Lung Cancer UPDATES
IASLC HIGHLIGHTS
09-12 SEPTIEMBRE 2023
Singapore

Iniciativa científica de:
GECP
lung cancer research

INMUNOTERAPIA

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DISCLOSURES

Iniciativa científica de: GECP lung cancer research

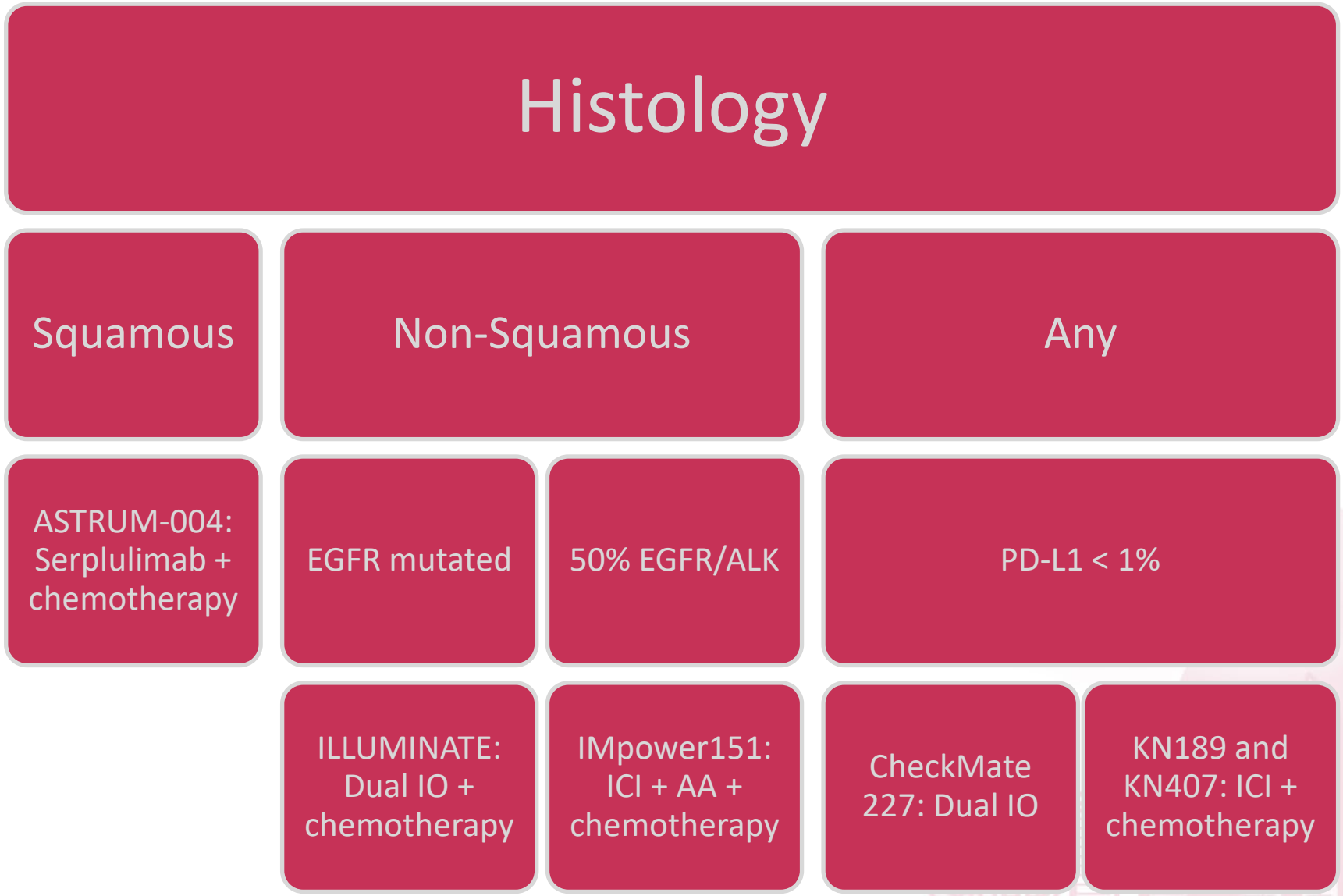
- **Advisory board:** Roche, AstraZeneca, MSD, BMS, Takeda, Sanofi, AMGEN

- **Speaking**: Roche, AstraZeneca, MSD, BMS, Takeda, Pfizer, Janssen

ORAL COMUNICATIONS

First-line ICI for advanced NSCLC

Iniciativa científica de: GECP lung cancer research



ORAL COMUNICATIONS

Iniciativa científica de:
GECP lung cancer research

- OA09.05: ASTRUM-004: A phase 3 study of serplulimab plus chemotherapy as first-line treatment for squamous non-small cell lung cancer
- OA09.04: ILLUMINATE: efficacy and safety of durvalumab-tremelimumab and chemotherapy in EGFR mutant NSCLC following progression on EGFR inhibitors
- 0A09.06: IMpower151: phase III study of atezolizumab + bevacizumab + chemotherapy in 1L metastatic nonsquamous NSCLC

OA09.05: ASTRUM-004: A phase 3 study of serplulimab plus chemotherapy as first-line treatment for squamous non-small cell lung cancer

Iniciativa científica de: GECP lung cancer research

Randomized, double-blind, multicenter, international phase 3 trial

Main eligibility criteria
- ≥18 years
- ECOG PS 0 or 1
- Stage IIIB/IIIC or IV squamous NSCLC
- No prior systemic anticancer therapy
- No known *EGFR* mutations or *ALK*/*ROS1* rearrangements

Stratification factors
- PD-L1 level (TPS <1% *vs* 1%≤ TPS <50% *vs* TPS ≥50%)
- Race (Asian *vs* non-Asian)
- Disease stage (stage IIIB/IIIC *vs* IV)

R 2:1

- Serplulimab (4.5 mg/kg; D1) + Nab-paclitaxel (100 mg/m²; D1, 8, 15) + Carboplatin (AUC 5 or 6; D1) → Serplulimab (4.5 mg/kg; D1)
- Placebo* (4.5 mg/kg; D1) + Nab-paclitaxel (100 mg/m²; D1, 8, 15) + Carboplatin (AUC 5 or 6; D1) → Placebo (4.5 mg/kg; D1)

IV, Q3W, 4–6 cycles for chemotherapy, up to 2 years for serplulimab

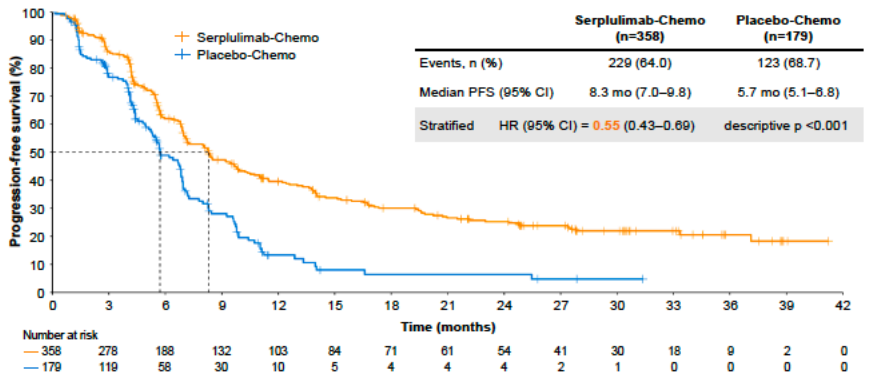
Safety and survival follow-up

*Eligible patients were allowed to crossover to serplulimab monotherapy after PD per protocol.

- **Primary endpoint:** PFS by IRRC per RECIST v1.1
- **Secondary endpoints:** OS, PFS, ORR, DOR, safety, exploration of biomarkers

Statistical analysis: The 1st interim analysis of OS was performed at the time of PFS final analysis, when approximately 99 deaths had occurred. The 2nd interim analysis of OS was performed when 198 deaths were observed. The final OS analysis were performed when 299 deaths had occurred. PFS and OS were tested sequentially at an overall 2-sided α level of 0.05. The multiplicity-adjusted 2-sided α level was 0.0002, 0.012, and 0.046 for OS at the 1st and the 2nd interim analysis, and the final analysis, respectively.

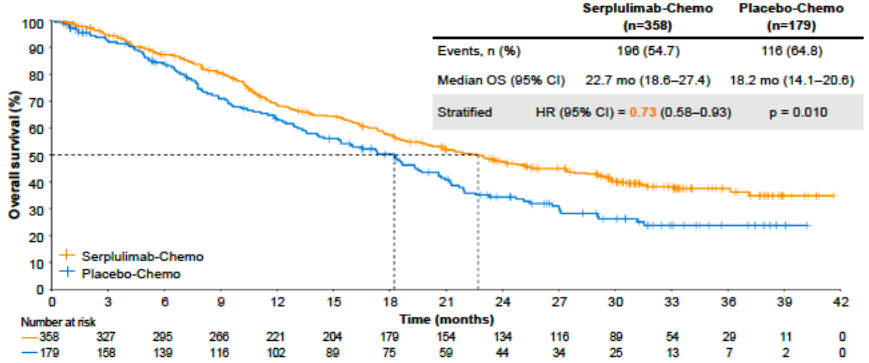
Updated PFS by IRRC per RECIST 1.1



	Serplulimab-Chemo (n=358)	Placebo-Chemo (n=179)
Events, n (%)	229 (64.0)	123 (68.7)
Median PFS (95% CI)	8.3 mo (7.0–9.8)	5.7 mo (5.1–6.8)
Stratified	HR (95% CI) = 0.55 (0.43–0.69)	descriptive p <0.001

Chemo, chemotherapy; CI, confidence interval; HR, hazard ratio; IRRC, independent radiological review committee; mo, month; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors

Overall Survival



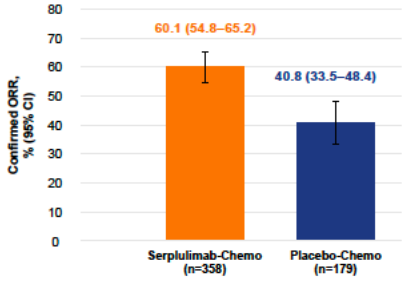
	Serplulimab-Chemo (n=358)	Placebo-Chemo (n=179)
Events, n (%)	196 (54.7)	116 (64.8)
Median OS (95% CI)	22.7 mo (18.6–27.4)	18.2 mo (14.1–20.6)
Stratified	HR (95% CI) = 0.73 (0.58–0.93)	p = 0.010

2-stage model adjusted OS for trial crossover

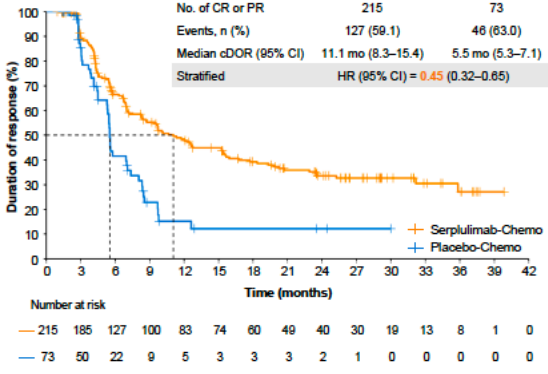
97 patients crossed over to serplulimab arm; adjusted median OS in placebo-chemo arm: 11.5 mo (95% CI 9.6–13.5); adjusted HR **0.49** (95% CI 0.37–0.64)

Chemo, chemotherapy; CI, confidence interval; HR, hazard ratio; mo, month; OS, overall survival

Tumor Response by IRRC per RECIST v1.1



Confirmed BOR, n (%)	Serplulimab-Chemo (n=358)	Placebo-Chemo (n=179)
Complete response	12 (3.4)	1 (0.6)
Partial response	203 (56.7)	72 (40.2)
Stable disease	85 (23.7)	62 (34.6)
Progressive disease	26 (7.3)	23 (12.8)
NE or NA	32 (8.9)	21 (11.7)



	Serplulimab-Chemo (n=358)	Placebo-Chemo (n=179)
No. of CR or PR	215	73
Events, n (%)	127 (59.1)	46 (63.0)
Median cDOR (95% CI)	11.1 mo (8.3–15.4)	5.5 mo (5.3–7.1)
Stratified	HR (95% CI) = 0.45 (0.32–0.65)	

BOR, best overall response; cDOR, confirmed duration of response; Chemo, chemotherapy; CI, confidence interval; CR, complete response; DOR, duration of response; HR, hazard ratio; IRRC, independent radiological review committee; mo, month; NA, not applicable; NE, not evaluable; ORR, objective response rate; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors

OA09.05: ASTRUM-004: A phase 3 study of serplulimab plus chemotherapy as first-line treatment for squamous non-small cell lung cancer

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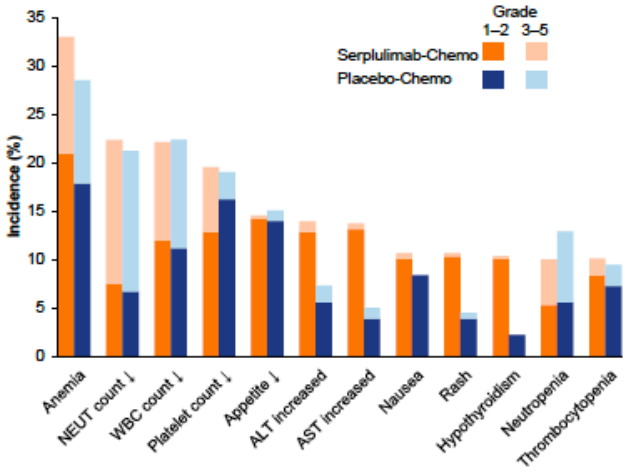
Safety Profile

	Serplulimab-Chemo (n=358)	Placebo-Chemo (n=179)
TEAE, n (%)	354 (98.9)	176 (98.3)
Grade ≥3	305 (85.2)	142 (79.3)
Serious	186 (52.0)	76 (42.5)
Leading to Tx discontinuation	80 (22.3)	27 (15.1)
Leading to death	49 (13.7)	19 (10.6)
AESI	109 (30.4)	31 (17.3)
irAE	106 (29.6)	31 (17.3)
IRR	4 (1.1)	0
TRAE, n (%)	345 (96.4)	170 (95.0)
Serious	119 (33.2)	49 (27.4)
Leading to death	4 (1.1)	5 (2.8)
Related to serplulimab/placebo	262 (73.2)	112 (62.6)
Grade ≥3	127 (35.5)	57 (31.8)
Leading to Tx discontinuation	37 (10.3)	9 (5.0)
Leading to death	4 (1.1)	2 (1.1)

AE, adverse event; AESI, adverse event of special interest; ALT, alanine transaminase; AST, aspartate aminotransferase; Chemo, chemotherapy; irAE, immune-related adverse event; IRR, infusion-related reaction; NEUT, neutrophil; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; Tx, treatment; WBC, white blood cell



[a] AEs related to serplulimab or placebo in ≥10% of patients in either group were shown.
[b] AEs occurred after trial crossover were not included.

- With 31.1 months of follow-up, serplulimab plus carboplatin/nab-paclitaxel showed consistent benefits in PFS, OS, ORR, and DOR.
  - Median OS at final analysis: 22.7 *vs* 18.2 months, HR = 0.73, p = 0.010
  - Updated median PFS at OS final analysis: 8.3 *vs* 5.7 months, HR = 0.55, descriptive p <0.001
- Serplulimab plus carboplatin/nab-paclitaxel showed a manageable safety profile, with no new safety signals being observed during the study.

In conclusion, adding serplulimab to carboplatin/nab-paclitaxel significantly improved survival in previously untreated patients with locally advanced or metastatic squamous NSCLC. The aforementioned combination regimen represents a new treatment option for this patient population in the global setting.

OA09.04: ILLUMINATE: efficacy and safety of durvalumab-tremelimumab and chemotherapy in EGFR mutant NSCLC following progression on EGFR inhibitors

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Population
EGFR +ve advanced NSCLC
Progressed on EGFR TKI therapy
ECOG PS 0-1
Measurable disease (RECIST 1.1)

Cohort 1
T790M –ve (N=50)

Cohort 2
T790M +ve (N=50)
with disease progression following a 3rd generation EGFR TKI

Exclusions
Prior immunotherapy or chemotherapy for metastatic disease

Open label, parallel cohort, non-comparative, multicentre phase 2 trial

Induction	Maintenance
Durvalumab 1500mg IV + Tremelimumab 75mg IV + Cisplatin 75mg/m² + Pemetrexed 500mg/m² q3/52	Durvalumab 1500mg IV + Pemetrexed 500mg/m² q4/52
4 cycles	Until progression

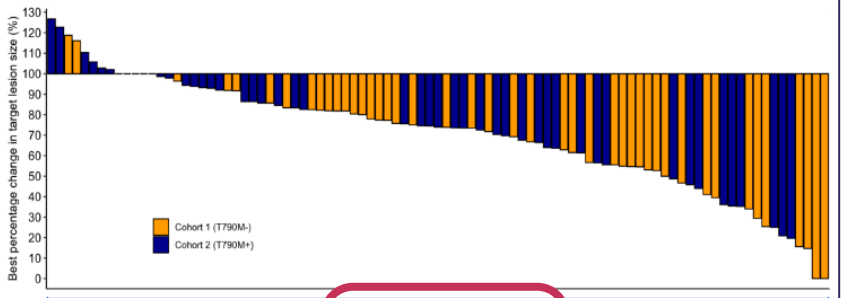
Outcomes

Best OTRR*

Best DCR*
OTRR**
PFS* **
$PFS_{12\ months}$* **
OS
Safety
Correlation with tumour PD-L1 expression, TIL, baseline and longitudinal cfDNA

* RECIST 1.1
** iRECIST

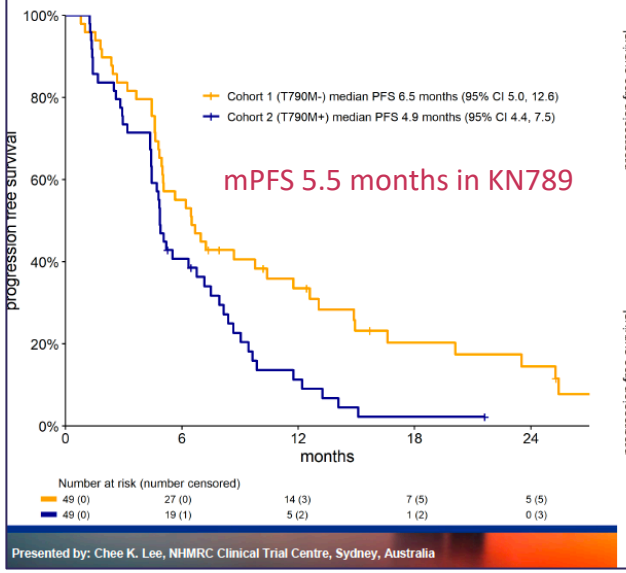
Primary Endpoint: Objective Response Rate

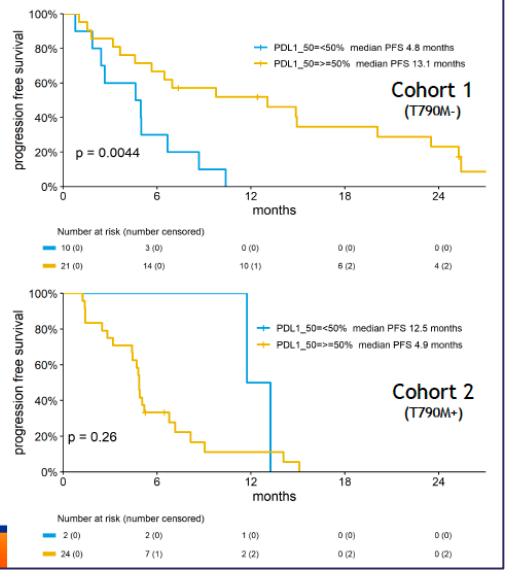


		Cohort 1 (T790M-)	Cohort 2 (T790M+)
Confirmed ORR	n/N	15/48	10/48
	%	31 (95% CI 20–45)	21 (95% 12-34)
Unconfirmed ORR	n/N	20/48	17/48
	%	42 (95% CI 29–56)	35 (95% CI 23–50)

ORR ~ 28% for Pemetrexed + platinum + pembro in KN789

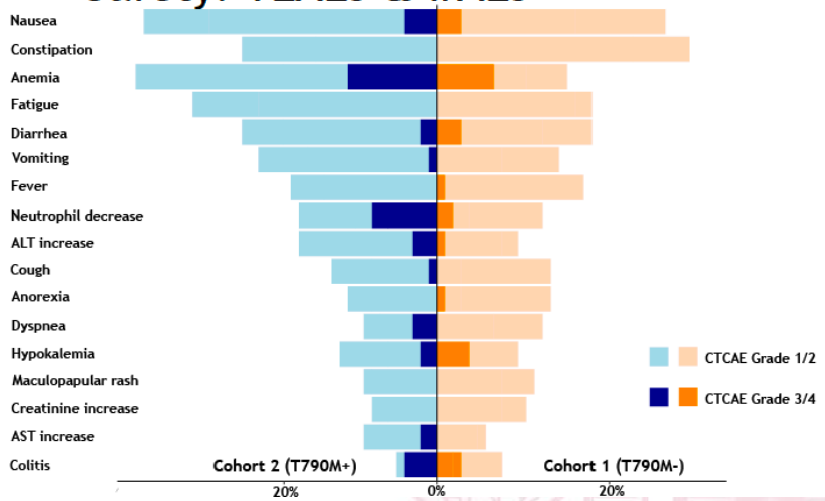
Progression-free survival by T790M status and PD-L1 status





Presented by: Chee K. Lee, NHMRC Clinical Trial Centre, Sydney, Australia

Safety: TEAEs & irAEs



Grade 3-4 immune-related AEs	n (%)
Colitis	8 (8)
Hepatitis	4 (4)
Adrenal insufficiency	2 (2)
Pneumonitis	1 (1)

- No fatal TEAEs
- No significant difference in G3-G4 irAE rates between cohorts
  10% vs 18%, p=0.40
- Treatment discontinuation for irAEs in 6 (6%)

Chee Lee, et al.

OA09.04: ILLUMINATE: efficacy and safety of durvalumab-tremelimumab and chemotherapy in EGFR mutant NSCLC following progression on EGFR inhibitors

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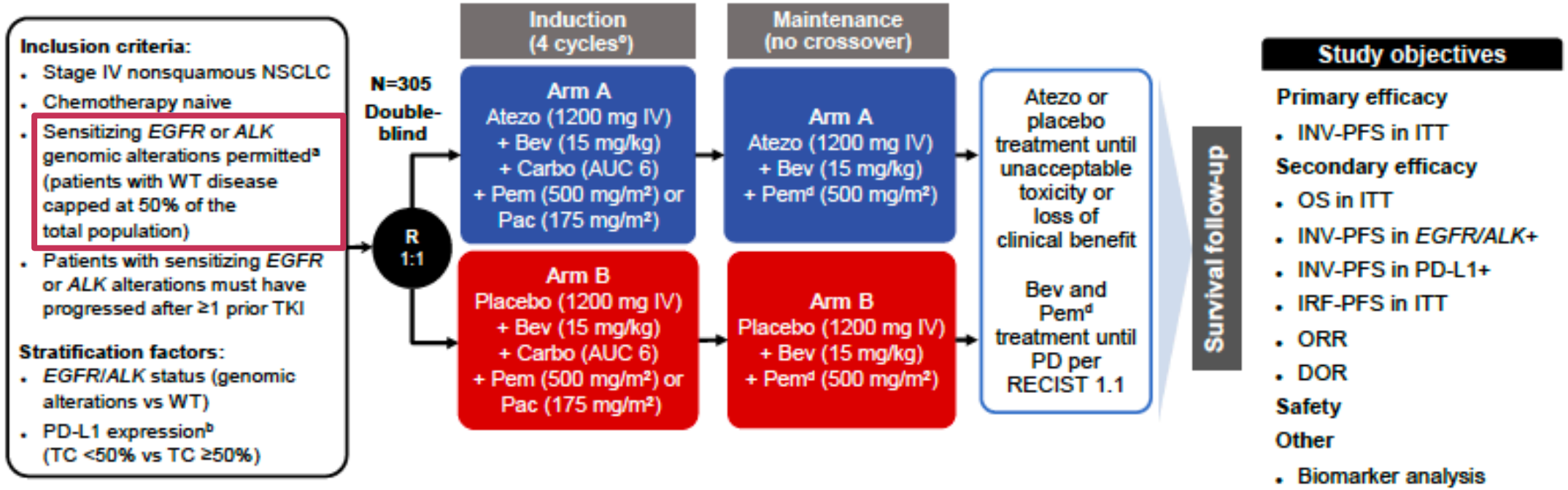
Summary

- The addition of durvalumab and tremelimumab to platinum-doublet chemotherapy has modest anti-tumor activity in advanced *EGFR* mutant NSCLC following progression on EGFR TKIs
- There was a numerically greater benefit for ORR and PFS in *EGFR* T790M-tumors (cohort 1)
- The safety profile was consistent with other chemoimmunotherapy regimens in advanced NSCLC and not increased with the addition of tremelimumab

0A09.06: IMpower151: phase III study of atezolizumab + bevacizumab + chemotherapy in 1L metastatic nonsquamous NSCLC



- A target sample size of 306 patients allowed for 90% power to detect a HR of 0.65, corresponding to an improvement in median PFS from 6.8 to 10.5 months in the ITT population

0A09.06: IMpower151: phase III study of atezolizumab + bevacizumab + chemotherapy in 1L metastatic nonsquamous NSCLC

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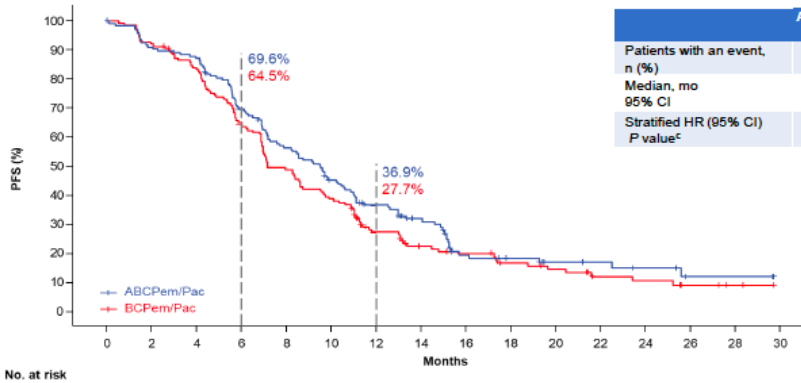
Primary Endpoint: INV-PFS in the ITT population[a]

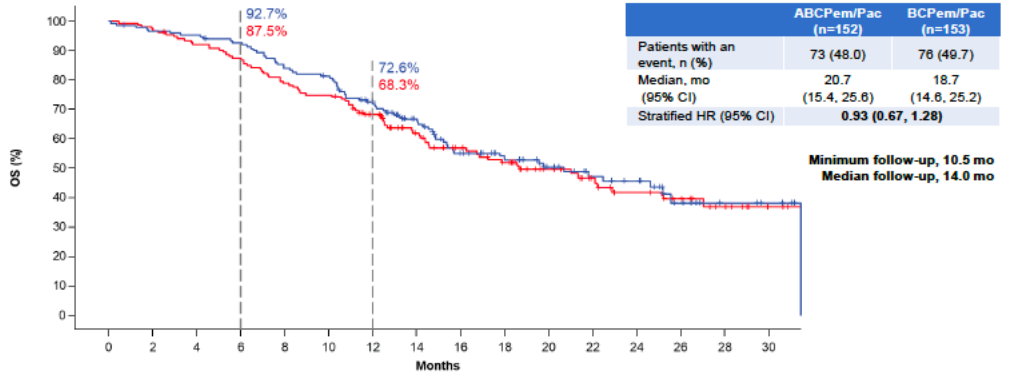


	ABCPem/Pac[b] (n=152)	BCPem/Pac[b] (n=153)
Patients with an event, n (%)	114 (75.0)	125 (81.7)
Median, mo 95% CI	9.5 (7.6, 10.6)	7.1 (6.9, 9.5)
Stratified HR (95% CI) *P* value[c]	0.84 (0.65, 1.09) 0.18	

Minimum follow-up, 10.5 mo
Median follow-up, 14.0 mo

Clinical cutoff date: 2 February 2023. [a] IRF-PFS (HR=0.88) was consistent with INV-PFS. [b] In the ABCPem/Pac arm, 98% of patients received Pem; in the BCP arm, 97% of patients received Pem. [c] Stratified log-rank.

OS in the ITT population

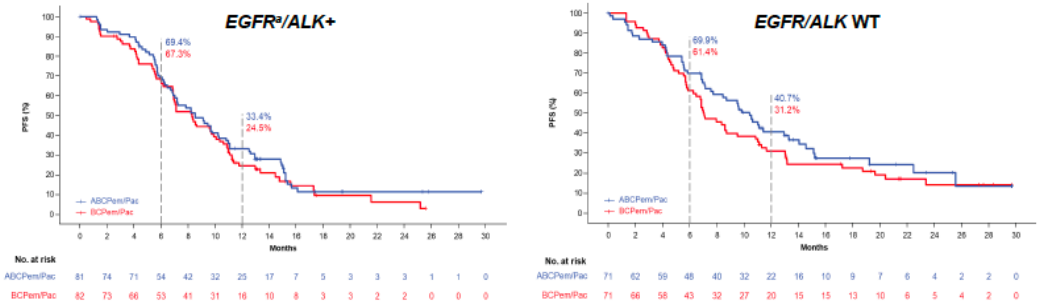


	ABCPem/Pac (n=152)	BCPem/Pac (n=153)
Patients with an event, n (%)	73 (48.0)	76 (49.7)
Median, mo (95% CI)	20.7 (15.4, 25.6)	18.7 (14.6, 25.2)
Stratified HR (95% CI)	0.93 (0.67, 1.28)	

Minimum follow-up, 10.5 mo
Median follow-up, 14.0 mo

Clinical cutoff date: 2 February 2023.

INV-PFS by *EGFR*/*ALK* genotype



	ABCPem/Pac (n=81)	BCPem/Pac (n=82)
Patients with an event, n (%)	65 (80.2)	68 (82.9)
Median, mo (95% CI)	8.5 (6.9, 10.3)	8.3 (6.9, 10.1)
Unstratified HR (95% CI)	0.86 (0.61, 1.21)	

	ABCPem/Pac (n=71)	BCPem/Pac (n=71)
Patients with an event, n (%)	49 (69.0)	57 (80.3)
Median, mo (95% CI)	10.4 (7.6, 13.3)	7.0 (6.2, 9.5)
Unstratified HR (95% CI)	0.81 (0.55, 1.19)	

Clinical cutoff date: 2 February 2023. Minimum follow-up, 10.5 mo; Median follow-up, 14.0 mo. Not powered to detect a difference in the treatment effect for INV-PFS by *EGFR*/*ALK* genomic alterations status. [a] Sensitizing *EGFR* mutations include exon 19 del, L858R, S768I, L861Q and G719X.

	ABCPem/Pac (n=152)	BCPem/Pac (n=153)
ORR, n (%)	73 (48.0)	76 (49.7)
Complete response	0	1 (0.7)
Partial response	73 (48.0)	75 (49.0)
Stable disease	60 (39.5)	61 (39.9)
Disease progression	10 (6.6)	9 (5.9)
DOR		
Responders, n (%)	73 (48.0)	76 (49.7)
Responders with subsequent event, n (%)	47 (64.4)	60 (78.9)
Median, mo (95% CI)	11.3 (7.4, 13.6)	8.3 (5.7, 9.9)

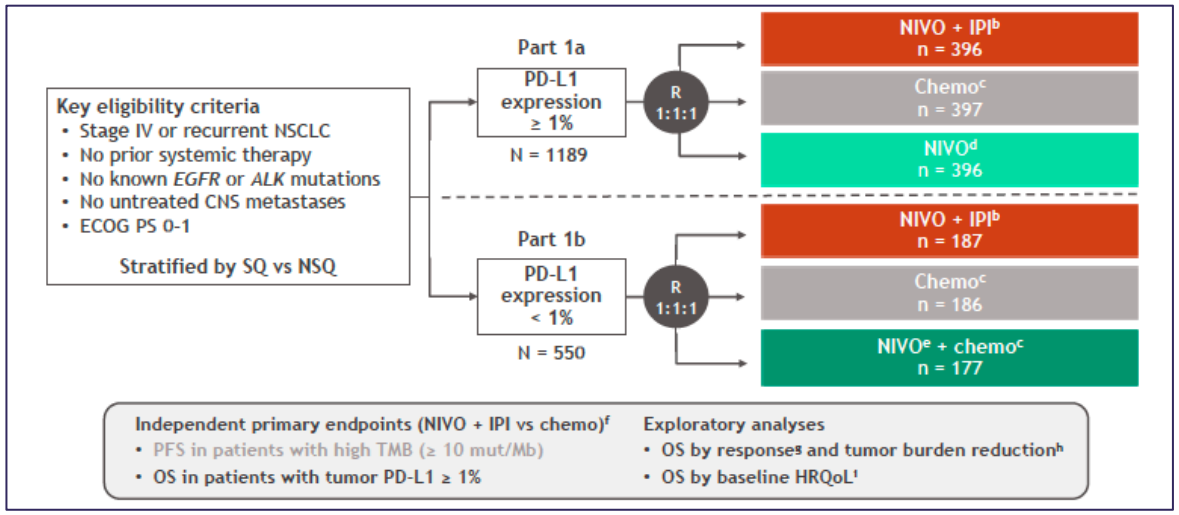
ORAL COMUNICATIONS

Iniciativa científica de:
GECP lung cancer research

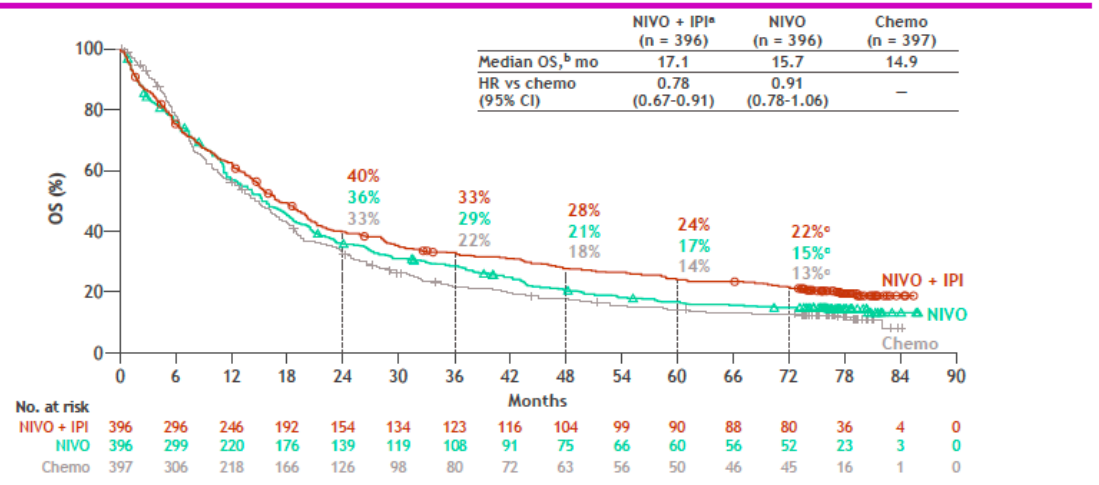
- 0A14.03: Six-year survival and HRQoL outcomes with 1L Nivolumab + Ipilimumab in patients with metastatic NSCLC from CheckMate227
- OA14.04: Three-year outcomes with first-line pembrolizumab, in patients with non-small cell lung cancer and a PD-L1 tumor proportion score > 90%
- OA14.05: 5-year survival of pembrolizumab plus chemotherapy for metastatic NSCLC with PD-L1 tumor proportion score < 1%

0A14.03: Six-year survival and HRQoL outcomes with 1L Nivolumab + Ipilimumab in patients with metastatic NSCLC from CheckMate227

Iniciativa científica de: GECP lung cancer research

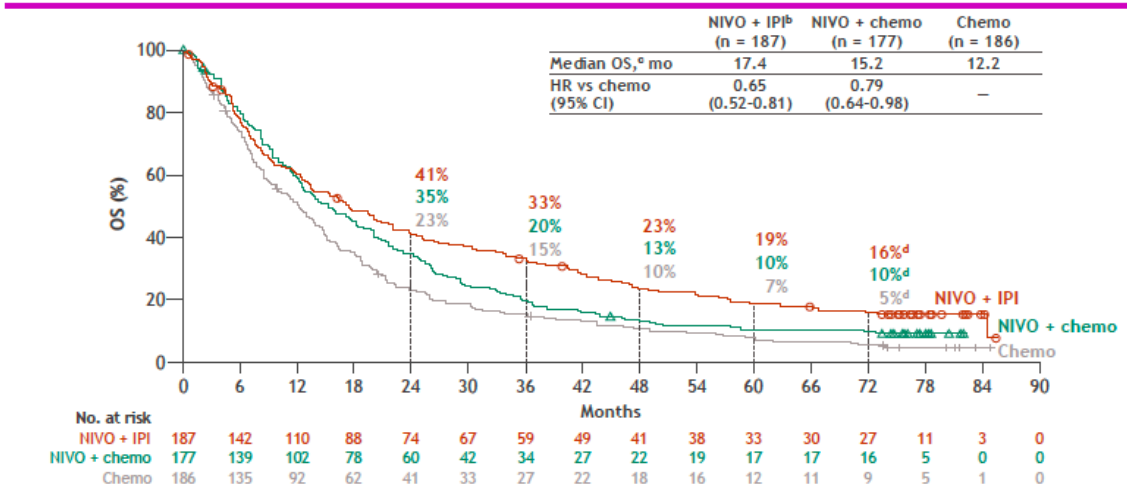


OS in patients with tumor PD-L1 ≥ 1%



- In an exploratory analysis of OS by histology in patients with tumor PD-L1 ≥ 1%, 6-year OS rates with NIVO + IPI vs chemo were 25% vs 16% (NSQ) and 14% vs 5% (SQ)[d]

OS in patients with tumor PD-L1 < 1%[a]

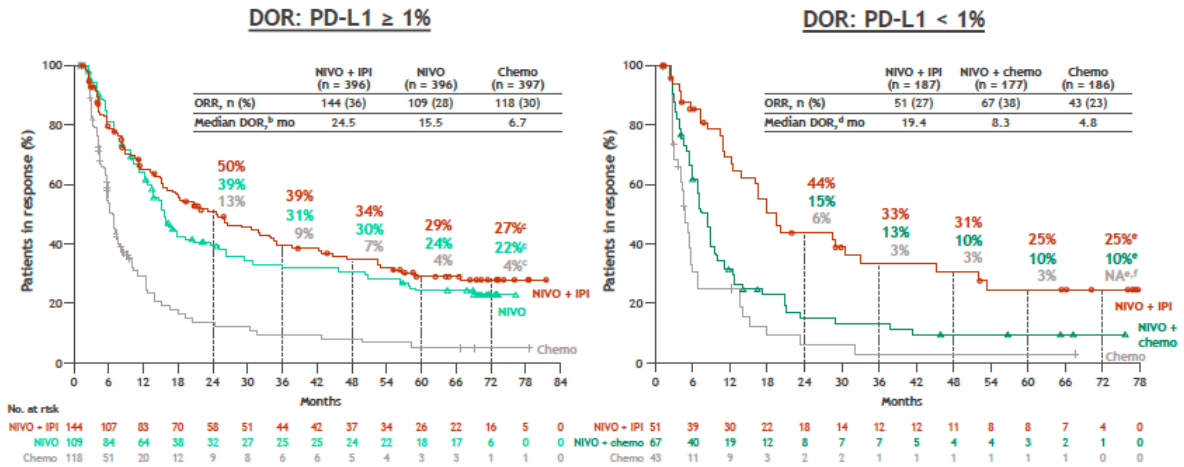


- In an exploratory analysis of OS by histology in patients with tumor PD-L1 < 1%, 6-year OS rates with NIVO + IPI vs chemo were 15% vs 6% (NSQ) and 18% and 4% (SQ)[e]

0A14.03: Six-year survival and HRQoL outcomes with 1L Nivolumab + Ipilimumab in patients with metastatic NSCLC from CheckMate227

Iniciativa científica de: GECP lung cancer research

DOR[a] and PFS[a] by tumor PD-L1 expression



- 6-year PFS rates with NIVO + IPI vs chemo were 11% vs 2% (PD-L1 ≥ 1%) and 8% vs NA[f] (PD-L1 < 1%)[g]

- With 6 years' minimum follow-up, patients treated with NIVO + IPI vs chemo continued to derive long-term, durable efficacy benefit in CheckMate 227 Part 1, regardless of tumor PD-L1 expression
  - 6-year OS rates: 22% vs 13% (PD-L1 ≥ 1%); 16% vs 5% (PD-L1 < 1%)
  - 6-year DOR rates: 27% vs 4% (PD-L1 ≥ 1%); 25% vs NA (PD-L1 < 1%)
- Greater tumor burden reduction was observed with NIVO + IPI vs chemo; deeper responses were associated with long-term OS benefit, regardless of tumor PD-L1 expression
- Better baseline HRQoL was associated with improved OS in both NIVO + IPI and chemo arms
- The safety profile of NIVO + IPI remained unchanged from previous reports
- Taken together, these results
  - Represent the longest reported follow-up across phase 3 studies of 1L immunotherapy in patients with metastatic NSCLC
  - Further highlight the clinical benefit of 1L NIVO + IPI as an effective treatment for patients with metastatic NSCLC and tumor PD-L1 ≥ 1% or tumor PD-L1 < 1%

OA14.04: Three-year outcomes with first-line pembrolizumab, in patients with non-small cell lung cancer and a PD-L1 tumor proportion score > 90%

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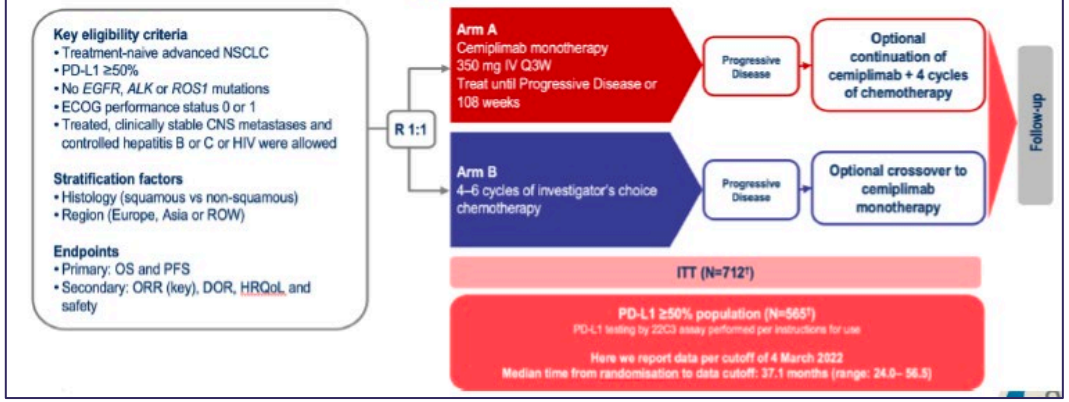
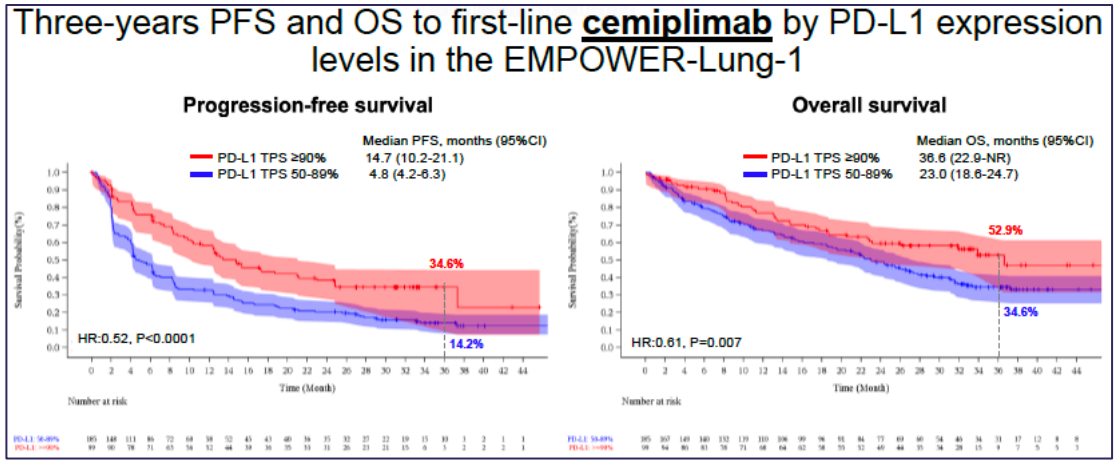
Methods

- We examined two independent cohorts of patients with advanced NSCLC and a PD-L1 TPS ≥50% who received PD-1 inhibition:
  - Cohort #1: EMPOWER-Lung-1
  - Cohort #2: retrospective academic cohort (DFCI, MSKCC, MDACC, MGH)
- Targeted exome sequencing and multiplexed immunofluorescence were performed on a subset of NSCLC samples at DFCI.

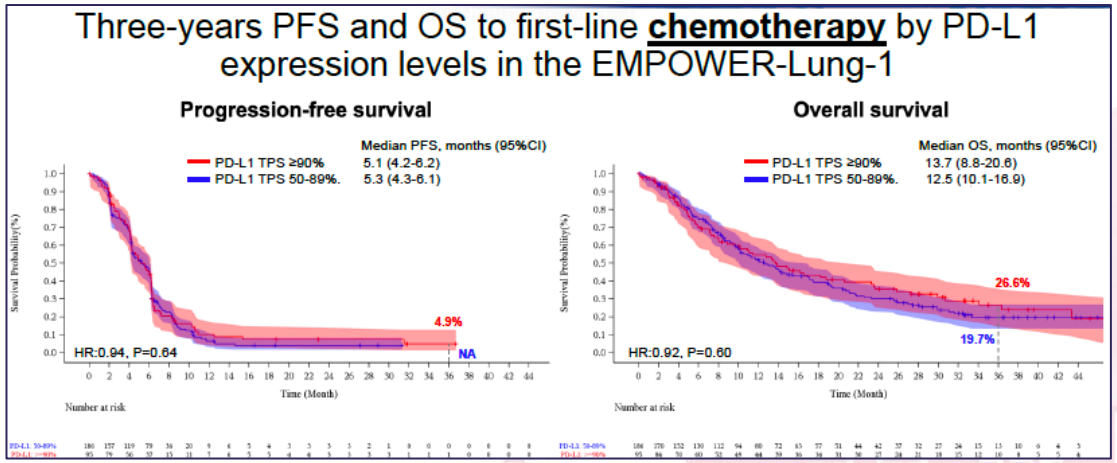
EMPOWER-Lung-1



Three-years PFS and OS to first-line **cemiplimab** by PD-L1 expression levels in the EMPOWER-Lung-1



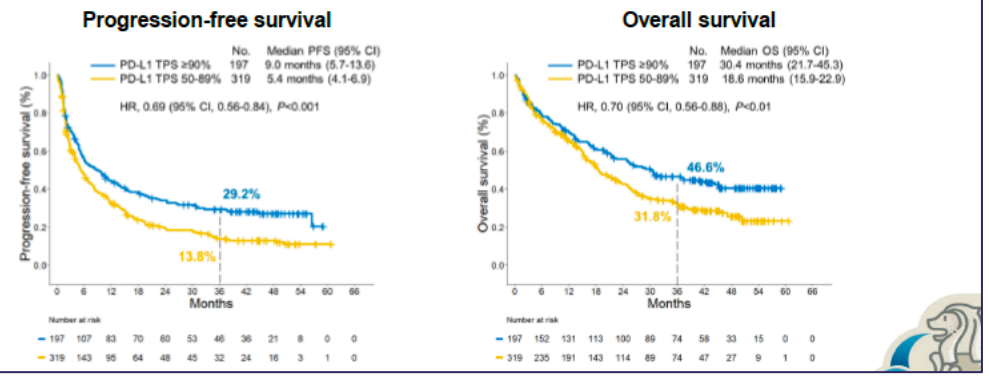
Three-years PFS and OS to first-line **chemotherapy** by PD-L1 expression levels in the EMPOWER-Lung-1



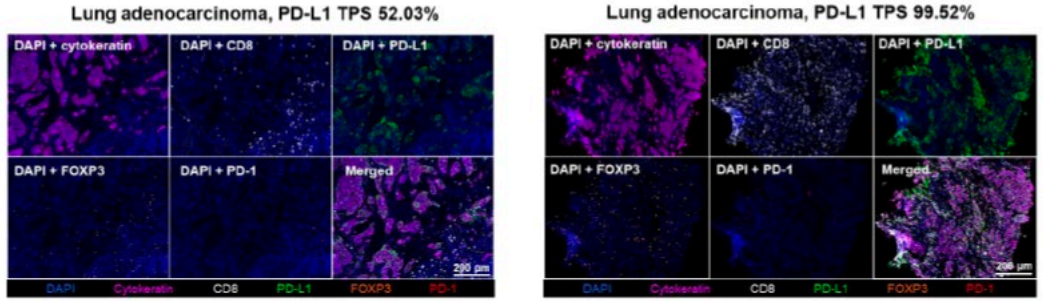
OA14.04: Three-year outcomes with first-line pembrolizumab, in patients with non-small cell lung cancer and a PD-L1 tumor proportion score > 90%

Iniciativa científica de: GECP lung cancer research

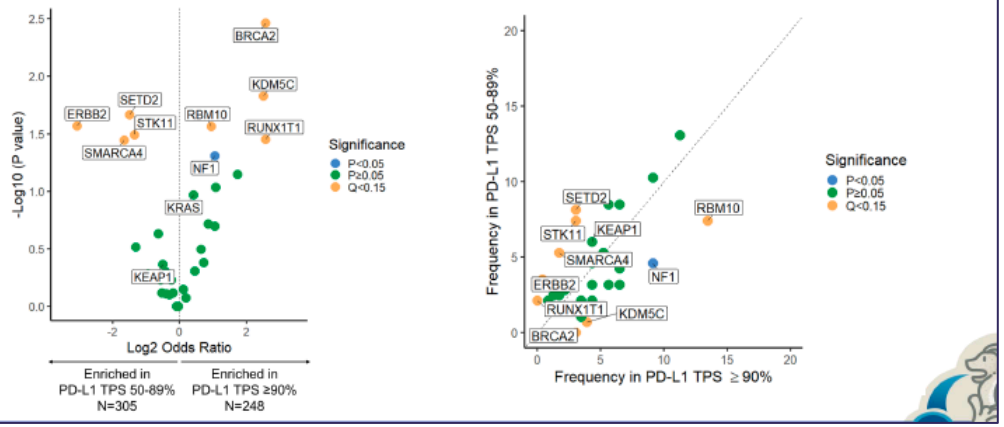
Three-year PFS and OS to first-line commercial **pembrolizumab** by PD-L1 expression levels in the retrospective academic cohort



Immunophenotype of NSCLCs with a PD-L1 TPS of 50-89% and ≥90%



Genomic profile of NSCLC with a PD-L1 TPS 50-89% and ≥90%



- PD-1 monotherapy continues to demonstrate a meaningful long-term survival benefit in patients with advanced NSCLC and a PD-L1 TPS ≥90%.
- NSCLCs with very high PD-L1 TPS may have a more favorable genomic and immunophenotypic profile (lower prevalence of *STK11/SMARCA4* mutations, increased CD8+PD1+ T cells).
- Implication for clinical decision making and for the interpretation and design of immunotherapy clinical trials in metastatic and early-stage NSCLC

OA14.05: 5-year survival of pembrolizumab plus chemotherapy for metastatic NSCLC with PD-L1 tumor proportion score < 1%

Iniciativa científica de: GECP lung cancer research

We present 5-year outcomes from a post-hoc exploratory pooled analysis of phase 3 trials of pembrolizumab plus chemotherapy vs placebo plus chemotherapy in patients with previously untreated metastatic NSCLC with PD-L1 TPS <1%

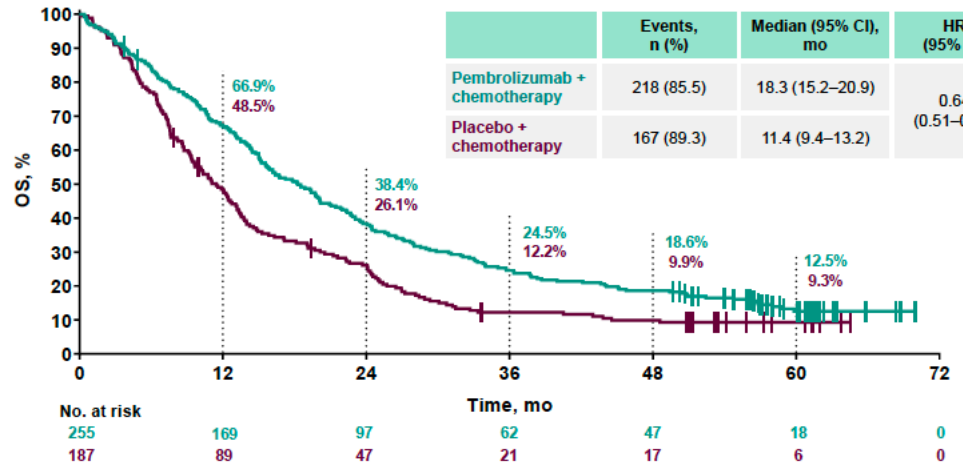
- **PD-L1 expression:** centrally assessed using PD-L1 IHC 22C3 pharmDx (Agilent Technologies, Carpinteria, CA, USA) from biopsy samples collected at diagnosis[1,2]
- **Tumor response:** assessed per RECIST version 1.1 by BICR
- **PFS2:** defined as time from randomization to second/subsequent tumor progression on next line of treatment or death; assessed per RECIST version 1.1 by investigator review

Clinical Study	Study Design
KEYNOTE-189 global[1] (NCT02578680) and **Japan Extension**[7] (NCT03950674)	• Previously untreated stage IV nonsquamous NSCLC; no *EGFR/ALK* alteration • Pembrolizumab 200 mg Q3W plus pemetrexed-platinum vs placebo plus pemetrexed-platinum • 2:1 randomization
KEYNOTE-407 global[2] (NCT02775435) and **China Extension**[8] (NCT03875092)	• Previously untreated stage IV squamous NSCLC • Pembrolizumab 200 mg Q3W plus carboplatin-paclitaxel/nab-paclitaxel vs placebo plus carboplatin-paclitaxel/nab-paclitaxel • 1:1 randomization

OA14.05: 5-year survival of pembrolizumab plus chemotherapy for metastatic NSCLC with PD-L1 tumor proportion score < 1%

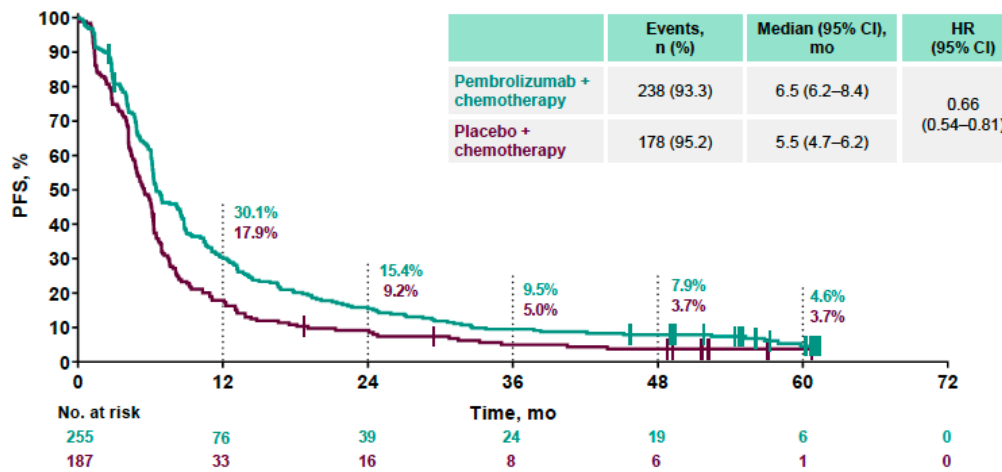
Iniciativa científica de: GECP lung cancer research

Overall Survival



	Events, n (%)	Median (95% CI), mo	HR (95% CI)
Pembrolizumab + chemotherapy	218 (85.5)	18.3 (15.2–20.9)	0.64 (0.51–0.79)
Placebo + chemotherapy	167 (89.3)	11.4 (9.4–13.2)	

Progression-Free Survival[a]

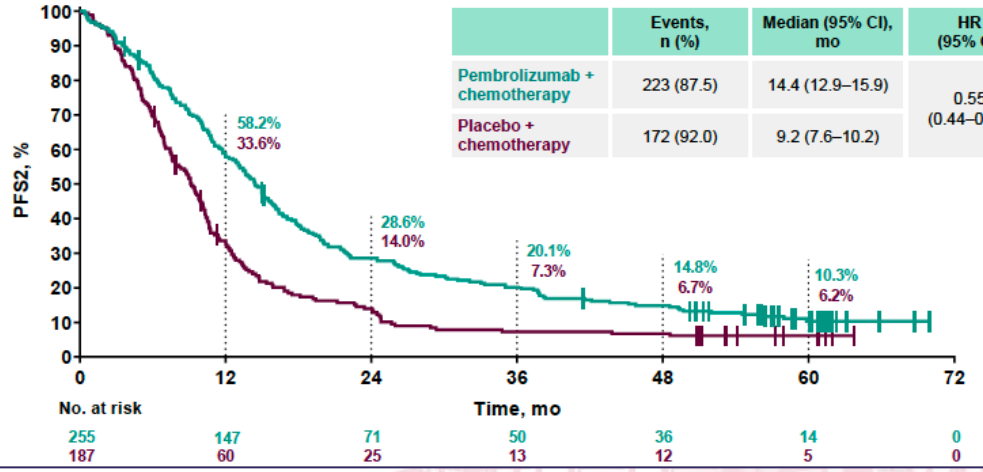


	Events, n (%)	Median (95% CI), mo	HR (95% CI)
Pembrolizumab + chemotherapy	238 (93.3)	6.5 (6.2–8.4)	0.66 (0.54–0.81)
Placebo + chemotherapy	178 (95.2)	5.5 (4.7–6.2)	

Antitumor Activity and Duration of Response[a]

	Pembrolizumab + Chemotherapy n = 255	Placebo + Chemotherapy n = 187
ORR (95% CI), %	50.6 (44.3–56.9)	33.2 (26.5–40.4)
Best overall response, n (%)		
Complete response	4 (1.6)	5 (2.7)
Partial response	125 (49.0)	57 (30.5)
Stable disease[b]	88 (34.5)	79 (42.2)
Progressive disease	20 (7.8)	31 (16.6)
Not evaluable[c]	11 (4.3)	6 (3.2)
No assessment[d]	7 (2.7)	9 (4.8)
Median DOR (range), mo	7.6 (1.1+ to 59.4+)	5.5 (1.4+ to 55.8+)

Progression-Free Survival 2



	Events, n (%)	Median (95% CI), mo	HR (95% CI)
Pembrolizumab + chemotherapy	223 (87.5)	14.4 (12.9–15.9)	0.55 (0.44–0.68)
Placebo + chemotherapy	172 (92.0)	9.2 (7.6–10.2)	

OA14.05: 5-year survival of pembrolizumab plus chemotherapy for metastatic NSCLC with PD-L1 tumor proportion score < 1%

Summary and Conclusions

- With ~5 years of follow-up in this pooled analysis, pembrolizumab plus chemotherapy provided clinically meaningful, durable improvements in OS, PFS, ORR, and PFS2 compared with chemotherapy alone in patients with previously untreated metastatic NSCLC with PD-L1 TPS <1% without *EGFR*/*ALK* alterations enrolled in KEYNOTE-189 and KEYNOTE-407
- Pembrolizumab plus chemotherapy had manageable safety
- Patients in this subgroup who completed 35 cycles (□2 years) of pembrolizumab experienced durable responses and 57% were alive 3 years after completion of 35 cycles (□5 years after randomization)
- These results continue to support pembrolizumab plus chemotherapy as a standard-of-care first-line therapy for metastatic NSCLC with PD-L1 TPS <1%

ORAL COMUNICATIONS

Immunotherapy-related biomarkers

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PD-L1

Other biomarkers

Digital vs manual

50-89% vs ≧ 90%

Pathologic response

Tumor transcriptomics

Blood

OA15.04: subgroup analysis IMpower110

OA14.04: ICI monotherapy

OA15.03: differential response

OA15.06: CALCULATION METHODS

OA09.03: STK11/LKB1

OA15.05: LIPI: Lung Immune Prognostic Index

Kirsty Lee, et al.

CONCLUSIONS

- **Impower 151:** Atezo + Beva + chemotherapy has no clear role in EGFR/ALK
- **ILLUMINATE:** Longer follow up and studies are needed: role of dual IO for EGFR mut NSCLC post-TKI progression
- Dual IO or pembro + chemotherapy. Consistent durable responses in PD-L1 negative
- Better biomarkers or combination of biomarkers are needed for ICI beyond genomic testing or PD-L1

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