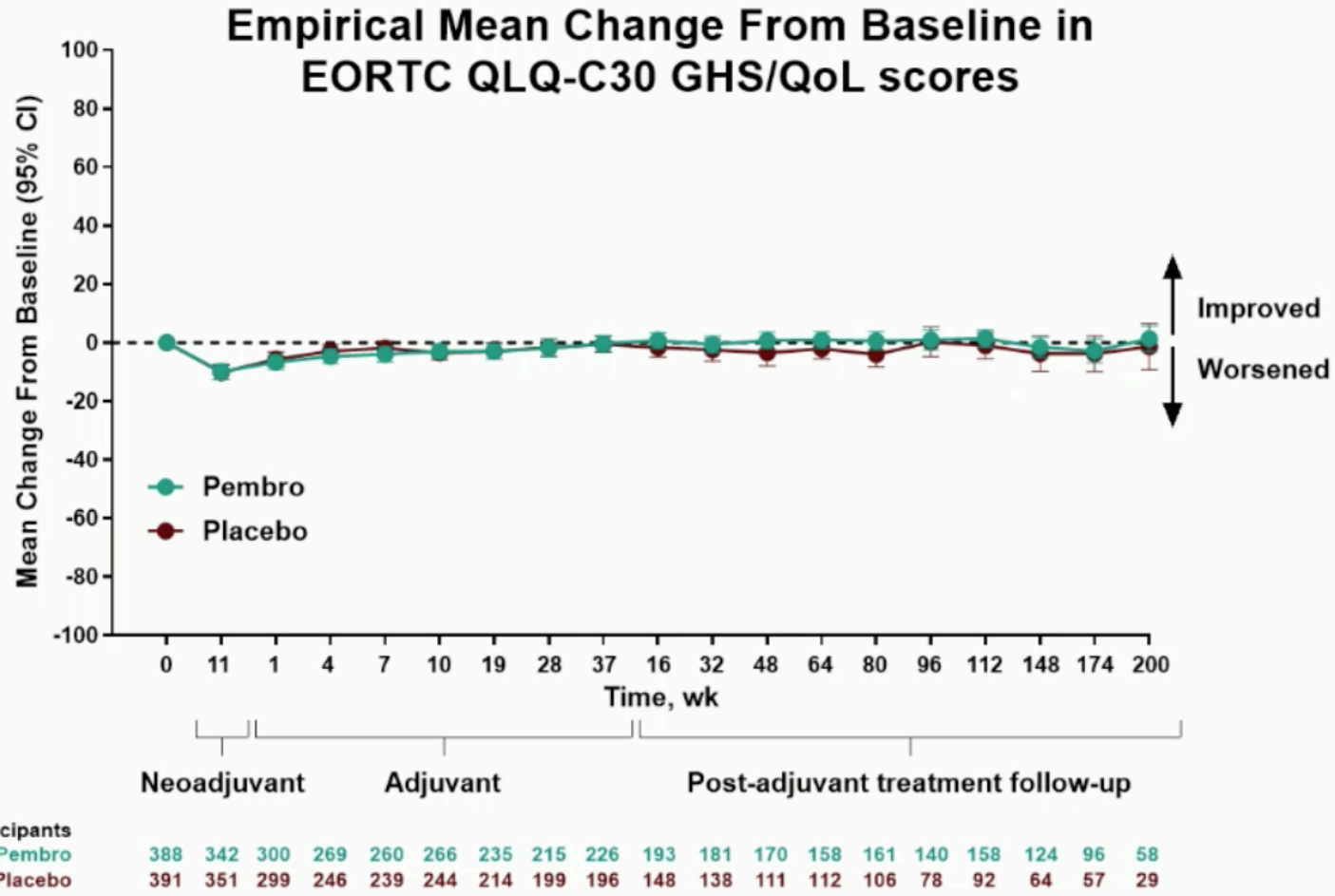


Key Subgroups

Subgroup	Events/participants Pembro	Events/participants Placebo	Hazard Ratio (95% CI)
Overall	191/397	273/400	0.58 (0.48–0.69)
Disease stage			
II	42/118	72/121	0.52 (0.35–0.76)
III	149/279	201/279	0.58 (0.47–0.72)
Nodal status			
N0	62/148	89/142	0.55 (0.40–0.77)
N1	31/82	48/73	0.48 (0.30–0.75)
N2	97/166	136/185	0.64 (0.49–0.83)
Histology			
Nonsquamous	114/226	147/227	0.66 (0.51–0.84)
Squamous	77/171	126/173	0.49 (0.37–0.65)
PD-L1 TPS			
≥50%	45/132	81/134	0.44 (0.31–0.64)
1%–49%	63/127	83/115	0.54 (0.39–0.75)
<1%	83/138	109/151	0.74 (0.55–0.98)

[a]Assessed per RECIST version 1.1 by investigator assessment.
Median time from randomization to data cutoff was 60.4 (range, 42.6–85.8) months.
Data cutoff date: July 3, 2025.

5-Year Update of Patient-Reported Outcomes



EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; GHS/QoL, global health status/quality of life.
Median time from randomization to data cutoff was 60.4 (range, 42.6–85.8) months.
Data cutoff date: July 3, 2025.

Molecular residual disease (MRD) analysis from the LAURA study of osimertinib (osi) in unresectable (UR) stage III EGFR-mutated (EGFRm) NSCLC

Edurne Arriola Aperribay (Barcelona, Spain)

LAURA study design*

Patients with locally advanced, unresectable stage III† EGFRm‡ NSCLC with no progression during / after definitive CRT§

Key inclusion criteria:

- ≥18 years (Japan: ≥20)
- WHO PS 0 / 1
- Confirmed locally advanced, unresectable stage III† NSCLC
- Ex19del / L858R‡
- Maximum interval between last dose of CRT and randomisation: 6 weeks§

Osimertinib 80 mg, once daily

Randomisation 2:1
(N=216)

Stratification by:
cCRT vs sCRT
Stage IIIA vs stage IIIB / IIIC
China vs non-China

Placebo, once daily

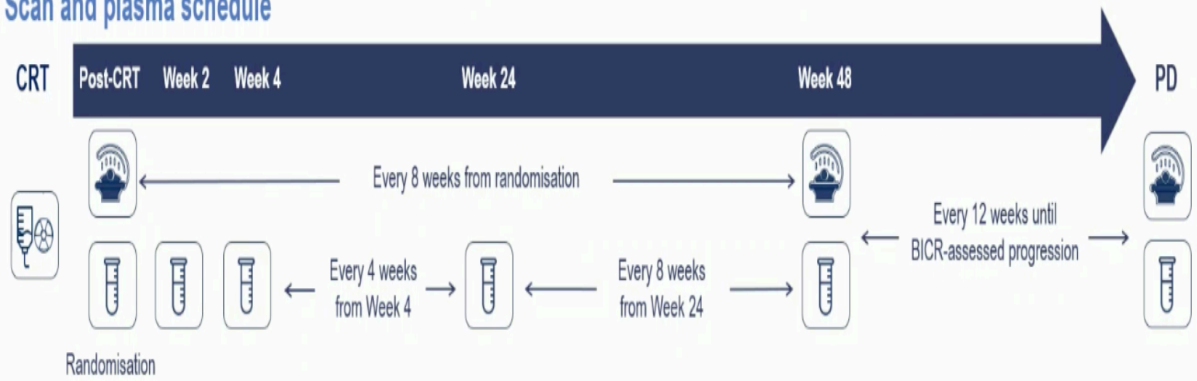
Treatment duration until BICR-assessed progression (per RECIST v1.1), toxicity or other discontinuation criteria

Open-label osimertinib after progression offered to both treatment arms‖

- **Primary endpoint:** PFS assessed by BICR per RECIST v1.1 (sensitivity analysis: PFS by investigator assessment)
- **Secondary endpoints:** OS (by BICR), TTDM (by BICR) and CNS PFS (by neuroradiologist BICR)

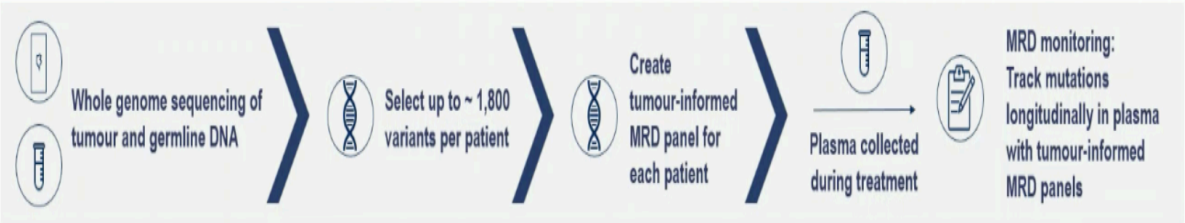
The Personalis NeXT Personal® assay, an ultra-sensitive, tumour-informed MRD assay, was used for testing plasma samples from LAURA

Scan and plasma schedule



Exploratory analysis: Determine potential of tumour-informed plasma-based MRD testing to correlate with patient outcomes and aid early clinical decision making during osimertinib treatment

Personalis NeXT Personal® assay workflow

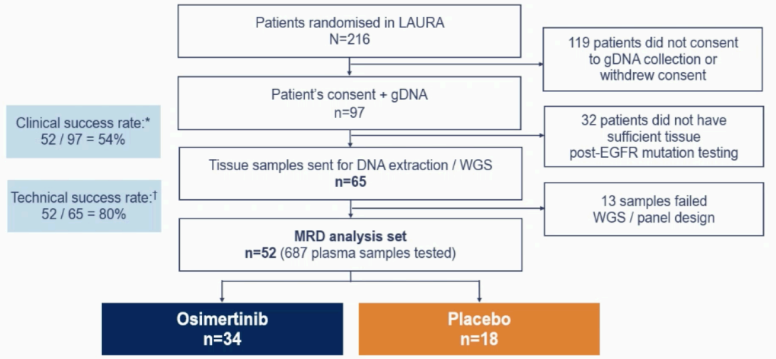


Definitions

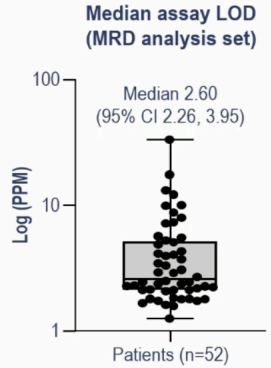
MRD clearance: 10-fold ctDNA decrease from post-CRT (randomisation) levels **or** undetected MRD for 2 consecutive timepoints by Week 12

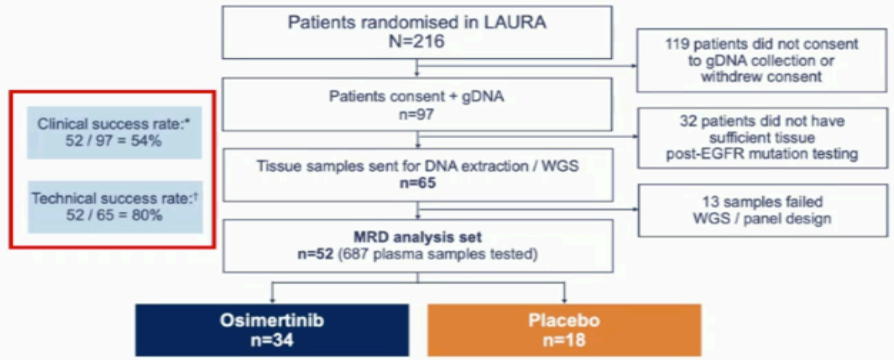
Molecular progression / MRD event: 100% increase in ctDNA at a single time point **or** detected MRD above the LLOQ

MRD panel build had a technical success rate of 80%; median LOD 2.6 PPM



Baseline characteristics and PFS outcomes were generally similar between the LAURA MRD analysis set and the FAS





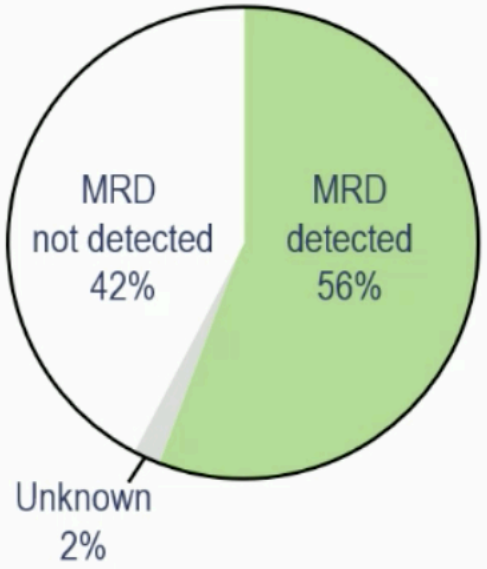
Concordance of MRD with PFS, % (95% CI)	
PPA (sensitivity)	**63 (46, 81)**
NPA (specificity)	**86 (72, 100)**
PPV	86 (72, 100)
NPV	63 (46, 81)

Main findings

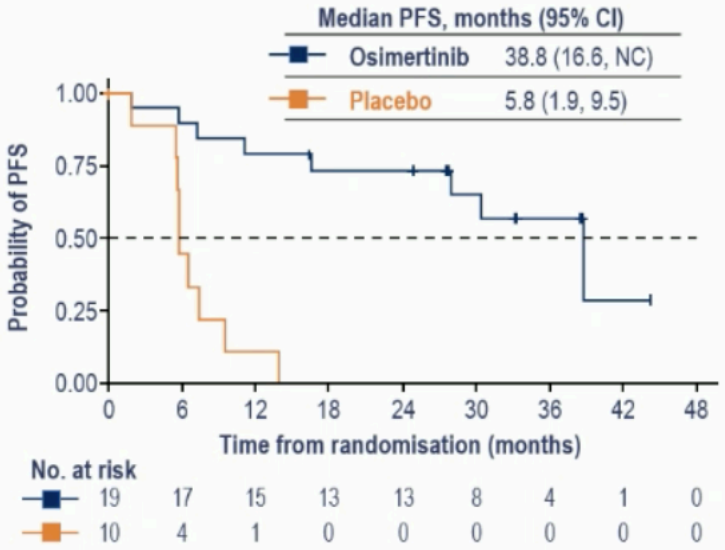
- 57% of pt samples MRD+

Irrespective of post-CRT (randomisation) MRD status, patients benefited from osimertinib treatment versus placebo

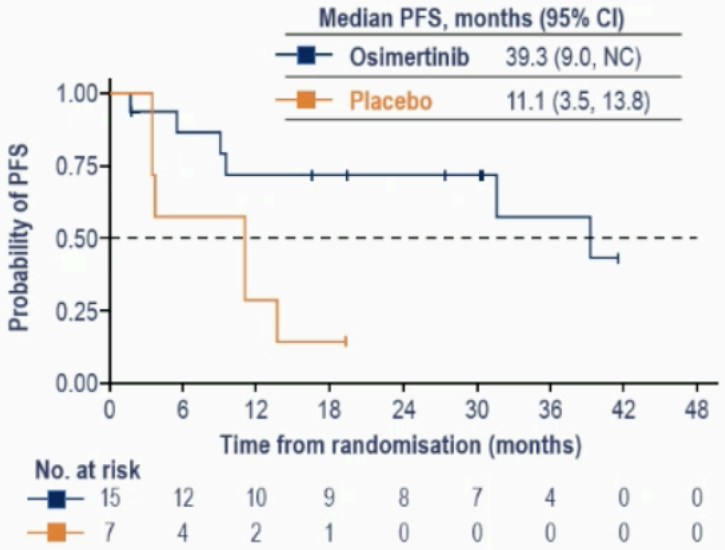
Post-CRT (randomisation) MRD status (n=52)



MRD detected post-CRT (randomisation)*†

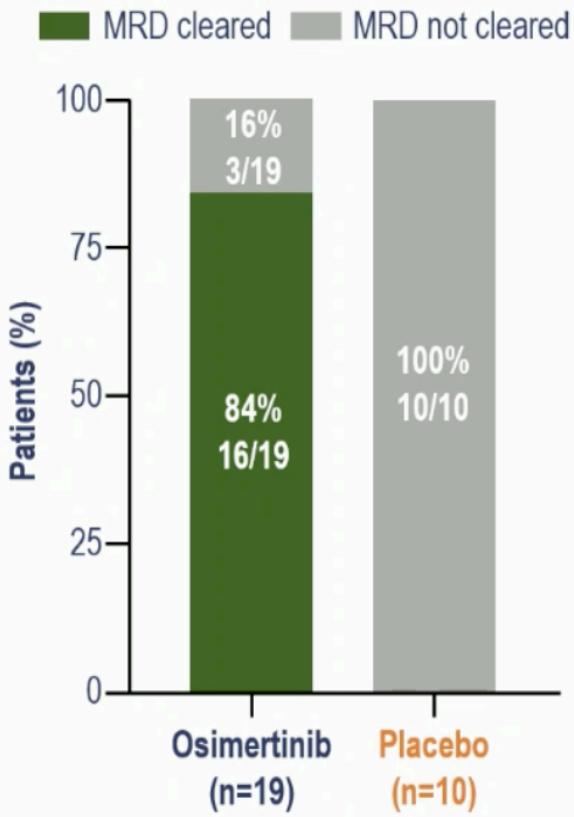


MRD not detected post-CRT (randomisation)*†

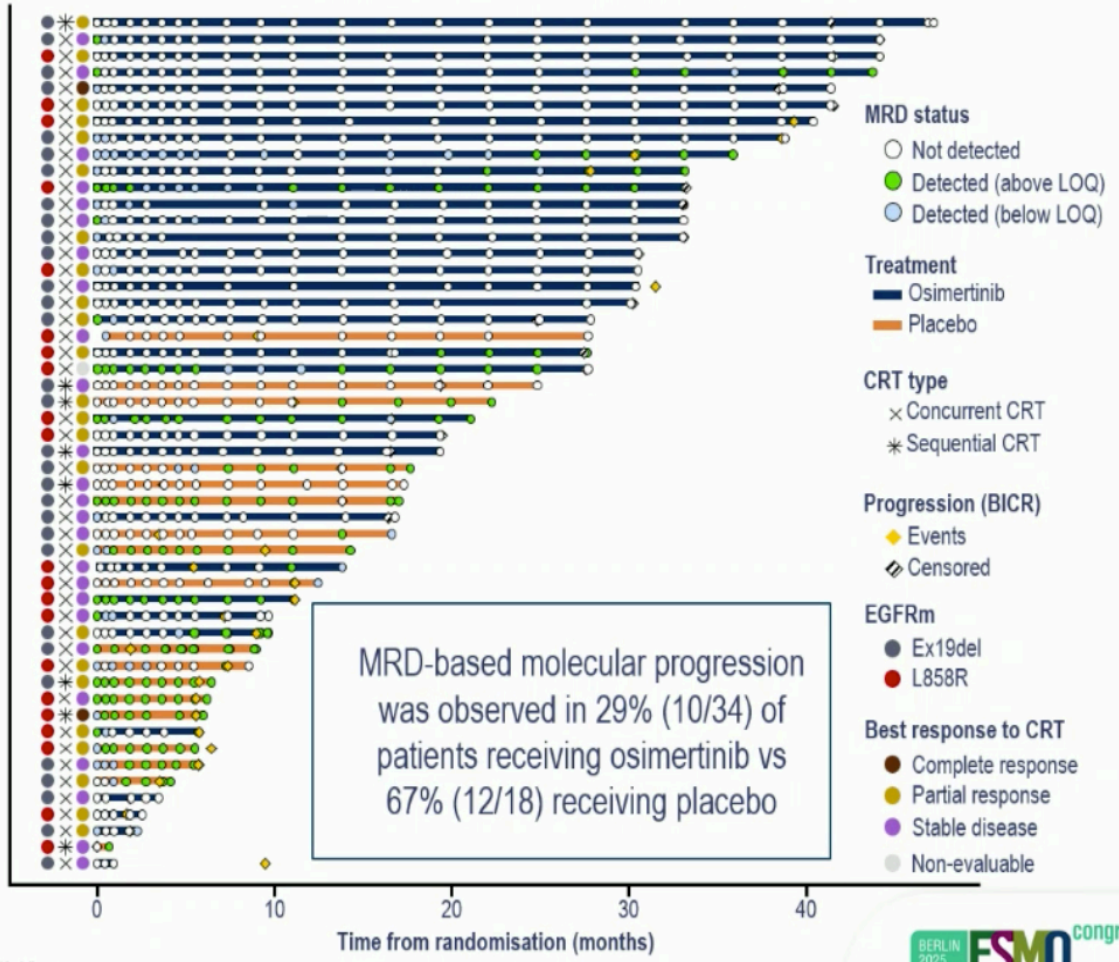


MRD clearance was observed exclusively in patients treated with osimertinib and molecular progression occurred less frequently with osimertinib than placebo

Clearance of post-CRT (randomisation) MRD



Longitudinal MRD analysis



Data cut-off: 5 January 2024.
MRD clearance was defined as a 10-fold ctDNA decrease from post-CRT (randomisation) levels or undetected MRD for 2 consecutive timepoints by Week 12.
BICR, blinded independent central review; CRT, chemoradiotherapy; ctDNA, circulating tumour DNA; Ex19del, exon 19 deletion; LOQ, limit of quantification; MRD, molecular residual disease.

Muchas Gracias

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