Perspectives on *EGFR*-mutant and wildtype NSCLC: Tailoring treatment advances in late-stage disease

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EGFR-wildtype NSCLC: Advances in the treatment landscape for *EGFR*-wildtype NSCLC

Dr Helena Yu

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New York, NY, USA

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Overview of course content

Current module

1

***EGFR*-mutant NSCLC**

- Unmet needs
- Latest advances
- Practical insights

2

***EGFR*-wildtype NSCLC**

- Unmet needs
- Latest advances
- Practical insights

3

Bringing it together for optimal care

- Patient management
- Biomarker landscape
- Key learnings

EGFR, epidermal growth factor receptor; NSCLC, non-small cell lung cancer.

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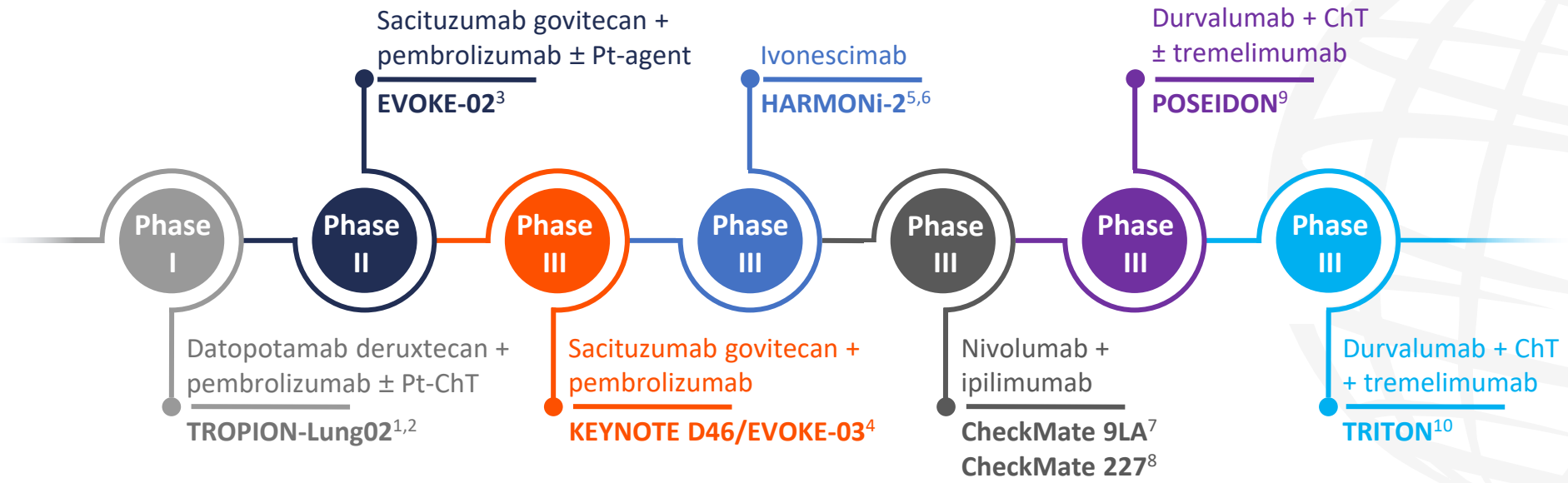
Key clinical trials in *EGFR*-WT NSCLC in the first line



Other ongoing trials of first-line datopotamab deruxtecan in this study population include: AVANZAR (NCT05687266), TROPION-Lung07 (NCT05555732) and TROPION-Lung08 (NCT05215340).
ChT, chemotherapy; *EGFR*-WT, epidermal growth factor receptor wildtype; NSCLC, non-small cell lung cancer; Pt, platinum.

1. Levy BP, et al. *J Clin Oncol.* 2024;42(Suppl. 16):8617; 2. ClinicalTrials.gov. NCT04526691; 3. Patel JD, et al. *J Clin Oncol.* 2024;42(Suppl. 16):8592; 4. ClinicalTrials.gov. NCT05609968;
5. ClinicalTrials.gov. NCT05499390; 6. Ryan C. OncLive. Available at: https://bit.ly/3Air5cA (accessed 10 September 2024); 7. Paz-Ares L, et al. *Lancet Oncol.* 2021;22:198–211;
8. Brahmer JR, et al. *J Clin Oncol.* 2022;41:1200–12; 9. Johnson ML, et al. *J Clin Oncol.* 202272;41:1213–27; 10. Skoulidis F, et al. *J Clin Oncol.* 2024;42(Suppl. 16):TPS8655.
All clinical trials searchable by NCT number. Available at: https://beta.clinicaltrials.gov/ (accessed 10 September 2024).

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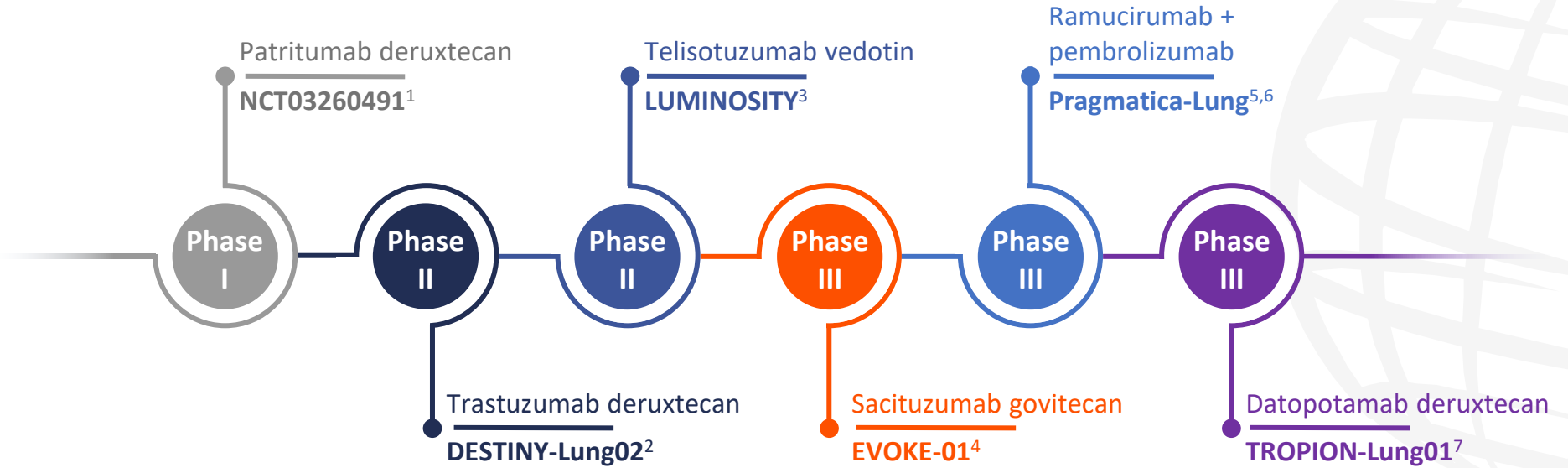
Key clinical trials in *EGFR*-WT NSCLC in the second line



EGFR-WT, epidermal growth factor receptor wildtype; NSCLC, non-small cell lung cancer.

1. ClinicalTrials.gov. NCT03260491; 2. Goto K, et al. *J Clin Oncol.* 2023;41:4852–63; 3. Camidge DR, et al. *J Clin Oncol.* 2024;42(Suppl. 16):103;
4. Paz-Ares LG, et al. *J Clin Oncol*. 2024;42:2860–72; 5. Reckamp KL, et al. *J Clin Oncol.* 2024;42(Suppl. 16):TPS8657;
6. ClinicalTrials.gov. NCT05633602; 7. Ahn M-J, et al. *Ann Oncol.* 2023;34(Suppl. 2):S1305–6.
All clinical trials searchable by NCT number. Available at: https://beta.clinicaltrials.gov/ (accessed 10 September 2024).

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EGFR-wildtype NSCLC: Insights from the latest data and strategies for improvement

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Chemoimmunotherapy: 5-year outcomes

CheckMate 9LA[1]

Phase III trial[2] in first-line stage IV or recurrent *EGFR*/*ALK*-WT NSCLC regardless of PD-L1 expression

Nivolumab + ipilimumab + ChT vs **ChT**

	N + I + ChT n=361	ChT n=358
At 5 years (median follow-up 64.5 months)		
OS, %	18	11
mOS, months	15.8	11.0
PFS, %	10	4
ORR, %	38	25
mDoR, months	12.4	5.6

POSEIDON[3]

Phase III trial in first line *EGFR*/*ALK*-WT stage IV NSCLC regardless of PD-L1 expression

Durvalumab + ChT ± tremelimumab vs **ChT**

	D + ChT + T	D + ChT	ChT
At 5 years (median follow-up 63.4 months)			
Non-squamous	**n=214**	**n=209**	**n=214**
mOS, months	17.2	14.8	13.0
Squamous	**n=124**	**n=128**	**n=122**
mOS, months	10.4	11.5	10.5

Long-term OS benefit with D + ChT + T **more pronounced with non-squamous** histology vs squamous histology

OS improvement **greater with triplet than with doublet** in the non-squamous population

Direct comparisons between trials should not be made due to differences in trial design.

ChT, chemotherapy; DoR, duration of response; m, median; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; WT, wildtype.

1. Reck M, et al. *J Clin Oncol.* 2024;42(Suppl. 16):8560; 2. Paz-Ares L, et al. *Lancet Oncol.* 2021;22:198–211;
3. Peters S, et al. Presented at: ESMO Immuno-Oncology 2023, Geneva, Switzerland. 6–8 December 2023. LBA3.

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Chemoimmunotherapy: 5-year outcomes

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Phase III trial[2] in first-line stage IV or recurrent *EGFR*/*ALK*-WT NSCLC regardless of PD-L1 expression

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mOS, months	17.2	14.8	13.0
Squamous	**n=124**	**n=128**	**n=122**
mOS, months	10.4	11.5	10.5
	n=330	**n=334**	**n=333**
All-cause SAEs, %	45.8	40.7	35.1
Serious TRAEs, %	27.6	19.8	17.7

Extended follow-up revealed no new safety signals

Direct comparisons between trials should not be made due to differences in trial design.

ChT, chemotherapy; DoR, duration of response; m, median; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; SAE, serious adverse event; TRAE, treatment-related adverse event; WT, wildtype.

1. Reck M, et al. *J Clin Oncol.* 2024;42(Suppl. 16):8560; 2. Paz-Ares L, et al. *Lancet Oncol.* 2021;22:198–211;
3. Peters S, et al. Presented at: ESMO Immuno-Oncology 2023, Geneva, Switzerland. 6–8 December 2023. LBA3.

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Chemoimmunotherapy: 5-year outcomes

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Ongoing phase III trial: TRITON[4]

Durvalumab + ChT + tremelimumab vs **pembrolizumab + ChT** in hard-to-treat patients[2] with NSQ *EGFR*/*ALK*-WT metastatic NSCLC with *STK11* and/or *KEAP1* and/or *KRAS* mutations

Primary completion: August 2027[5]

Direct comparisons between trials should not be made due to differences in trial design.

ALK, anaplastic lymphoma kinase; ChT, chemotherapy; DoR, duration of response; EGFR, epidermal growth factor receptor; KEAP1, kelch like ECH associated protein 1; KRAS, Kirsten rat sarcoma viral oncogene homolog; m, median; NSCLC, non-small cell lung cancer; NSQ, non-squamous; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; STK11, serine/threonine kinase 11; WT, wildtype.

1. Reck M, et al. *J Clin Oncol.* 2024;42(Suppl. 16):8560; 2. Paz-Ares L, et al. *Lancet Oncol.* 2021;22:198–211; 3. Peters S, et al. Presented at: ESMO Immuno-Oncology 2023, Geneva, Switzerland. 6–8 December 2023. LBA3; 4. Skoulidis F, et al. *J Clin Oncol.* 2024;42(Suppl. 16):TPS8655; 5. ClinicalTrials.gov. NCT06008093. Available at: https://clinicaltrials.gov/study/NCT06008093 (accessed 10 September 2024).

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Ivonescimab: A PD-1/VEGF bispecific antibody[1]

HARMONi-2: Phase III trial of ivonescimab vs pembrolizumab (conducted in China)[1,2]

Trial population

- Locally advanced or mNSCLC[1–3]
- PD-L1-positive[1,2] (PD-L1 TPS ≥1%)[3]
- *EGFR*/*ALK* wildtype[1,2]
- No prior systemic treatment[1,2]
- ECOG PS 0 or 1[1,2]
- Adequate organ function[1,2]

Primary efficacy outcome: PFS by blinded IRRC[2]

- **Primary endpoint met at a prespecified interim analysis**[1]
- Ivonescimab monotherapy demonstrated a statistically significant and clinically meaningful improvement in PFS vs pembrolizumab monotherapy[1]
- PFS benefit was also observed in different subgroups, including patients with a PD-L1 TPS 1–49%, a PD-L1 TPS ≥50%, squamous histology, non-squamous histology, and other high-risk features[1]
- The safety profile was manageable and consistent with treatments intended to inhibit PD-1 and VEGF[1]

Ongoing phase III trial: HARMONi-3[4]

Ivonescimab for first-line treatment of patients with metastatic squamous NSCLC

Primary completion: September 2027

ECOG PS, Eastern Cooperative Oncology Group performance status; IRRC, independent radiology review committee; mNSCLC, metastatic non-small cell lung cancer; PD-1, programmed cell death 1; PD-L1, programmed death-ligand 1; PFS, progression-free survival; TPS, tumour proportion score; VEGF, vascular endothelial growth factor.

1. Ryan C. OncLive. Available at: https://bit.ly/3Air5cA (accessed 31 July 2024); 2. ClinicalTrials.gov. NCT05499390;
3. PR Newswire. Available at: https://prn.to/3LUJEWW (accessed 10 September 2024); 4. ClinicalTrials.gov. NCT05899608.
All clinical trials searchable by NCT number. Available at: https://beta.clinicaltrials.gov/ (accessed 10 September 2024).

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ADCs targeting TROP2 in the first-line setting

EVOKE-02[1]

Phase II multi-cohort trial in first-line metastatic NSCLC with no actionable genomic alterations

Sacituzumab govitecan + pembrolizumab ± Pt-ChT

Efficacy by histology	PD-L1 TPS ≥50%	PD-L1 TPS <50%
Non-squamous	**n=18**	**n=19**
ORR,* %	67	37
DCR, %	89	74
Squamous	**n=11**	**n=13**
ORR,* %	73	54
DCR, %	82	85

Median DOR was not reached in either cohort

TROPION-Lung02[2]

Phase Ib trial in advanced/metastatic NSCLC (Subgroup analysis: First-line therapy)

Datopotamab deruxtecan + pembrolizumab ± Pt-ChT

Subgroup analysis	Doublet	Triplet
All patients	**n=42**	**n=54**
ORR, %	52	56
mPFS, months	11	7
PD-L1 TPS ≥50%	**n=5**	**n=15**
ORR, %	100	53
mPFS, months	NE	7
PD-L1 TPS <50%	**n=37**	**n=39**
ORR, %	46	56
mPFS, months	9	7

Direct comparisons between trials should not be made due to differences in trial design.

*By investigator assessment. ADC, antibody–drug conjugate; DCR, disease control rate; DOR, duration of response; mPFS, median progression-free survival; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD-L1, programmed death-ligand 1; Pt-ChT, platinum-based chemotherapy; TPS, tumour proportion score; TROP2, trophoblast cell surface antigen 2. 1. Capuzzo F, et al. *Ann Oncol.* 2024;9(Suppl. 3):60P; 2. Levy BP, et al. *J Clin Oncol.* 2024;42(Suppl. 16):8617.

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ADCs targeting TROP2 in the first-line setting

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Efficacy by histology	PD-L1 TPS ≥50%	PD-L1 TPS <50%
Non-squamous	**n=18**	**n=19**
ORR,* %	67	37
DCR, %	89	74
Squamous	**n=11**	**n=13**
ORR,* %	73	54
DCR, %	82	85

Any-grade TEAEs reported in 100% of patients in the safety population (n=63); grade ≥3, 70%

TROPION-Lung02[2]

Phase Ib trial in advanced/metastatic NSCLC (Subgroup analysis: First-line therapy)

Datopotamab deruxtecan + pembrolizumab ± Pt-ChT

Subgroup analysis	Doublet	Triplet
All patients	**n=42**	**n=54**
ORR, %	52	56
mPFS, months	11	7
Stomatitis,† %	57	33
Nausea,† %	40	46
Grade ≥3 TEAEs, %	57	76
Serious TEAEs, %	38	44
TEAEs associated with discontinuation, %	29	39

Direct comparisons between trials should not be made due to differences in trial design. *By investigator assessment. †Most common any-grade TEAEs (mainly grade 1 and 2). ADC, antibody–drug conjugate; DCR, disease control rate; mPFS, median progression-free survival; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD-L1, programmed death-ligand 1; Pt-ChT, platinum-based chemotherapy; TEAE, treatment-emergent adverse event; TPS, tumour proportion score; TROP2, trophoblast cell surface antigen 2.

1. Capuzzo F, et al. *Ann Oncol.* 2024;9(Suppl. 3):60P; 2. Levy BP, et al. *J Clin Oncol.* 2024;42(Suppl. 16):8617.

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ADCs targeting TROP2 in the second-line setting

EVOKE-01[1]

Phase III trial in stage IV NSCLC with progression on/after Pt-ChT ± anti-PD-(L)1 or targeted treatment for AGA

Sacituzumab govitecan vs docetaxel

	SG n=299	Docetaxel n=304
Median follow-up 12.7 months		
mOS, months*	11	10
mPFS, months	4	4
ORR, %	14	18
	n=296	**n=288**
Any-grade TRAEs, %	94	91
Grade ≥3 TRAEs, %	67	60
TRAEs leading to discontinuation, %	7	14

TROPION-Lung01[2]

Phase III trial in stage IIIB, IIIC or IV NSCLC with or without AGA

Datopotamab deruxtecan vs docetaxel

Non-squamous population	Dato-Dxd n=234	Docetaxel n=234
Median follow-up ~10–12 months		
Interim mOS, months*	13	11
mPFS, months*	6	4
ORR, %	31	13
	n=232	**n=221**
Any-grade TRAEs, %	88	88
Grade ≥3 TRAEs, %	22	41
TRAEs leading to discontinuation, %	9	12

Direct comparisons between trials should not be made due to differences in trial design. *Primary endpoint(s).
ADC, antibody–drug conjugate; AGA, actionable genomic alteration; mOS, median overall survival; mPFS, median progression-free survival; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD-(L)1, programmed death-(ligand) 1; Pt-ChT, platinum-based chemotherapy; TRAE, treatment-related adverse event; TROP2, trophoblast cell surface antigen 2.

1. Paz-Ares LG, et al. *J Clin Oncol.* 2024;42:2860–72; 2. Girard N, et al. Presented at: ELCC 2024, Prague, Czech Republic. 20–23 March 2024. 59P.

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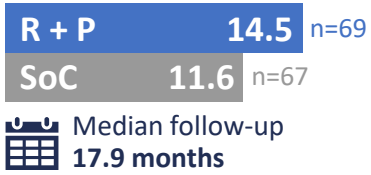
Combination therapy in the second line: ICI + VEGFRi[1]

Lung-MAP S1800A: Phase II randomized trial of ramucirumab + pembrolizumab vs SoC[1]

Trial population: Stage IV or recurrent NSCLC[1]

Received ≥1 line of anti-PD-(L)1 therapy for stage III, IV, or recurrent NSCLC, ≤1 line of anti-PD-(L)1 therapy for stage IV or recurrent disease (sequentially or combined); must have received Pt-ChT

mOS, months



Treatment-related deaths	4% (3/69)	vs	7% (4/60)
Grade 4 TRAEs	6% (4/69)	vs	25% (15/60)

S2302/Pragmatica-Lung (follow-on from Lung-MAP S1800A): Phase III randomized, registration-intent trial of ramucirumab + pembrolizumab vs SoC[2,3]

Trial population: Stage IV or recurrent NSCLC[2]

- Received ≥1 line of anti-PD-(L)1 therapy for any stage of NSCLC, given sequentially or in combination with other therapy; disease progression >84 days following initiation of most recent anti-PD-(L)1 therapy
- Must have received Pt-ChT with disease progression during or after this regimen
- Patients with a known AGA must have received ≥1 prior approved therapy

Primary outcome: Overall survival[2,3]

- Secondary outcomes: Serious TRAEs, unexpected grade 3 or 4 TRAEs and all grade 5 AEs[3]
- Estimated enrolment: 700[2,3]
- Primary completion: March 2025[2]

AE, adverse event; AGA, actionable genomic alteration; ICI, immune checkpoint inhibitor; mOS, median overall survival; NSCLC, non-small cell lung cancer; PD-(L)1, programmed death-(ligand) 1; Pt-ChT, platinum-based chemotherapy; R + P, ramucirumab + pembrolizumab; SoC, standard of care; TRAE, treatment-related AE; VEGFRi, vascular endothelial growth factor receptor inhibitor.

1. Reckamp KL, et al. *J Clin Oncol.* 2022;40:2295–307; 2. ClinicalTrials.gov. NCT05633602; 3. Reckamp KL, et al. *J Clin Oncol.* 2024;42(Suppl. 16):TPS8657.

All clinical trials searchable by NCT number. Available at: https://beta.clinicaltrials.gov/ (accessed 10 September 2024).

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EGFR-wildtype NSCLC: Practical insights and implications for NSCLC practice

Dr Sara Pilotto

University of Verona
Verona, Italy

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Patient case: Initial presentation

Patient demographics

Age: 52 years

Sex: Female

Ethnicity: Caucasian

Occupation: Primary school teacher

Medical history

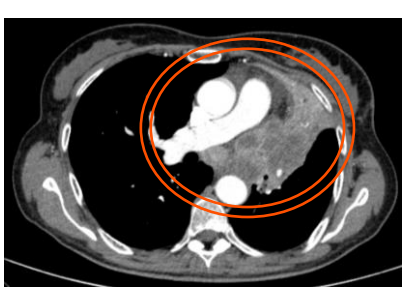
Current smoker (20 p/y)

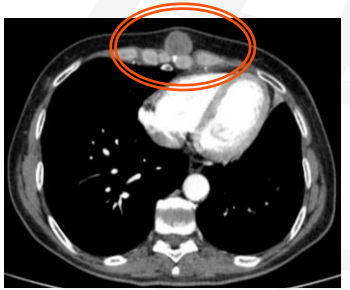
No reported comorbidities

Disease diagnosis

Symptomatic with cough and chest pain

ECOG PS 1





Lung adenocarcinoma [cT4 N2 M1c, **stage IVB** – TNM 8th edition]
PD-L1 negative – SP263
Molecular testing [NGS analysis - 324 genes]
KRAS p.Q61H, ***STK11*** p.Y60fs*1, ***KEAP1*** p.M409fs*42
TMB 0 muts/Mb

Images courtesy of Dr S. Pilotto.
ECOG PS, Eastern Cooperative Oncology Group performance status; KEAP1, kelch like ECH associated protein 1; KRAS, Kirsten rat sarcoma viral oncogene homolog; NGS, next-generation sequencing; p/y, packs per year; PD-L1, programmed death-ligand 1; STK11, serine/threonine kinase 11; TMB, tumour mutation burden.

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Guideline recommendations: First-line therapy

ESMO 2023[1]

Stage IV non-squamous NSCLC
Molecular tests negative
ECOG PS 0–1, any expression of PD-L1

No contraindication to immunotherapy

- Pembro–Pt–pemetrexed → Pembro–pemetrexed
- Atezo–carboplatin–nab-paclitaxel → Atezo
- Atezo–beva–carboplatin–paclitaxel → Atezo–beva
- Nivo–ipi–Pt-doublet ChT → Nivo–ipi
- Cemiplimab–Pt-doublet ChT → Cemiplimab + pemetrexed*
- Durva–trem–Pt-doublet ChT → Durva–trem + pemetrexed*
- Nivo–ipi (only PD-L1 ≥1%)

With contraindication to immunotherapy

- Pt-doublet ChT → pemetrexed*
- Carboplatin–paclitaxel–beva → beva*
- Pt–pemetrexed–beva → pemetrexed–beva*

NCCN 2024[2]

Advanced or metastatic adenocarcinoma, large cell,
or NSCLC not otherwise specified
ECOG PS 0–1, PD-L1 <1%

No contraindication to PD-1 or PD-L1 inhibitors

Preferred

- Pembro–carboplatin–pemetrexed
- Pembro–cisplatin–pemetrexed
- Cemiplimab-rwlc–pemetrexed–(carboplatin or cisplatin)

With contraindication to PD-1 or PD-L1 inhibitors

Useful in certain circumstances

- Beva–carboplatin–paclitaxel
- Carboplatin-combination therapy
- Cisplatin-combination therapy
- Gemcitabine–docetaxel
- Gemcitabine–vinorelbine

*Maintenance.
→, followed by; atezo, atezolizumab; beva, bevacizumab; ChT, chemotherapy; durva, durvalumab; ECOG PS, Eastern Cooperative Oncology Group performance status; ipi, ipilimumab; nivo, nivolumab; NSCLC, non-small cell lung cancer; pembro, pembrolizumab; PD-1, programmed cell death protein 1; PD-L1; programmed death-ligand 1; Pt, platinum; trem, tremelimumab. 1. Hendriks LE, et al. *Ann Oncol.* 2023;34:358–76; 2. NCCN Clinical Practice Guidelines in Oncology. NSCLC Version 9.2024 — September 9, 2024. Available at: NCCN.org (accessed 11 September 2024).

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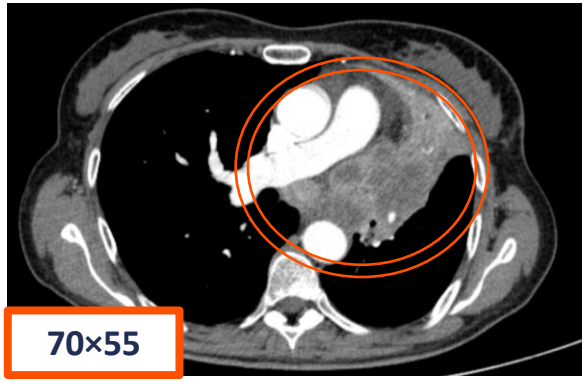
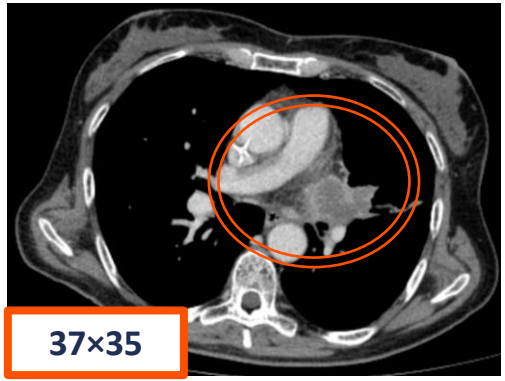
Patient case: First-line treatment

cisplatin-pemetrexed-pembro (× 4) → **pemetrexed-pembro maintenance** (× 2)



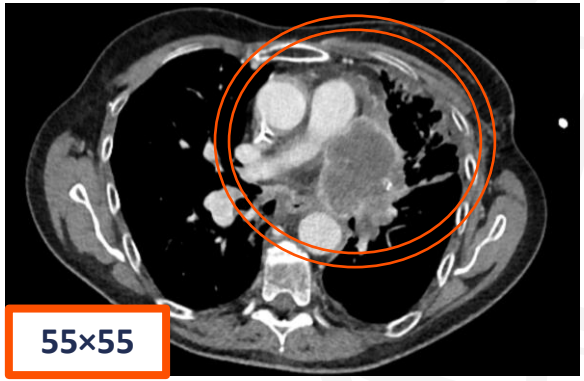
Nov 2023



Jan 2024

PR (–36%)

ECOG PS 0, symptom improvement



Mar 2024

PD (+57%)

ECOG PS 1, worsening of symptoms, weight loss

PFS 5 months

Images courtesy of Dr S Pilotto.

ECOG PS, Eastern Cooperative Oncology Group performance status; PD, progressive disease; pembro, pembrolizumab; PFS, progression-free survival; PR, partial response.

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Guideline recommendations: Second-line therapy

ESMO 2023[1]

Stage IV non-squamous NSCLC
Molecular tests negative

ECOG PS 0–2

- Pemetrexed
- Docetaxel
- Nintedanib–docetaxel
- Ramucirumab–docetaxel
- ICI re-challenge (if no contraindication to immunotherapy)

ECOG PS 3–4: Best supportive care

NCCN 2024[2]

Advanced or metastatic adenocarcinoma, large cell, or NSCLC not otherwise specified

No previous immunotherapy; ECOG PS 0–2

Preferred

- Nivolumab
- Pembrolizumab (PD-L1 ≥1%)
- Atezolizumab

Previous or no previous immunotherapy

Recommended (if not previously given)

- Docetaxel
- Pemetrexed
- Gemcitabine
- Ramucirumab–docetaxel
- Albumin-bound paclitaxel
- Fam-trastuzumab deruxtecan-nxki (HER2 overexpression; IHC 3+)

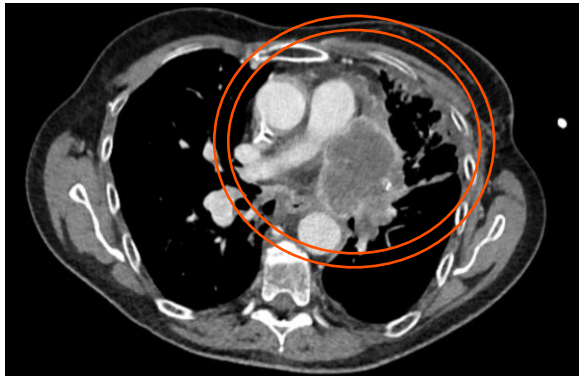
ECOG PS 3–4: Best supportive care

ECOG PS, Eastern Cooperative Oncology Group performance status; HER2, human epidermal growth factor receptor 2; ICI, immune checkpoint inhibitor; IHC, immunohistochemistry; NSCLC, non-small cell lung cancer; PD-L1, programmed death-ligand 1.

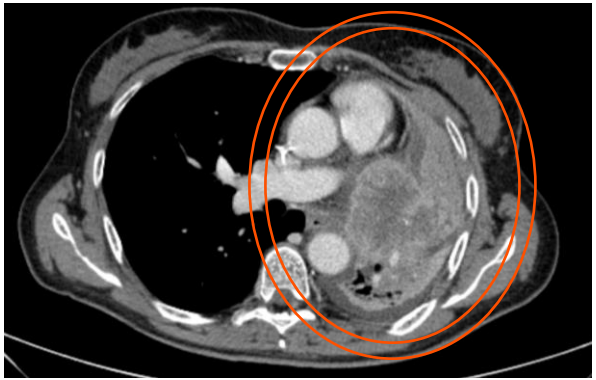
1. Hendriks LE, et al. *Ann Oncol.* 2023;34:358–76; 2. NCCN Clinical Practice Guidelines in Oncology. NSCLC Version 9.2024 — September 9, 2024. Available at: NCCN.org (accessed 11 September 2024).

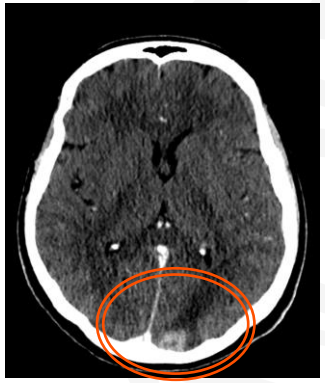
Patient case: Second-line treatment

Docetaxel (× 3)



Mar 2024





Jun 2024

Lung and brain progression

ECOG PS 3, worsening of symptoms, weight loss

PFS 3 months

Images courtesy of Dr S Pilotto.
ECOG PS, Eastern Cooperative Oncology Group performance status; PFS, progression-free survival.

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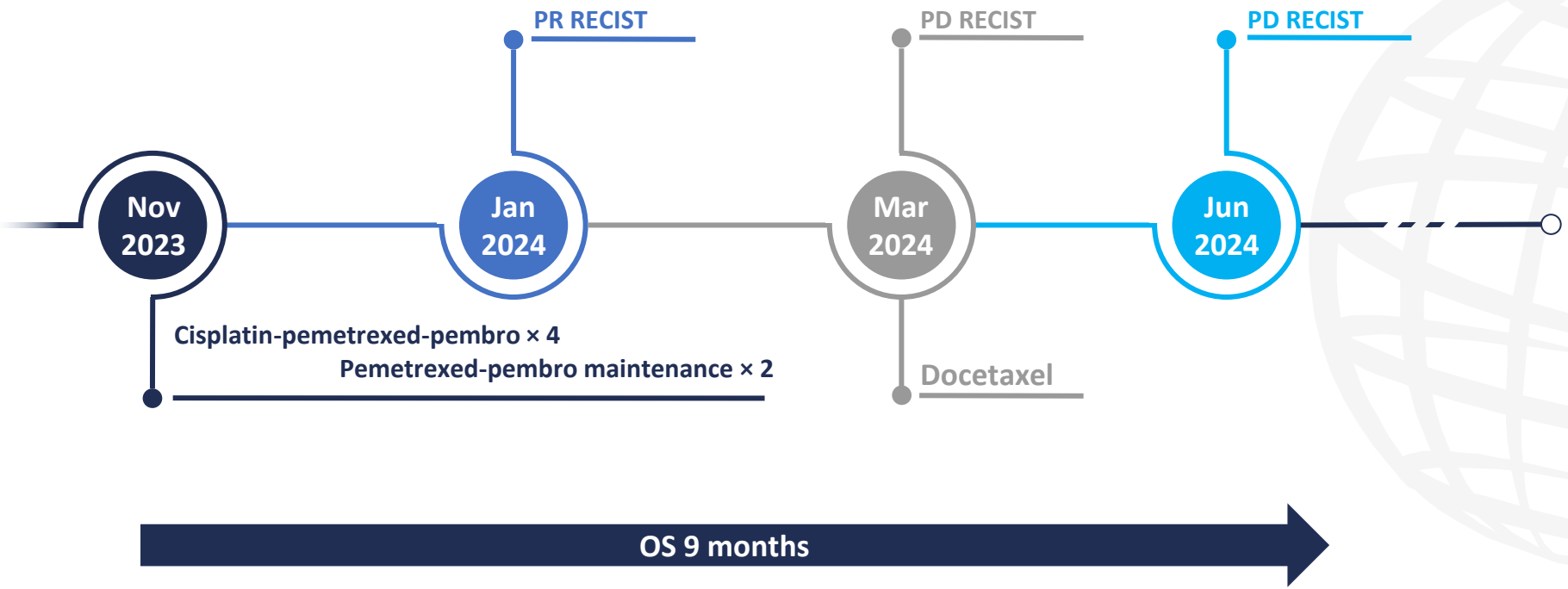
Patient case: Summary timeline



OS, overall survival; PD, progressive disease; pembro, pembrolizumab; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumours.

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