Amivantamab with lazertinib for untreated EGFR mutation-positive advanced non-small-cell lung cancer

For projection – confidential information redacted

Technology appraisal committee D [12th November 2025]

Chair: Raju Reddy

External assessment group: Sheffield Centre for Health and Related Research (SCHARR)

Technical team: Harsimran Sarpal, George Millington, Samuel Slayen, Emily Crowe

Company: Johnson & Johnson

Amivantamab with lazertinib for untreated EGFR mutation-positive advanced non-small-cell lung cancer

- ✓ **Background and key issues**
- ❑ Updated Clinical data from FLAURA 2
- ❑ Modelling and cost effectiveness
- ❑ Other considerations
- ❑ Summary

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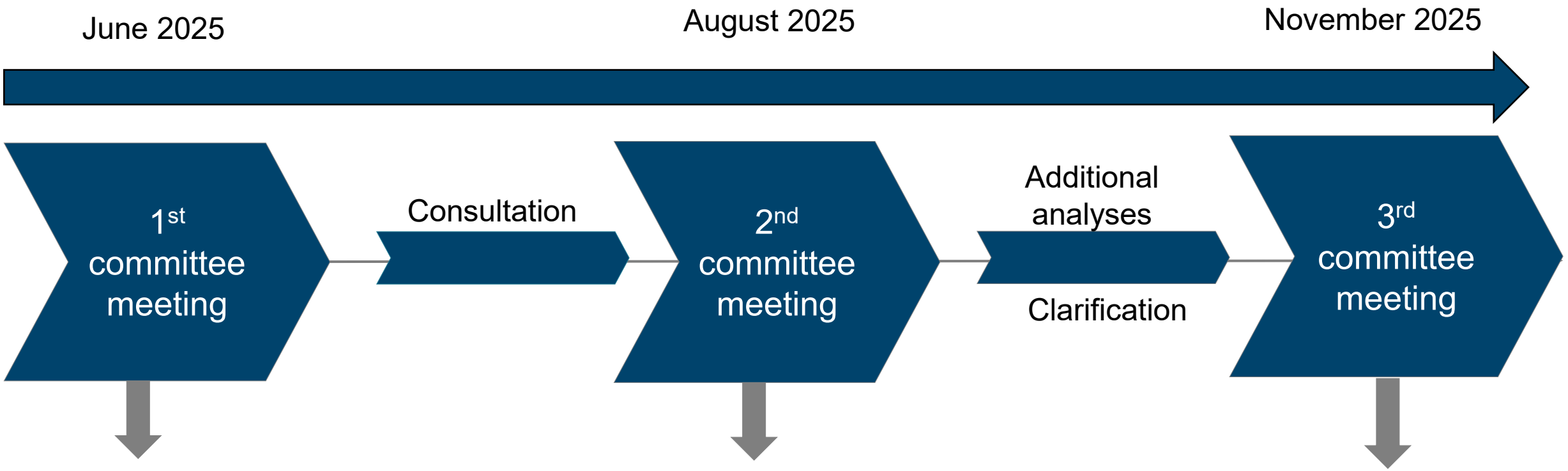
History of evaluation



Uncertainties:

- Osi-chemo not included as a comparator
- Generalisability of MARIPOSA and PFS not used latest data cut

High level of uncertainty:

- Added osi-chemo as comparator
- Requested additional ITC methods
- Requested updated OS data and explore utilities, TTD and subsequent treatments

Updated analyses

- Re-assessment of survival assumptions using updated comparator data and alternate ITC methods
- ITC comparison of AEs
- Updated PAS for Ami-laz

Abbreviations: AE, adverse events; ITC, indirect-treatment comparison; OS, overall survival; PAS, patient access scheme; PFS, progression-free survival; TTD, time to treatment discontinuation

Draft guidance recommendation

Amivantamab plus lazertinib should not be used for untreated advanced non-small-cell lung cancer (NSCLC) in adults whose tumours have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations

ACM 2 – uncertainties and requested information

		Committee requested information	Addressed?	ICER impact	
				OSI	Osi-chemo
ITCs of OS/PFS		• To explore ITCs which allow for both time-varying hazards and population adjustment	Yes	Small	Large
ITC	**Adverse events**	• Adverse events profiles of both treatments compared and modelled or a full explanation if not possible	Yes	Unknown	Unknown
	TTD	• Explore modelling based upon ITC compared TTD values for comparison with osi-chemo	Yes	N/A	Large
OS	**Extrapolation**	• Effect of different OS extrapolations for osi-mono and osi-chemo	Yes	Moderate	Large
Utility values	**PF**	• Explore different progression-free utility values for 3 treatment arms	Partially	Small	Moderate
	PD	• TA1060 more appropriate than MARIPOSA • Explore differences in utility due to different subsequent treatments between arms			
Subsequent treatments		• Align with its preferred assumptions at 2nd & 3rd line scenarios and explore scenarios	No	Small	Moderate

EAG and company base cases are aligned on all parameters. EAG provide additional scenarios to explore uncertainty in some parameters.

Abbreviations: AE, adverse events; ITC, indirect-treatment comparison; OS, overall survival; PF, progression-free; PFS, progression-free survival; PD, progressed disease; TA, technology appraisal; TTD, time to treatment discontinuation

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Updated OS results: FLAURA2 (June 2025)

Company

- Osi-chemo demonstrated a statistically significant improvement in OS compared with osi-mono with a median follow of 51.2 months
- Increasing hazard ratio and persistent narrowing of curves around 39 months suggest uncertainty around the long-term durability of survival benefit See slide

	DCO: 12th June 2025		DCO: 8th January 2024	
	Osi-chem (N=279)	Osi-mono (N=278)	Osi-chemo (N=279)	Osi-mono (N=278)
Event, n (%)	144 (51.6)	171 (61.5)	100 (35.8)	126 (45.3)
mOS, months (95% CI)	47.5 (41.0, NC)	37.6 (33.2, 43.2)	NR (38.0, NC)	36.7 (33.2, NC)
HR (95% CI)	0.77 (0.61, 0.96)		0.75 (0.57, 0.97)	
p-value	0.0202		0.0280	

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Abbreviations: AE, adverse event; CI, confidence interval; DCO, data cut-off; HR, hazard ratio; mOS, median overall survival; NC, not calculable; OS, overall survival

Relative proportion Grade ≥3 AEs & SAEs in MARIPOSA & FLAURA2

Company

- Osi-chemo has a higher relative incidence of Grade ≥3 AEs and SAEs compared to ami-laz
- AEs comparable in both trials with most taking place in 1st 4 months, indicating being time-dependent rather than combination dependent
- COCOON trial shows dermatologic management reduces burden of skin AEs with ami-laz. This management is available in routine practice and would reduce AE profile of ami-laz

	MARIPOSA		FLAURA2	
	Ami-laz	OSI	Osi-Chemo	Osi
Median follow-up, months	38		51	
Grade ≥3 AEs, %	80	52	70	34
% difference, intervention vs. comparator arm	+54		+106	
SAEs, %	55	41	46	27
% difference, intervention vs. comparator arm	+34		+70	

EAG

- AEs of ami-laz and osi-chemo appear to be different → ami-laz associated with a higher Grade ≥3 AEs (rash, paronychia, IRRs and DVT) while osi-chemo associated with higher rates of Grade ≥3 anaemia, neutropenia and thrombocytopenia
- For osi-mono from FLAURA2 and MARIPOSA, rates of Grade ≥3 events, SAE and treatment discontinuations differed suggesting people in MARIPOSA more prone to having a SAE or Grade ≥3 AEs

Abbreviations: AE, adverse events; IRRs, infusion-related reactions; DVT; deep-vein thrombosis; SAE, serious adverse events

Key Issue: Indirect treatment comparison for PFS, OS and TTD 1/3

ICER Impact: Large

Background

- Committee requested exploration of time-varying hazards and population adjustment, including MAICs, parametric ITC, FP and piecewise Cox models and ML-NMR

Company

- Piecewise Cox, Fractional polynomial models and parametric ITCs are not appropriate, and did not explore ML-NMR (it would not add benefit in a simple network with one target population):
  - Piecewise Cox: HR fluctuate and is unstable with wide confidence intervals
  - FP model: do not capture complexity → unsuitable for decision making
  - Parametric ITCs: unstable because long-term OS in FLAURA2 shows complex hazard over time
- Used unanchored MAIC in its base case → clinically plausible results with greater certainty than the other methods
- OS, PFS and TTD of ami-laz and osimertinib modelled by fitting standard parametric and spline-based distributions to MARIPOSA data weighted with MAIC-derived weights
- OS, PFS and TTD for Osi-chemo modelled with distributions fitted individually to FLAURA2 data without any adjustment → ensuring FLAURA2 was used as the target population

Abbreviations: AE, adverse events; FP, fractional polynomial; HR, hazard ratio; ITC, indirect-treatment comparison; MAIC, matching-adjusted indirect comparison; ML-NMR, Multilevel network meta-regression; NMA, network meta-analysis; OS, overall survival; PFS, progression-free survival; TTD, time to treatment discontinuation

Key Issue : Indirect treatment comparison PFS, OS and TTD 2/3

ICER Impact: Large

EAG align with the company's base case

EAG

- Company's unanchored MAICs are appropriate as they allow for population adjustment, accommodate time-varying HRs and allow for extrapolation of all arms in a FLAURA2 like population
- But the unanchored MAICs do not provide a hazard ratio estimate of relative clinical effectiveness for ami-laz vs. osi-chemo
- Anchored MAICs adjust for population differences between MARIPOSA and FLAURA2 but require the PH assumption, which is violated
- Parametric ITC, fractional polynomial ITC using parametric models, piecewise Cox regression models and fractional polynomial ITC using Cox regression do not adjust for population differences between MARIPOSA and FLAURA2
- Overall, EAG does not prefer any alternative ITC method over the company's base case but the EAG included both parametric ITC and fractional polynomial ITC using Cox regression as part of its scenario analyses (noting the limitations of these approaches)

Abbreviations: HR, hazard ratio; ITC, indirect-treatment comparison; MAIC, matching-adjusted indirect comparison; OS, overall survival; PH, proportional hazard; PFS, progression-free survival; TTD, time to treatment discontinuation

Key Issue : ITC - PFS, OS and TTD 3/3

ICER Impact: Large

ITC Method	Population adjustment?	Time-varying HR?	Advantages	Drawbacks
Anchored MAIC	Y	N	Retains randomisation	Not suitable as PH assumption doesn't hold.
Unanchored MAIC – **both base cases**	Y	Y	Allows extrapolation for all treatments in FLAURA2 population	Breaks randomisation
Company ACM2 HR adjustment	Y	N	Simple	Requires PH assumption
EAG ACM2 naïve comparison	N	Y	Simple	High risk of bias, descriptive only
Parametric ITC **[Scenario]**	N	Y	Can model long term extrapolation consistently	Requirement for same parametric distribution (often poor/implausible fits)
Piecewise Cox regression **[Scenario]**	N	Y	Relaxes constant HR assumption	Relies on last HR carried forward (implausible)
Fractional polynomial ITC (Cox regression) **[Scenario]**	N	Y	Better estimate of the hazard ratio	Modelled HR can show different trend to smoothed time-dependent HR
Fractional polynomial ITC (parametric)	N	Y	Flexible	Provide extreme estimates to the hazard function or inadequate fit to KM

Base cases

See scenario ASA5 – Demonstrates implausibility of using same curves

Abbreviations: HR, hazard ration; ITC, indirect-treatment comparison; MAIC, matching-adjusted indirect comparison; OS, overall survival; PH, proportional hazard

Which ITC is preferred for decision making?

Key Issue: Indirect treatment comparison: Safety

ICER Impact: Unknown

Background

- Explore adjusted comparison of AEs of ami+ laz compared with osi-chemo

Company

- Difference in MOA results in distinct safety profiles and adverse event patterns for each regimen
- Explored comparative safety using a Bayesian NMA: results indicate osi-chemo has worse safety profile than ami-laz for both Grade ≥3 AEs and SAEs with 80% probability
- Further anchored MAIC was applied to the Bayesian and matched baseline characteristics results suggesting trend in favour of ami-laz for SAEs and favourable results for Grade ≥3 AEs

Type	Intervention	Osi-chemo (OR)
Grade 3	OSI	[redacted]
	Ami-laz	[redacted]
SAE	OSI	[redacted]
	Ami-laz	[redacted]

Odds ratios of different types of AEs compared to osi-chemo

EAG

- OR of ami-laz vs. osi-chemo favours ami-laz for Grade ≥3 AEs and for SAEs but credible intervals for OR cross 1
- Noted similarity between the adjusted and unadjusted ORs suggests a minor impact on results
- Consider the company's ITC analysis appropriate

What are the committee's views of the safety profiles of ami-laz vs. osi-chemo?

See: Unanchored MAICs results

Abbreviations: AE, adverse events; MAIC, matching-adjusted indirect comparison; MOA, mechanism of action; NMA, network meta-analysis; OR, odds ratio; SAE, serious adverse events

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Key Issue: Longer term modelling of osi-chemo

ICER Impact: Large

Company: ami-laz is likely to have a survival benefit over osi-chemo

Company

- Updated FLAURA2 data informs unanchored MAIC
- Fitted standard parametric and spline models to inform the osi-chemo extrapolation
- Selected 2-knot hazard spline model for osi-chemo extrapolation based on updated FLAURA2 OS data, time-dependent smoothed hazards of observed data, visual inspection, AIC, BIC and clinical validation
- Clinical experts thought other spline models gave clinically implausible long term survival estimates

EAG comments

- Use the 2-knot hazard spline in base case
- 2-knot odds & 2-knot normal spline also plausible based on AIC/BIC, visual fit, hazard plots and clinical plausibility
- AIC/BIC were almost identical across 3 models, but long-term prediction slightly differed
- Hazard plots for 2-knot odds & 2-knot normal spline model show a decreasing tail of smoothed hazard plot, while hazard plot from 2-knot hazard model has an increasing tail
- Due to uncertainty consider 2-knot hazard, odds and normal spline models plausible
- Provided a scenario for extrapolation of OS for osi-chemo using a 2-knot normal spline model showing a big impact on incremental QALYs

Which model is most appropriate for osi-chemo OS extrapolation?

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Abbreviations: AIC, Akaike information criterion, BIC, Bayesian Information Criterion; CP, chemotherapy; KM, Kaplan-Meier MAIC, matching-adjusted indirect comparison; OS, overall survival; QALY, quality-adjusted life years

ICER Impact: Large

EAG scenario: Comparison of long-term OS extrapolations with company base case

EAG comments

- 2-knot normal spline scenario → more favourable long-term extrapolation for osi-chemo 12.3% vs 8.4% (10-year survival) and reflecting long-term survival for osi-chemo similar to Weibull for ami-laz

Key issue: Utility values

ICER Impact: Moderate

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Background

- Explore progression-free utilities for 3 treatment arms and use TA1060 progressed utilities
- Explore differences in subsequent treatments between arms

		Company & EAG	Scenario
PF	Ami-laz	[redacted]	[redacted]
	Osi-mono	[redacted]	[redacted]
	Osi-chemo	[redacted]	[redacted]
PD (TA1060)		0.678	0.678

Company

- Using higher treatment-specific PF utility for osi-mono, while assuming equal PF HSUVs for ami-laz and osi-chemo is conservative → a more favourable safety profile for ami-laz vs. osi-chemo;
  - FLAURA2 may underestimate Grade ≥3 AEs and serious AEs (as osi-mono AEs lower than in MARIPOSA)
  - Fewer AEs with SC versus IV amivantamab, with less time spent in clinical setting
  - enhanced dermatological management due to reduce dermatological AEs
- Used value from TA1060 as requested but maintain that MARIPOSA is most appropriate source as it matches efficacy data

EAG comments

- Agree with the company's rationale for lower osi-chemo utilities and higher utilities for ami-laz in clinical practice than MARIPOSA but unclear about the size of utility gain. It is likely conservative but the magnitude is unclear.
- Disagreed with company's pooled HSUV (0.794) scenario → unable to verify & reasoning not supported by evidence:
- Preferred to use treatment-dependent PF utility estimates from MARIPOSA in its base case in line with ACM2 and same utility values for ami-laz and osi-chemo but considers magnitude of any difference is uncertain
- Notes company has not explored improving PD utilities for osi-chemo patients who discontinue pemetrexed or having different utilities to reflect the differing subsequent treatments

Which progression free utility values should be used for each arm?

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Abbreviations: AE, adverse events; HSUV, health state utility values; OS, overall survival; PF, progression-free; PFS, progression-free survival; PD, progressed disease; TA, technology appraisal; *EAG model both values in different scenarios

Key Issue: Time to treatment discontinuation

ICER Impact: Large

Background

- Request to explore modelling based upon ITC compared TTD values for comparison with osi-chemo

Company

- Selected a higher TTD for osimertinib component of osi-chemo than suggested by EAG at ACM2
- Used average of Gompertz and gamma curves in line with clinical validation, visual fits, and curve comparison with osi-mono TTD, osi-chemo PFS and osi-chemo OS

EAG comments

- No new TTD data to inform extrapolation and company choice unchanged from ACM2
- Aligned its base case with the company choice of TTD curve and provided scenario using its preferred approach at ACM2 (Gompertz capped at osi-mono TTD)
- Using average of the Gompertz and the gamma extrapolations for TTD has a bigger gap to osi-chemo PFS compared to the gap for the capped Gompertz extrapolation
- Note that when using the exploratory scenario 5 (parametric ITC) the same distribution is required for each arm. The distributions chosen result in much lower discontinuation for the osimertinib component of osi-chemo, higher costs for osi-chemo and a lower ICER for ami-laz

Which curves should be used to extrapolate TTD for each arm?

Abbreviations: ITC, indirect-treatment comparison; OS, overall survival; PFS, progression-free survival; TTD, time to treatment discontinuation

Key Issue: Time to treatment discontinuation

Which curves should be used to extrapolate TTD for each arm?

Abbreviations: ITC, indirect-treatment comparison; OS, overall survival; PFS, progression-free survival; TTD, time to treatment discontinuation

Key issue: subsequent treatments

ICER Impact: Moderate

Background

- EAG's assumption 50% of treatment at 2nd line platinum-based chemotherapy and 50% docetaxel
- Explore the proportion of nintedanib use with docetaxel and proportion of people using ABCP at 3rd line

Company

- Updated subsequent treatments at 2nd line + → 50% platinum chemo and 50% docetaxel at 2nd line for 3 treatment arms
- 100% BSC at 3rd line

EAG comments

- Assuming 50% platinum chemo and 50% docetaxel for all arms misunderstood request
- EAG used 100% of 2nd line as platinum chemotherapy for people having ami-laz or osi-mono as 1st line
- Disagreed assuming 100% people will have BSC at 3rd line for people having ami-laz or osi-mono at 1st line because they can have non-platinum-based chemotherapy
- Preferred to apply proportion receiving BSC at the 3rd line based on MARIPOSA and
- Specifically, for osi-chemo modelled subsequent treatments as:
  - Second line: 50% platinum chemo, 50% docetaxel (half of that with nintedanib). Scenarios vary the proportion of nintedanib with docetaxel from 0% to 100%)
  - Third line: 100% BSC

How should subsequent treatments following osi-chemo be modelled?

Abbreviations: 2L, second line ABCP, BSC, best supportive care; ITC, indirect-treatment comparison; OS, overall survival; PFS, progression-free survival; TTD, time to treatment discontinuation

Subsequent treatment summary

ICER Impact: Moderate

Uncertainty around subsequent treatments for osi-chemo

			% of people having active treatment		
Treatment	**Line**	**% going to BSC**	**Platinum chemo**	**Docetaxel**	**Docetaxel + nintedanib**
Osi-chemo	Second line	[redacted]	50%	25%	25%
	Third line	[redacted]	0%	0%	0%
Osi-mono**	Second line	[redacted]	100%	0%	0%
	Third line	[redacted]	25%	37.5%	37.5%
Ami-laz**	Second line	[redacted]	100%	0%	0%
	Third line	[redacted]	25%	37.5%	37.5%

Notes

- *The EAG offers scenarios for second line after osi-chemo which show nobody having nintedanib and everyone who has docetaxel having it with nintedanib.
- **For ACM3 the company responded to the committee request by applying the proportions for osi-chemo to osi-mono and ami-laz as well. The EAG disagrees with this as the logic for not having 100% platinum chemo at 2L was that people would have already had platinum chemo at 1L.

Abbreviations: 1L, first-line ; 2L, second-line

Cost-effectiveness results

All ICERs are reported in PART 2 slides

because they include confidential

PAS discounts

When the company and EAG base case ICERs are calculated using confidential prices:
Both the company base case and the EAG deterministic base cases are below **£30,000 per QALY** for the comparison with **osimertinib monotherapy** and **osimertinib plus chemotherapy.**

The probabilistic EAG base case ICER is over **£30,000 per QALY** for the comparison with osimertinib plus chemotherapy

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Equality considerations

Socio-economic, ethnicity, and gender factors may affect outcomes

The company highlighted a number of potential equalities issues:

- The UKLCC (UK Lung Cancer Coalition) reports highlight significant impact of lower socio-economic factors on health inequalities, particularly in relation to lung cancer
- EGFR mutations are more common in women and people with Asian heritage
- Compared with patients of White ethnicity, patients of Asian ethnicity were more likely to be diagnosed with later-stage lung cancer and had a longer median time to treatment initiation
- Stigma is a major concern for lung cancer patients, as it is largely driven by a perception that it is ‘self-inflicted’ due to the public recognising the link between lung cancer and smoking

Are there any further equality considerations not previously discussed?

Abbreviations: EGFR, epidermal growth factor receptor

Managed access

Criteria for a managed access recommendation

The committee can make a recommendation with managed access if:

- the technology cannot be recommended for use because the evidence is too uncertain
- the technology has the **plausible potential** to be cost effective at the **currently agreed price**
- new evidence that could **sufficiently support the case for recommendation** is expected from ongoing or planned clinical trials, or could be collected from people having the technology in clinical practice
- data could feasibly be collected within a reasonable timeframe (up to a **maximum of 5 years**) without **undue burden**.

Company has not submitted a proposal for managed access

Key issues: question for committee

Issue	Question
ITCs of OS/PFS	• Which ITC is preferred for decision making?
Model output, ITC adverse events and TTD	• Which model is most appropriate for osi-chemo OS extrapolation? • What are the committee's views of the safety profiles of ami-laz vs. osi-chemo? • Which model is most appropriate for osi-chemo OS extrapolation?
Utility values	• Which progression free utility values should be used for each arm?
Subsequent treatments	• How should subsequent treatments following osi-chemo be modelled?
Equality	• Are there any further equality considerations not previously discussed?

Abbreviations: AE, adverse events; ITC, indirect-treatment comparison; OS, overall survival; survival; TA, technology appraisal; TTD, time to treatment discontinuation

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Supplementary appendix

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FLAURA2: updated safety data

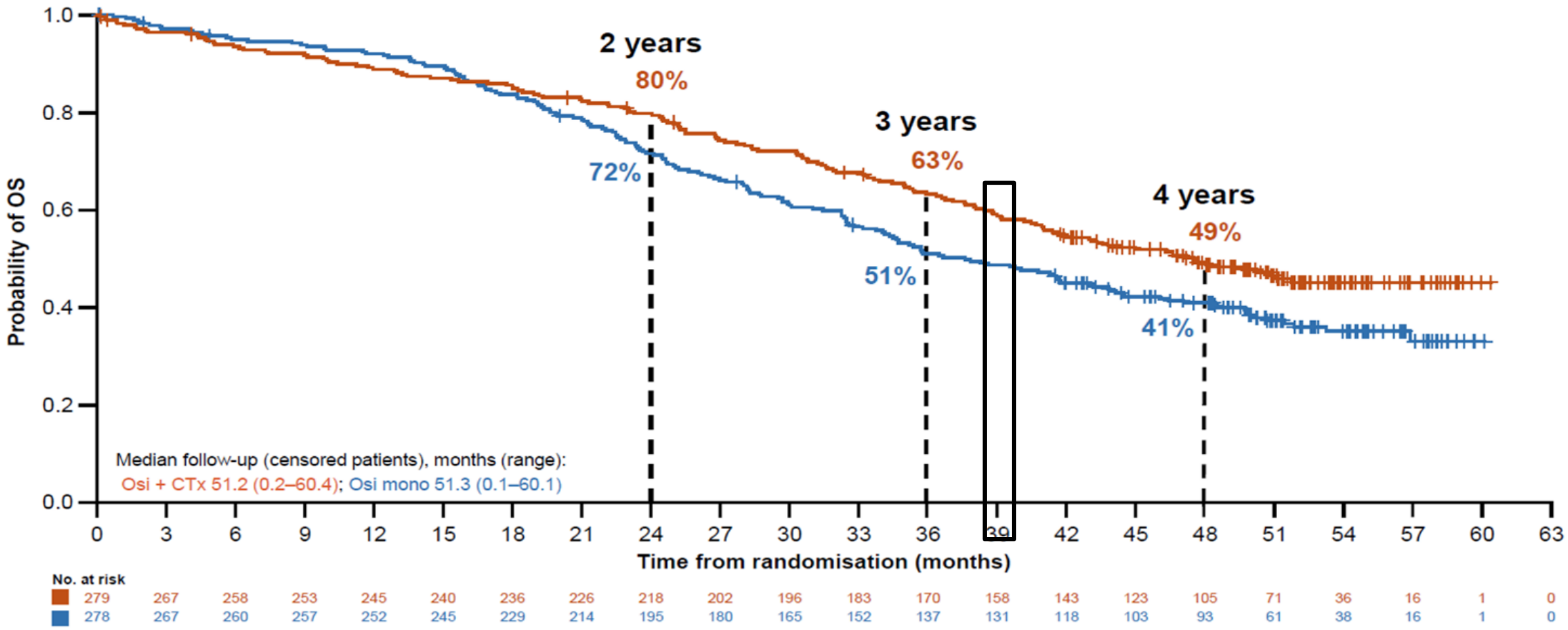
Company

- Higher proportion of people having osi-chemo had grade ≥3 and serious AEs compared to osimertinib
- 12% people discontinued in osi-chemo vs. 7% in osimertinib due to AEs
- No new safety signals identified from updated FLAURA2 with comparable safety profile b/w 2 DCOs

	DCO: 12th June 2025	
	Osimertinib-chemotherapy (N=276)	**Osimertinib monotherapy (N=275)**
Any grade	276 (100)	269 (98)
Grade ≥3	193 (70)	94 (34)
Serious	126 (46)	75 (27)
AE leading to death	22 (8)	10 (4)

Abbreviations: AE, adverse event; CI, confidence interval; DCO, data cut-off

Updated OS results: FLAURA2



Abbreviations: OS, overall survival

How company incorporated evidence into updated model

Input		Committee preference
Mean starting age		68.5 years
Drug administration costs	IV admin within osi-chemo	Average of SB13Z and SB15Z (NHS Reference Costs, Day Case; £477.00)
	Platinum chemo component of osi-chemo	Modelled as 100% carboplatin
	SC admin of amivantamab	SB12Z OP (£133.39)
	Continuation of oral treatment	Costed on a four-weekly schedule
	Subsequent treatments	Alignment to 1L administration costing
Subsequent treatments	Initiation of 2L treatments following osi-chemo	Aligned with the discontinuation of the osimertinib component (as per osimertinib TDD curve)
	2L treatment distribution following osi-chemo	50% docetaxel, 50% platinum-based chemotherapy
	3L treatment distribution following osi-chemo	100% BSC
AEs	Incidence in osi-chemo arm	FLAURA2 January 2024 DCO (not June 2025 DCO)

Abbreviations: 2L, second line; 3L, third line; BSC, best supportive care; DCO, data cut-off; IV, intravenous: NHS: National Health Service; SC, subcutaneous; TTD, time to treatment discontinuation

ITC: Safety anchored MAICs

Grade ≥3 AEs

SAE

Abbreviations: AE, adverse events; SAE, serious adverse events

Amivantamab (Rybrevant, Janssen) with lazertinib (Lazcluze, Janssen)

Marketing authorisation	• Amivantamab in combination with lazertinib is indicated for the first-line treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations
Mechanism of action	• Amivantamab is a bispecific antibody binds to both the EGFR and MET receptors • Lazertinib is third-generation EGFR tyrosine kinase inhibitor that selectively inhibits both common EGFR mutations and the EGFR T790M mutation

Administration	• **Amivantamab** (*each vial is 350mg)*
	  • Body weight at baseline <80 kg:
	  • Weeks 1–4: 1,050 mg (3 vials) weekly - week 1 – split infusion on Day 1 and 2, Weeks 2 to 4 – infusion on Day 1 of week
	  • Week 5 onwards: 1,050 mg every 2 weeks
	  • Body weight at baseline ≥80 kg:
	  • Weeks 1–4: 1,400 mg (4 vials) weekly - week 1 – split infusion on Day 1 and 2, weeks 2 to 4 – infusion on Day 1 of week
	  • Week 5 onwards: 1,400 mg every 2 weeks
	• **Lazertinib** *(tablets are either 80mg or 240mg)*
	  • 240 mg once daily

Price	• The list price of amivantamab is £1,079 per 7ml infusion vial (350mg) • The list price for lazertinib 80 mg (56 tablets) is £4,128.50 per pack, and the list price for lazertinib 240 mg (28 tablets) is £6,192.75 per pack. • Amivantamab and lazertinib are subject to a simple PAS discount