IASLC 2026 World Conference on Lung Cancer

SEPTEMBER 12 – 15, 2026 | SEOUL, REPUBLIC OF KOREA

Subcutaneous Amivantamab + Lazertinib With Supportive Care in *EGFR*-Mutant NSCLC: Longer Follow-Up From the Pragmatic COPERNICUS Study

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Disclosures

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Served in a consulting or advisory role for: AstraZeneca, Genentech/Roche, Pfizer, Novartis, Merck, Bristol Myers Squibb, Johnson & Johnson, Eli Lilly, Bayer, Nuvalent Inc., Daiichi Sankyo/ AstraZeneca, and GSK

Received research funding from: Merck, AstraZeneca, Mirati Therapeutics, Boehringer Ingelheim, Roche/Genentech, Pfizer, Takeda, AbbVie, Bristol Myers Squibb, GSK, Blueprint Medicines, Novartis, Advaxis, Johnson & Johnson, Elevation Oncology, Daiichi Sankyo/AstraZeneca, Amgen, Black Diamond Therapeutics, Forward Pharma, Tesaro/GSK, Regeneron, and Jazz Pharmaceuticals

The authors report that generative AI was not used in the preparation of this presentation.

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Background

- In MARIPOSA,[a] IV amivantamab + lazertinib significantly prolonged OS versus osimertinib in participants with 1L common *EGFR*-mutated advanced NSCLC (HR, 0.75; *P*=0.005); 34% discontinued amivantamab due to TEAEs[1,2,b]
  - IRRs, rash, and VTE were more common within the first 4 months of amivantamab + lazertinib treatment[3,4]
- SC amivantamab[c] and enhanced prophylactic treatment protocols have substantially reduced administration time, as well as rates and severity of TEAEs of interest seen in MARIPOSA[5–7]
- COPERNICUS[d] Cohort 1 evaluates SC amivantamab + lazertinib in 1L *EGFR*-mutated NSCLC using a pragmatic design that closely mirrors the real-world setting in addition to VTE and dermatologic prophylaxis
  - A prior report[e] among US participants demonstrated low rates of ARRs (0.9%), VTE (9%), and grade ≥3 rash[f] (4%)[8]

Here, we characterize early-onset TEAEs after longer follow-up in a subset of COPERNICUS Cohort 1 participants enrolled ≥4 months prior to data cutoff[g]

[a]NCT04487080. [b]Defined as any new or worsening AE occurring at or after the initial administration of any study treatment through the day of last dose plus 30 days or prior to the start of subsequent systemic anticancer therapy, whichever is earlier. [c]Co-formulated with recombinant human hyaluronidase PH20. [d]NCT06667076. [e]Median follow-up, 4.9 months. [f]Preferred term. [g]Data cutoff: June 12, 2026; this population included those who prematurely discontinued treatment.

1L, first-line; AE, adverse event; ARR, administration-related reaction; EGFR, epidermal growth factor receptor; HR, hazard ratio; IRR, infusion-related reaction; IV, intravenous; NSCLC, non-small cell lung cancer; OS, overall survival; SC, subcutaneous; TEAE, treatment-emergent adverse event; VTE, venous thromboembolism.

1. RYBREVANT® (amivantamab-vmjw) injection, for intravenous use [package insert]. Janssen Biotech, Inc.; 2025. 2. Yang JCH, et al. *N Engl J Med*. 2025;393(17):1681–1693. 3. Cho BC, et al. *N Engl J Med*. 2024;391(16):1486–1498. 4. García Campelo MDR, et al. Presented at: European Lung Cancer Congress (ELCC); March 20–23, 2024; Prague, Czech Republic. 5. Leighl NB, et al. *J Clin Oncol*. 2024;42(30):3593–3605. 6. Cho BC, et al. *J Thorac Oncol*. 2025;20(10):1517–1530. 7. Spira AI, et al. *J Thorac Oncol*. 2025;20(6):809–816. 8. Goldberg SB, et al. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 29–June 2, 2026; Chicago, IL, USA.

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COPERNICUS Study Design[1–3]

Focus of this presentation

Eligibility criteria

- Locally advanced or metastatic *EGFR* Ex19del- or L858R-mutated NSCLC
- ECOG PS score of 0 or 1
- Cohort 1: eGFR ≥30 mL/min
- Cohort 2: eGFR ≥45 mL/min

n=300 (US)
n=150 (EMEA)

Cohort 1: Newly diagnosed, no prior systemic treatment (1L)

SC amivantamab[a] Q4W[b] + lazertinib[c] PO QD

n=29 (US)

Cohort 2: Progression on/after EGFR TKI monotherapy (2L)

SC amivantamab[a] Q3W[d] + IV carboplatin Q3W + IV pemetrexed Q3W

Cohort 1

Primary endpoint:
- INV PFS per RECIST v1.1

Key secondary endpoints:
- Incidence and severity of dermatologic AEs and VTE
- OS
- CBR
- ORR
- DoR

Cohort 1: Dermatologic AE + VTE prophylaxis

Dermatologic prophylactic regimen (COCOON)[e,f]
- Oral minocycline or doxycycline 100 mg BID (Weeks 1–12)
- 4% chlorhexidine on fingernails and toenails daily for 12 months (Week 1+)
- Ceramide-based moisturizer at least daily for 12 months[g] (Week 1+)
- 1% topical clindamycin lotion on the scalp daily (Weeks 13+)

VTE prophylactic regimen (PALOMA-2, PALOMA-3)
- Direct oral anticoagulants or low molecular weight heparin as per NCCN, ESMO, or local guidelines (first 4 months)

Comparison of outcomes in real-world cohorts vs Cohorts 1 and 2 (US participants), conducted separately[h]

COPERNICUS (ClinicalTrials.gov identifier: NCT06667076).

[a]SC abdominal injection 1600 mg (2240 mg if ≥80 kg) weekly for the first 4 weeks, and 3520 mg (4640 mg if ≥80 kg) Q4W thereafter. [b]In 28-day cycles until disease progression, withdrawal of consent, or the investigator decides to discontinue treatment, whichever comes first. [c]Lazertinib 240 mg. [d]In 21-day cycles until disease progression, withdrawal of consent, or the investigator decides to discontinue treatment, whichever comes first. [e]Prophylactic antibiotics: oral minocycline or doxycycline 100 mg BID and topical clindamycin lotion 1% on the scalp daily before bedtime. Paronychia prophylaxis: chlorhexidine 4% on the fingernails and toenails daily. Skin moisturization of the body and face at least daily. [f]Tacrolimus was added as a reactive management recommendation in COPERNICUS based on positive results from the COCOON treatment substudy.[4] In addition, a protocol amendment for COPERNICUS recommended zinc supplementation for participants with established zinc deficiency who experienced dermatologic AEs. [g]La Roche-Posay Lipikar AP+M moisturizer was used in COCOON. [h]The comparison of clinical and health outcomes between real-world patients and participants from Cohorts 1 and 2 (US participants only) will be assessed under a separate protocol.

1L, first-line; 2L, second-line; AE, adverse event; BID, twice daily; CBR, clinical benefit rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; eGFR, estimated glomerular filtration rate; EGFR, epidermal growth factor receptor; EMEA, Europe, the Middle East, and Africa; ESMO, European Society for Medical Oncology; Ex19del, exon 19 deletion; INV, investigator-assessed; IV, intravenous; L858R, exon 21 L858R substitution; NCCN, National Comprehensive Cancer Network; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PFS, progression-free survival; PO, orally; Q3W, every 3 weeks; Q4W, every 4 weeks; QD, once a day; RECIST, Response Evaluation Criteria in Solid Tumors; SC, subcutaneous; TKI, tyrosine kinase inhibitor; VTE, venous thromboembolism.

1. Leighl NB, et al. *J Clin Oncol*. 2024;42(30):3593–3605. 2. Cho BC, et al. *J Thorac Oncol*. 2025;20(10):1517–1530. 3. Lim SM, et al. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 31–June 4, 2024; Chicago, IL, USA. 4. Spira AI, et al. Presented at: International Association for the Study of Lung Cancer (IASLC) | American Society of Clinical Oncology (ASCO) North America Conference on Lung Cancer (NACLC); December 5–7, 2025; Chicago, IL, USA.

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Baseline Demographic and Clinical Characteristics

- 274 participants were enrolled in the United States
- 214 were enrolled ≥4 months prior to data cutoff[a]
  - Median follow-up was 8.3 months (range, 0.2–16.5), with 86% of participants ongoing in the study
- Notably, 56% and 22% of the 214 participants were ≥65 and ≥75 years of age, respectively; this is higher than MARIPOSA (45% were ≥65 years of age and 12% were ≥75 years of age)[1]
- The COPERNICUS pragmatic design allowed for enrollment of a population with a higher level of racial and ethnic diversity compared with other studies of EGFR inhibitors[1,2]

Characteristic, n (%)	SC amivantamab Q4W + lazertinib (n=214)
Median (range) age, years	67 (34–90)
≥65 years	120 (56)
≥75 years	47 (22)
Female	141 (66)
Race	
White	107 (50)
Asian	58 (27)
Black or African American	22 (10)
Other[b]	27 (13)
Hispanic or Latino	22 (10)
ECOG PS score of 1	117 (55)
History of smoking	67 (31)
Brain metastases at screening	80 (37)
EGFR mutation type	
Ex19del	124 (58)
L858R	90 (42)
Received 1 cycle of chemotherapy prior to enrollment[c]	6 (3)

[a]Data cutoff: June 12, 2026; this population included those who prematurely discontinued treatment. [b]Includes American Indian or Alaska Native (<1%), Native Hawaiian or other Pacific Islander (<1%), unknown (5%), and not reported (7%). [c]Includes adjuvant (17%), curative/palliative/any other intent (50%), and neoadjuvant (33%).

ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; Ex19del, exon 19 deletion; L858R, exon 21 L858R substitution; Q4W, every 4 weeks; SC, subcutaneous.

1. Cho BC, et al. *N Engl J Med*. 2024;391(16):1486–1498. 2. Goldberg SB, et al. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 29–June 2, 2026; Chicago, IL, USA.

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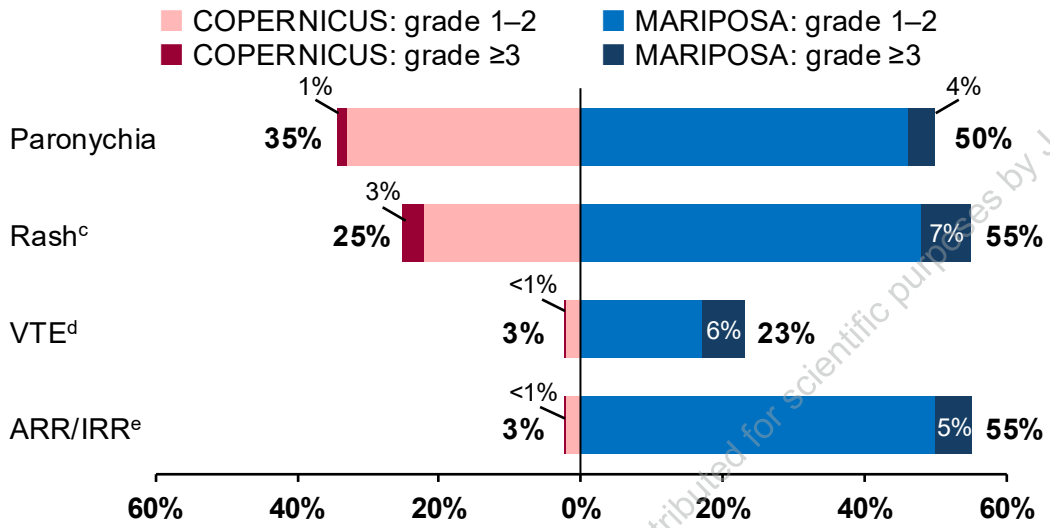
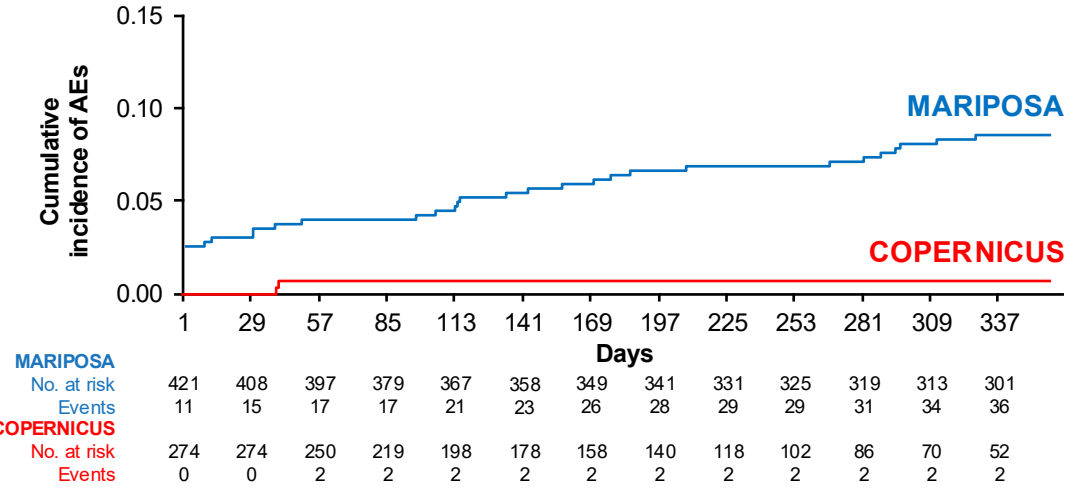
Adverse Events of Special Interest

- Paronychia, rash, VTE, and ARRs/IRRs during the first 4 months of treatment were reduced in COPERNICUS versus MARIPOSA[a]
- In COPERNICUS, 1 participant each discontinued amivantamab due to rash and VTE in the first 4 months; none discontinued due to ARRs
- 1-year cumulative incidence of amivantamab discontinuations due to selected AESIs was **<1% in COPERNICUS versus 9% in MARIPOSA**[b]

Selected AESIs in the first 4 months of treatment



Cumulative incidence of IRR/ARR, VTE, and rash leading to amivantamab discontinuation



MARIPOSA													
No. at risk	421	408	397	379	367	358	349	341	331	325	319	313	301
Events	11	15	17	17	21	23	26	28	29	29	31	34	36
COPERNICUS													
No. at risk	274	274	250	219	198	178	158	140	118	102	86	70	52
Events	0	0	2	2	2	2	2	2	2	2	2	2	2

[a]No formal, head-to-head statistical comparison was performed. Because follow-up in COPERNICUS is limited, these results are presented for contextual reference only and should not be used for direct comparison. Follow-up durations were different between studies. [b]Analysis includes all participants treated, including those who did not receive amivantamab for ≥4 months (COPERNICUS, N=274; MARIPOSA, n=421). [c]Preferred term. [d]Grouped term. [e]The term ARR was used in COPERNICUS and the term IRR was used in MARIPOSA due to different routes of administration.
AE, adverse event; AESI, adverse event of special interest; ARR, administration-related reaction; IRR, infusion-related reaction; VTE, venous thromboembolism.

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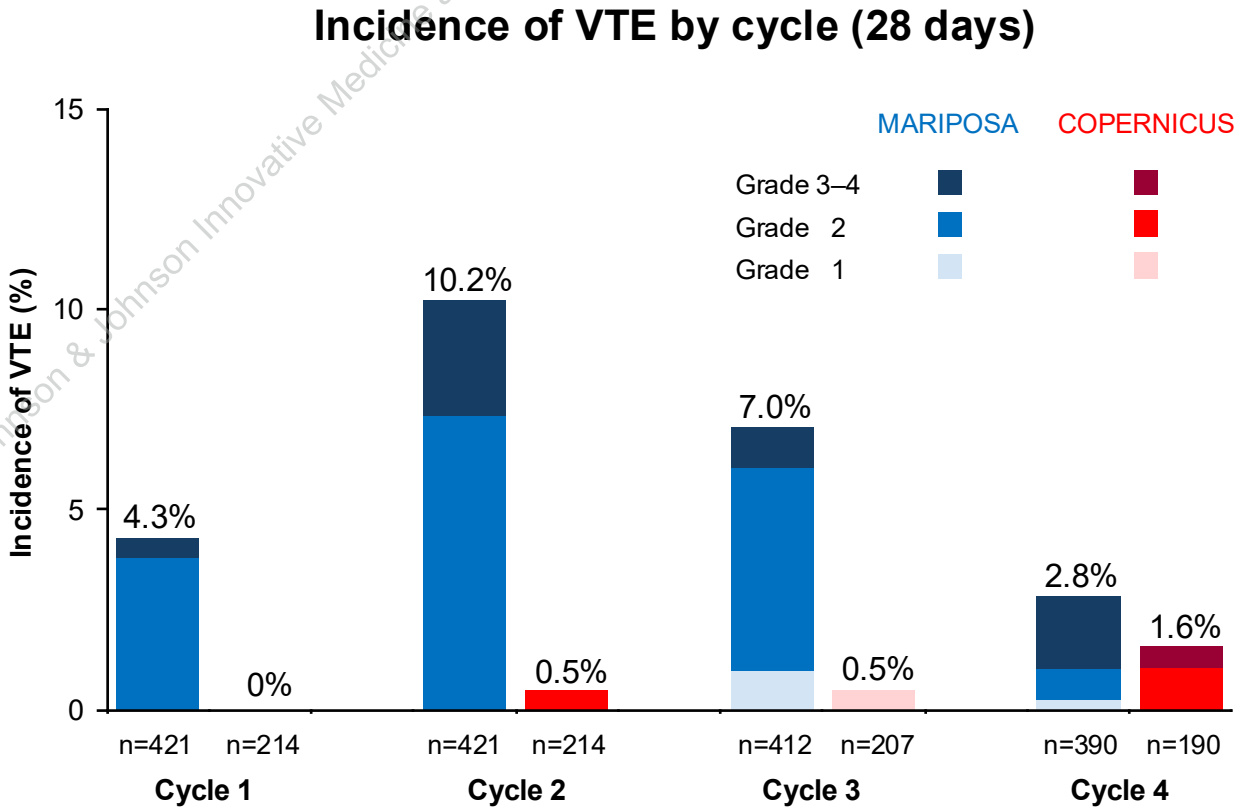
VTE

- Incidence of VTE during the first 4 months of treatment was reduced in COPERNICUS versus MARIPOSA (3% vs 23%)[a]
  - No grade ≥3 bleeding events were reported in COPERNICUS[1]
- In COPERNICUS, rates of VTE were similar across age subgroups[b]



[a]No formal, head-to-head statistical comparison was performed. Because follow-up in COPERNICUS is limited, these results are presented for contextual reference only and should not be used for direct comparison. Follow-up durations were different between studies. [b]VTE incidence was similar across age subgroups (3.2% vs 2.5% in <65 vs ≥65 years, respectively). These data are not based on a formal subgroup comparison.
VTE, venous thromboembolism.
1. Goldberg SB, et al. Presented at: American Society of Clinical Oncology (ASCO) Annual Meeting; May 29–June 2, 2026; Chicago, IL, USA.

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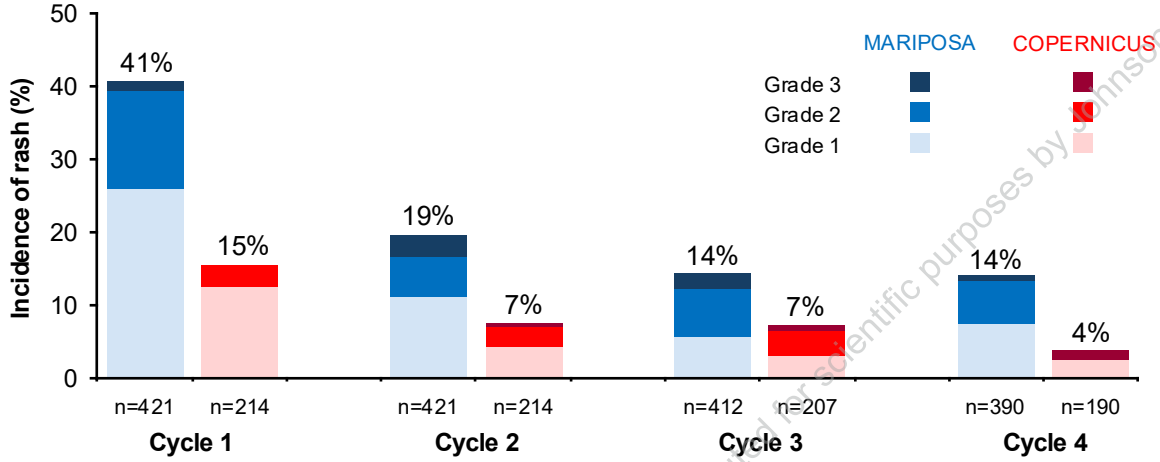
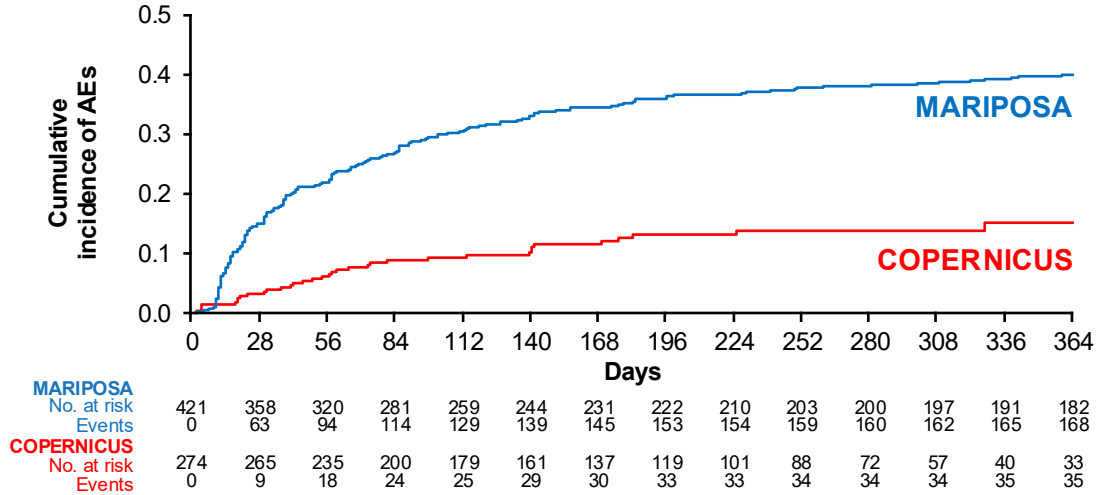
Rash[a]

- Incidence of rash during the first 4 months of treatment was lower in COPERNICUS versus MARIPOSA (25% vs 55%),[b] with lower incidence over time
- In COPERNICUS, overall incidence of rash during the first 4 months of treatment was similar across age subgroups[c]
- Compared with MARIPOSA, COPERNICUS demonstrated a meaningful reduction in grade ≥2 rash occurring in the first 4 months, with a lower cumulative incidence by 1 year[d]

Incidence of rash by cycle (28 days)[e]



Cumulative incidence of grade ≥2 rash[e]



MARIPOSA No. at risk	421	358	320	281	259	244	231	222	210	203	200	197	191	182
Events	0	63	94	114	129	139	145	153	154	159	160	162	165	168
COPERNICUS No. at risk	274	265	235	200	179	161	137	119	101	88	72	57	40	33
Events	0	9	18	24	25	29	30	33	33	34	34	34	35	35

[a]Preferred term. [b]No formal, head-to-head statistical comparison was performed. Because follow-up in COPERNICUS is limited, these results are presented for contextual reference only and should not be used for direct comparison. Follow-up durations were different between studies. [c]Rash incidence was similar across age subgroups (24% vs 25% in <65 vs ≥65 years, respectively). These data are not based on a formal subgroup comparison. [d]Analysis includes all participants treated, including those who did not receive amivantamab for ≥4 months (COPERNICUS, N=274; MARIPOSA, n=421). [e]No grade 4 or grade 5 rash occurred in either study. AE, adverse event.

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Safety Profile

- Majority of TEAEs[a] were grade 1–2, with no new safety signals compared with previous reports[1,2]
- Incidence of grade ≥3 dermatologic TEAEs was low (dermatitis acneiform, 4%; rash, 3%; maculopapular rash, 3%; paronychia, 1%; pruritus, <1%)
- Incidence of any TEAE with onset during the first 4 months and leading to discontinuation of both amivantamab + lazertinib was 8%
  - TEAEs leading to dose reduction and dose interruption of any study drug were 20% and 46%, respectively

TEAEs by preferred term (≥20%), n (%)	Cohort 1 (n=214)	
	All grades	Grade ≥3
EGFR-related		
Dermatitis acneiform	85 (40)	8 (4)
Stomatitis	82 (38)	6 (3)
Paronychia	74 (35)	3 (1)
Rash	53 (25)	6 (3)
Pruritus	50 (23)	1 (<1)
Maculopapular rash	46 (21)	6 (3)
MET-related		
Peripheral edema	80 (37)	3 (1)
Hypoalbuminemia	69 (32)	5 (2)
Other		
Fatigue	101 (47)	10 (5)
Nausea	93 (43)	2 (1)
Diarrhea	64 (30)	5 (2)
Constipation	59 (28)	0
Increased ALT	55 (26)	9 (4)
Decreased appetite	50 (23)	1 (<1)
Myalgia	48 (22)	0
Vomiting	46 (21)	2 (1)

[a]Defined as any new or worsening AE occurring at or after the initial administration of any study treatment through the day of last dose plus 30 days or prior to the start of subsequent systemic anticancer therapy, whichever is earlier.
AE, adverse event; ALT, alanine aminotransferase; EGFR, epidermal growth factor receptor; TEAE, treatment-emergent adverse event.
1. Cho BC, et al. *N Engl J Med.* 2024;391(16):1486–1498. 2. Yang JCH, et al. *N Engl J Med.* 2025;393(17):1681–1693.

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Conclusions

- COPERNICUS, with its pragmatic design, supported enrollment of a more representative real-world population
  - This analysis focused on Cohort 1 participants who were enrolled ≥4 months prior to data cutoff[a]
- Dermatologic and VTE prophylaxis with SC amivantamab + lazertinib led to a reduction in ARRs,[b] rash, VTE, and paronychia compared with MARIPOSA
- Amivantamab discontinuations by 1 year due to ARRs,[b] rash, or VTE were markedly lower in COPERNICUS (<1% vs 9% in MARIPOSA)[c]

COPERNICUS safety data show that dermatologic and VTE prophylaxis reduces the incidence of AESIs and support the broad use of SC amivantamab + lazertinib as foundational 1L therapy for patients with *EGFR*-mutated advanced NSCLC

Note: No formal, head-to-head statistical comparison was performed. Because follow-up in COPERNICUS is limited, these results are presented for contextual reference only and should not be used for direct comparison. Follow-up durations were different between studies.
[a]Data cutoff: June 12, 2026; this population included those who prematurely discontinued treatment. [b]Versus IRRs in MARIPOSA. [c]Analysis includes all participants treated, including those who did not receive amivantamab for ≥4 months (COPERNICUS, N=274; MARIPOSA, n=421).
1L, first-line; AESI, adverse event of special interest; ARR, administration-related reaction; EGFR, epidermal growth factor receptor; IRR, infusion-related reaction; NSCLC, non-small cell lung cancer; SC, subcutaneous; VTE, venous thromboembolism.

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Acknowledgments

- Participants who were enrolled in the study and their families and caregivers
- Physicians and nurses who cared for participants and staff members who supported this clinical trial
- Staff members at the study sites and those who were involved in data collection/analyses
- Medical writing assistance was provided by Katie Bretland, PhD, of Lumanity Communications Inc., and funded by Johnson & Johnson

2026

Thank You.