Amivantamab Plus Lazertinib vs Osimertinib in First-Line *EGFR*-Mutant Advanced NSCLC: Final Overall Survival From the Phase 3 MARIPOSA Study

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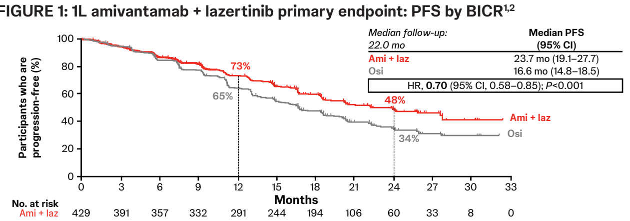
Background

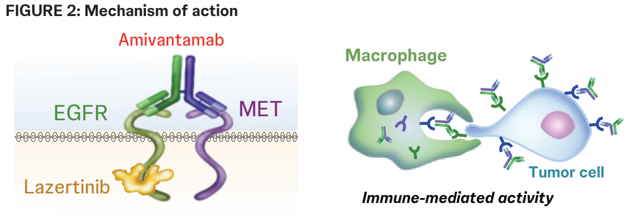
- In MARIPOSA, first-line (1L) amivantamab + lazertinib significantly improved progression-free survival (PFS) vs osimertinib (**Figure 1**)[1,2]
- Amivantamab + lazertinib is approved for patients with 1L epidermal growth factor receptor (*EGFR*)-mutant advanced non-small cell lung cancer (NSCLC)[3,4]
- 1L amivantamab + lazertinib exhibits a triple mechanism of action with a reduction in the spectrum and complexity of acquired resistance (**Figure 2**)[5]
- Here, we report the protocol-specified final overall survival (OS) results of 1L amivantamab + lazertinib vs osimertinib from MARIPOSA

FIGURE 1: 1L amivantamab + lazertinib primary endpoint: PFS by BICR[1,2]



1L, first-line; Ami, amivantamab; BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; laz, lazertinib; osi, osimertinib; PFS, progression-free survival.

FIGURE 2: Mechanism of action

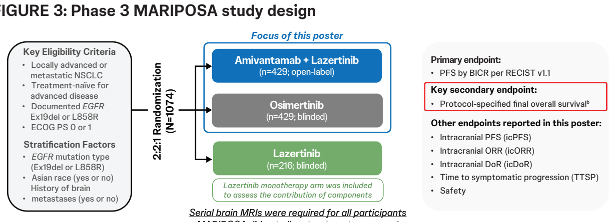


EGFR, epidermal growth factor receptor; MET, mesenchymal-epithelial transition.

Methods

- The study design of MARIPOSA can be seen in **Figure 3**
- OS was a key secondary endpoint with prespecified alpha to assess significance
- Protocol-specified final OS analysis was planned for when ~390 deaths had occurred in the amivantamab + lazertinib and osimertinib arms
- OS was tested with a 2-sided alpha of 0.05, determined by O'Brien-Fleming alpha spending approach as implemented by the Lan-DeMets method
  - In the prespecified interim analysis, a 2-sided alpha of 0.005 was allocated for OS
  - The protocol-specified final analysis of OS was subsequently evaluated at a 2-sided significance level of 0.0484

FIGURE 3: Phase 3 MARIPOSA study design



MARIPOSA (ClinicalTrials.gov Identifier: NCT04487080) enrollment period: November 2020 to May 2022; clinical cut-off: 04 December 2024. OS analysis was evaluated by means of the *P*-value generated from the stratified log-rank test, with *EGFR* mutation type, Asian race, and history of brain metastases as stratification factors. HRs and 95% CIs were calculated using the stratified Cox regression model with treatment as the sole explanatory variable. Dosing (in 28-day cycles): amivantamab: 1050 mg (1400 mg if ≥80 kg) weekly for the first 4 weeks, then every 2 weeks; lazertinib: 240 mg daily; osimertinib: 80 mg daily.
[a]MARIPOSA did not allow crossover as amivantamab-based regimens were not approved in the 2L setting during MARIPOSA enrollment.
[b]Continued follow-up is planned to evaluate long-term overall survival.
2L, second-line; BICR, blinded independent central review; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; Ex19del, exon 19 deletion; icDoR, intracranial duration of response; icORR, intracranial overall response rate; icPFS, intracranial progression-free survival; MRI, magnetic resonance imaging; NSCLC, non-small cell lung cancer; OS, overall survival; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; TTSP, time to symptomatic progression.

Results

Study population

- Participant disposition is presented in **Figure 4**
- Baseline characteristics were well balanced across both arms (**Table 1**)

TABLE 1: Baseline demographics[1,2]

Characteristic, n (%)	Amivantamab + lazertinib (n=429)	Osimertinib (n=429)
Median age, years (range)	64 (25–88)	63 (28–88)
Female	275 (64)	251 (59)
Race		
Asian	250 (58)	251 (59)
White	164 (38)	165 (38)
Other[a]	15 (3)	13 (3)
ECOG PS 1	288 (67)	280 (65)
History of smoking	130 (30)	134 (31)
History of brain metastases	178 (41)	172 (40)
EGFR mutation type[b]		
Ex19del	258 (60)	257 (60)
L858R	172 (40)	172 (40)
Adenocarcinoma subtype	417 (97)	415 (97)

Note: percentages may not sum to 100 due to rounding.
[a]Other includes American Indian or Alaska Native, Black or African American, multiple, and unknown.
[b]One patient in the amivantamab + lazertinib arm had both Ex19del and L858R.
ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; Ex19del, exon 19 deletion.

Efficacy

- OS was significantly longer with amivantamab + lazertinib (**Figure 5**)
- OS curves continue to widen over time with a projected >1-year median OS benefit
  - Based on an exponential distribution assumption of OS in both arms, the improvement in median OS is projected to exceed 1 year
- A generally consistent OS benefit for amivantamab + lazertinib over osimertinib was observed across predefined subgroups (**Figure 6**)
- The most common subsequent therapy class was chemotherapy-based regimens in both arms (**Figure 7**)
  - 74% of participants received second-line therapy, suggesting a long-term treatment plan after 1L amivantamab + lazertinib is feasible
- Amivantamab + lazertinib demonstrated a clinically meaningful improvement in intracranial PFS (icPFS) with durable responses (**Figure 8**)
  - 3-year landmark icPFS was 36% vs 18% for amivantamab + lazertinib vs osimertinib
- Amivantamab + lazertinib demonstrated greater durability of response, with improved intracranial duration of response (icDoR) vs osimertinib (**Figure 9**)
- Symptomatic progression is a patient-relevant endpoint that measures time from randomization to the onset of new/worsening lung cancer symptoms requiring a change in therapy, clinical intervention, or death based on investigator discretion
- Amivantamab + lazertinib continues to significantly delay, by a median of >14 months, the time to onset or worsening of lung cancer symptoms (**Figure 10**)

Safety

- Median duration of treatment was **27.0 months** for amivantamab + lazertinib and **22.4 months** for osimertinib
- Safety profile was consistent with the primary analysis (**Table 2**)[1]
  - Adverse events (AEs) were mostly EGFR- and MET-related and grades 1–2[1,6]
- A minority of participants were prescribed antibiotics for rash (21%) at study initiation[6]
- Few were on anticoagulation (5%) at baseline,[6] with venous thromboembolism occurring in **40%** in the amivantamab + lazertinib arm and **11%** in the osimertinib arm

TABLE 2: Safety

AEs by preferred term (≥20% of participants in either group)	Amivantamab + lazertinib (n=421)		Osimertinib (n=428)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Related to EGFR inhibition				
Paronychia	291 (69)	49 (12)	127 (30)	2 (<1)
Rash	271 (64)	73 (17)	136 (32)	3 (<1)
Diarrhea	133 (32)	9 (2)	200 (47)	4 (<1)
Dermatitis acneiform	127 (30)	37 (9)	55 (13)	0
Stomatitis	126 (30)	5 (1)	92 (21)	1 (<1)
Pruritus	107 (25)	2 (<1)	75 (18)	1 (<1)
Related to MET inhibition				
Hypoalbuminemia	216 (51)	26 (6)	29 (7)	0
Peripheral edema	162 (38)	8 (2)	29 (7)	1 (<1)
Other				
Infusion-related reaction	275 (65)	27 (6)	0	0
ALT increased	170 (40)	28 (7)	66 (15)	8 (2)
AST increased	139 (33)	15 (4)	68 (16)	6 (1)
Constipation	130 (31)	0	70 (16)	0
COVID-19	125 (30)	8 (2)	112 (26)	9 (2)
Anemia	114 (27)	20 (5)	112 (26)	10 (2)
Decreased appetite	114 (27)	4 (1)	84 (20)	7 (2)
Nausea	99 (24)	5 (1)	65 (15)	1 (<1)
Hypocalcemia	96 (23)	11 (3)	37 (9)	0
Asthenia	84 (20)	13 (3)	54 (13)	7 (2)
Muscle spasms	84 (20)	3 (<1)	36 (8)	0
Thrombocytopenia	74 (18)	4 (1)	92 (21)	6 (1)

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; EGFR, epithelial growth factor receptor.

- Most first onset AEs occur early (0–4 months), with longer-term follow-up showing no new safety signals and indicating that long-term treatment is feasible (**Figure 11**)
- Early onset AEs can be reduced using simple and accessible preventive approaches (**Figure 12**)

FIGURE 4: Participant disposition

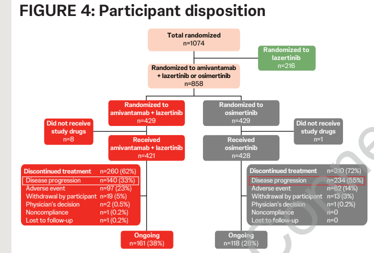
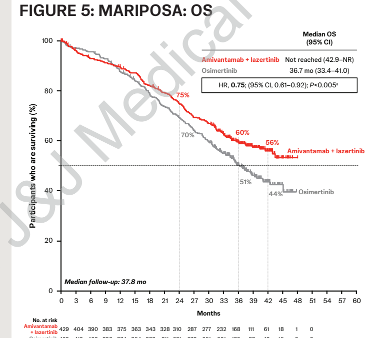
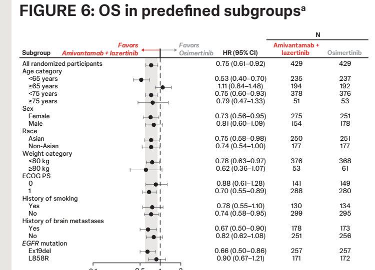


FIGURE 5: MARIPOSA: OS



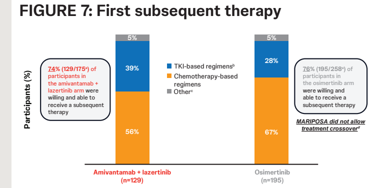
Note: Last participant was enrolled in May 2022. Clinical cutoff date was December 4, 2024. In total, 390 deaths had occurred in the amivantamab + lazertinib (173 deaths) and osimertinib (217 deaths) arms.
[a]*P*-value was calculated from a log-rank test stratified by mutation type (Ex19del or L858R), race (Asian or Non-Asian), and history of brain metastasis (present or absent). Hazard ratio was calculated from a stratified Cox regression model.
CI, confidence interval; Ex19del, exon 19 deletion; HR, hazard ratio; NR, not reached; OS, overall survival.

FIGURE 6: OS in predefined subgroups[a]



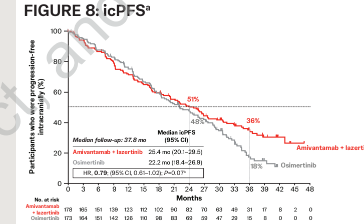
Note: Gray box indicates 95% CI of HR for all randomized participants.
[a]Subgroup analyses were not part of the hypothesis testing of the trial and should not be used to infer definitive treatment effects.
CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; Ex19del, exon 19 deletion; HR, hazard ratio.

FIGURE 7: First subsequent therapy



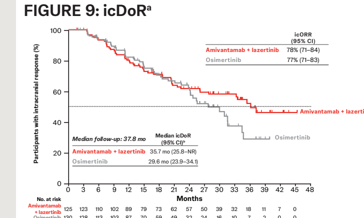
Note: Percentages may not total 100 due to rounding.
[a]Denominator is the number of participants who had disease progression and discontinued randomized treatment.
[b]TKI-based regimens include TKI + chemotherapy (5% in both arms).
[c]Other therapy included VEGFi alone, IO alone, herbals, antibody-drug conjugates, ALK tyrosine kinase inhibitors, c-MET tyrosine kinase inhibitors, amivantamab (1 participant received amivantamab-chemotherapy after amivantamab-lazertinib; after osimertinib, 1 participant received amivantamab-chemotherapy, 1 participant received amivantamab-lazertinib, and 1 participant received amivantamab monotherapy), and investigational agents.
[d]MARIPOSA did not allow crossover as amivantamab-based regimens were not approved in the 2L setting during MARIPOSA enrollment.
2L, second-line; ALK, anaplastic lymphoma kinase; IO, immuno-oncology; TKI, tyrosine kinase inhibitor; VEGFi, vascular endothelial growth factor inhibitor.

FIGURE 8: icPFS[a]



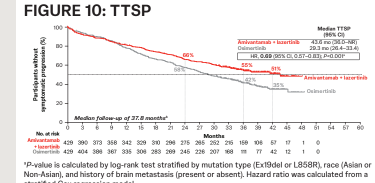
[a]icPFS was defined as time from randomization until the date of intracranial disease progression (progression of brain metastasis or occurrence of new brain lesions) or death, based on BICR using RECIST v1.1 among participants with a history of brain metastases.
[b]*P*-value was calculated from a log-rank test stratified by mutation type (Ex19del or L858R) and race (Asian or Non-Asian). Hazard ratio was calculated from a stratified Cox regression model.
BICR, blinded independent central review; CI, confidence interval; Ex19del, exon 19 deletion; HR, hazard ratio; icPFS, intracranial progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors.

FIGURE 9: icDoR[a]



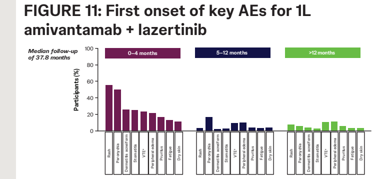
[a]icDoR was analyzed as the time from the date of first documented intracranial response (CR or PR) until the date of documented intracranial progression or death, whichever occurred first, among participants with a brain lesion at screening who have intracranial CR or PR based on BICR using RECIST v1.1.
[b]95% CIs were estimated with the Kaplan-Meier method.
CI, confidence interval; CR, complete response; icDoR, intracranial duration of response; icORR, intracranial overall response rate; NR, not reached; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors.

FIGURE 10: TTSP



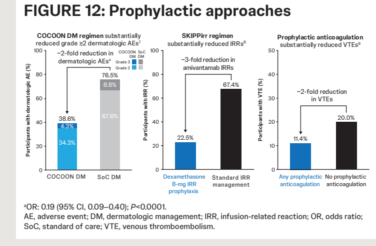
[a]*P*-value is calculated by log-rank test stratified by mutation type (Ex19del or L858R), race (Asian or Non-Asian), and history of brain metastasis (present or absent). Hazard ratio was calculated from a stratified Cox regression model.
[b]Data with median follow-up of 22.0 months were previously presented.[10]
CI, confidence interval; Ex19del, exon 19 deletion; HR, hazard ratio; NR, not reached; TTSP, time to symptomatic progression.

FIGURE 11: First onset of key AEs for 1L amivantamab + lazertinib



[a]VTE is a grouped term, which included pulmonary embolism, deep vein thrombosis, limb venous thrombosis, venous thrombosis, thrombosis, superficial vein thrombosis, thrombophlebitis, embolism, venous embolism, jugular vein thrombosis, sigmoid sinus thrombosis, axillary vein thrombosis, pulmonary infarction, vena cava thrombosis, central venous catheterization, portal vein thrombosis, post thrombotic syndrome, pulmonary thrombosis, superior sagittal sinus thrombosis, transverse sinus thrombosis, pelvic venous thrombosis, and superior vena cava syndrome.
1L, first-line; AE, adverse event; VTE, venous thromboembolism.

FIGURE 12: Prophylactic approaches



[a]OR: 0.19 (95% CI, 0.09–0.40); *P*<0.0001.
AE, adverse event; DM, dermatologic management; IRR, infusion-related reaction; OR, odds ratio; SoC, standard of care; VTE, venous thromboembolism.

Key takeaway

Patients live longer with 1L amivantamab + lazertinib, with MARIPOSA demonstrating practice-changing superior OS vs osimertinib and extending median survival beyond 3 years

Conclusions

- 1L amivantamab + lazertinib led to a statistically significant and clinically meaningful reduction in mortality vs osimertinib (HR, **0.75**; *P*<0.005) in participants with previously untreated *EGFR*-mutant advanced NSCLC
  - A **>12-month median OS benefit** is projected for amivantamab + lazertinib vs osimertinib; based on an exponential distribution assumption of OS in both arms, the improvement in median OS is projected to exceed 1 year
  - **60% of participants were alive at 3 years in the amivantamab + lazertinib arm** vs 51% for osimertinib; benefit continued at 42-months with survival rates of 56% and 44%, respectively
- **Twice as many** participants receiving amivantamab + lazertinib were **intracranially progression-free** at 3 years (36% vs 18%) with a **longer icDoR** vs osimertinib (35.7 vs 29.6 months) among participants with a history of brain metastases
- Amivantamab + lazertinib delayed the time to a participant experiencing symptoms from their lung cancer by a median of >14 months (time to symptomatic progression; *P*<0.001)
- AEs with 1L amivantamab + lazertinib occurred early; prophylactic interventions have now been shown to substantially **reduce the incidence of these key AEs** (dermatologic AEs, infusion-related reactions, and VTE)

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