PALOMA-3
Ami + Laz in
3L *EGFR*+ NSCLC

Subcutaneous vs Intravenous Amivantamab: Patient Satisfaction and Resource Utilization Results from the PALOMA-3 Study

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Background

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- Amivantamab + lazertinib has shown antitumor activity in treatment naïve *EGFR*-mutated advanced NSCLC, leading to its FDA approval[1–3]
- In the randomized, phase 3 PALOMA-3 study, third-line SC amivantamab demonstrated noninferior pharmacokinetics and ORR vs IV amivantamab[4]
- Compared to IV, SC administration also offered:
  - A 5-fold reduction of IRRs (**13% vs 66%**)[4]
  - Substantially faster administration times (C1D1: **<5 minutes vs 5.0 hours**; C3D1: **<5 minutes vs 2.3 hours**)[3]
  - Significantly higher patient-reported convenience (C1D1: **85% vs 52%**; C3D1: **85% vs 35%**)[4]
- Subcutaneous amivantamab has shown a consistent PK and safety profile across other lines of therapy in *EGFR*-mutated advanced NSCLC[5]

We present patient treatment satisfaction and resource utilization for SC amivantamab, providing further insights into its clinical benefits

C, cycle; D, day; EGFR, epidermal growth factor receptor; IRR, infusion-related reaction; IV, intravenous; NSCLC, non-small cell lung cancer; ORR, objective response rate; PK, pharmacokinetics; SC, subcutaneous.

1. Cho BC, et al. *Nat Med*. 2023;29(10):2577-2585. 2. Cho BC, et al. *N Engl J Med*. 2024. doi: 10.1056/NEJMoa2403614. 3. RYBREVANT® (amivantamab-vmjw) injection, for intravenous use [package insert]. Horsham, PA: Janssen Biotech, Inc.; 2024.
4. Leighl NB, et al. *J Clin Oncol*. 2024. doi:10.1200/JCO.24.01001. 5. Lim SM, et al. Poster presented at the American Society of Clinical Oncology (ASCO) Congress; May 31–June 4; Chicago, USA.

PALOMA-3 Study Design

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Key eligibility criteria

- Locally advanced or metastatic NSCLC
- Disease had progressed on or after osimertinib and platinum-based chemotherapy, irrespective of order
- Documented *EGFR* Ex19del or L858R
- ECOG PS 0–1

1:1 randomization (N=418)

SC Amivantamab + Lazertinib (n=206)

IV Amivantamab + Lazertinib (n=212)

Prophylactic anticoagulation recommended for the first 4 months of treatment

Co-primary endpoints:

- C_{trough} (noninferiority)
- C2 AUC (noninferiority)

Select secondary endpoints:

- PROs by mTASQ[a]
- Health care resource utilization[b]
  - Chair time
  - Time in treatment room
  - Duration of treatment administration
  - Active healthcare provider time

PALOMA-3 (ClinicalTrials.gov Identifier: NCT05388669) enrollment period: August 2022 to October 2023; clinical cutoff: Jan-03-2024.

[a]The mTASQ is an 11-item questionnaire measuring the impact of each mode of treatment administration on 5 domains: physical impact, psychological impact, impact on activities of daily living, convenience, and satisfaction. Patients completed the mTASQ following treatment administration on C1D1 (+C1D2 for the IV arm), C3D1, and EOT. All data are site-reported values. [b]Assessed on C1D1 and C3D1. Immediate feedback at C1D1 and experience-based feedback at C3D1 offers a thorough evaluation of administration impact, patient comfort, ease of use, and potential issues.

AUC, area under the concentration-time curve; C, Cycle; C_{trough}, observed serum concentration of amivantamab at steady state; D, day; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; EOT, end of treatment; Ex19del, exon 19 deletion; IV, intravenous; mTASQ, modified Therapy Administration Satisfaction Questionnaire; NSCLC, non-small cell lung cancer; PRO, patient-reported outcome; SC, subcutaneous.

Recap of ASCO 2024; Leighl NB, et al.[1]

Efficacy of SC Amivantamab

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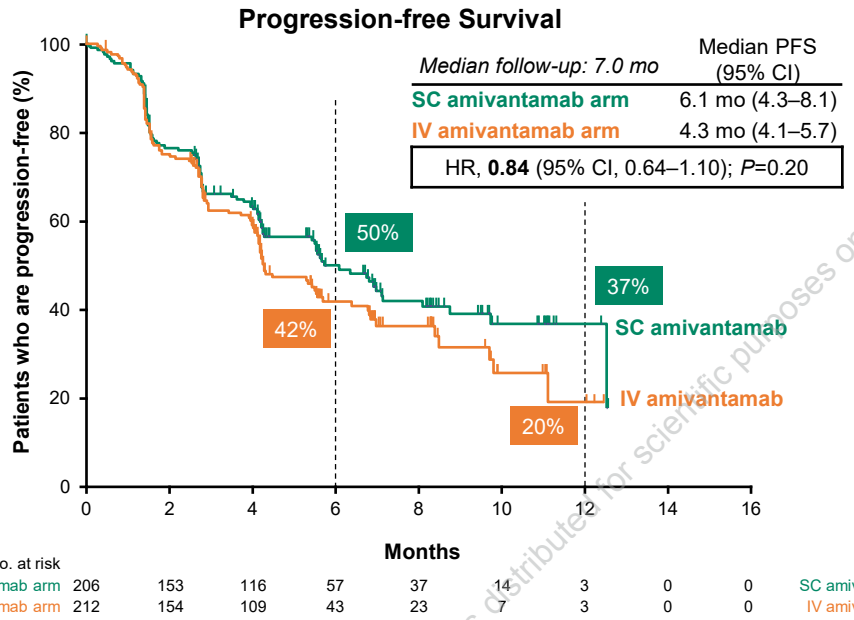
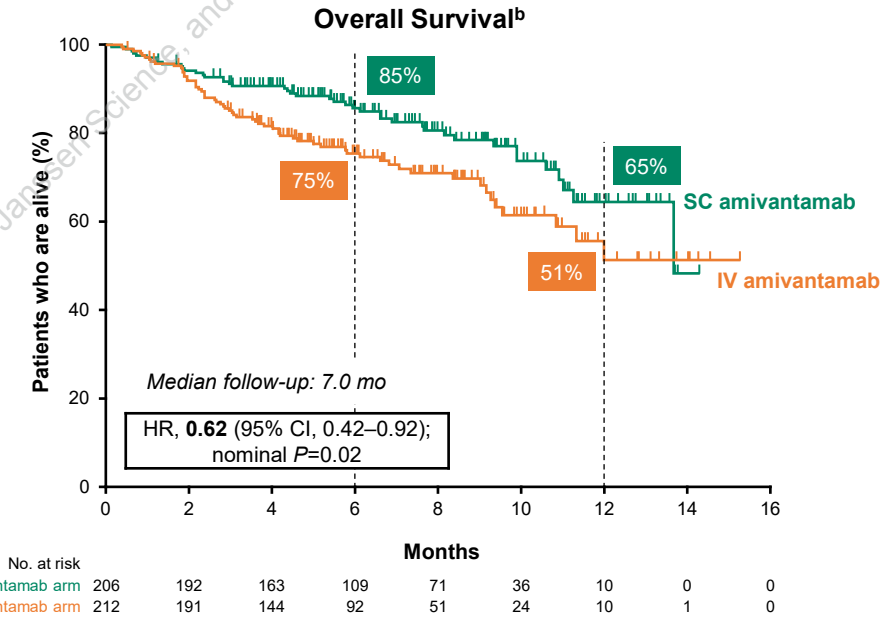
SC amivantamab met the non-inferiority criteria for the co-primary PK endpoints[a] and ORR





[a]C_{trough} and C2 AUC were the co-primary endpoints. [b]There were 43 deaths in the SC amivantamab arm and 62 deaths in the IV amivantamab arm. *P* value was nominal; the prespecified endpoint was exploratory and not part of hierarchical hypothesis testing.

AUC, area under the concentration-time curve; C, Cycle; C_{trough}, observed serum concentration of amivantamab at steady state; CI, confidence interval; HR, hazard ratio; IV, intravenous; ORR, objective response rate; PK, pharmacokinetics; SC, subcutaneous.

1. Leighl NB, et al. Presented at the American Society of Clinical Oncology (ASCO) Congress; May 31–June 4; Chicago, USA.

Recap of ASCO 2024; Leighl NB, et al.[1]

Safety of SC Amivantamab

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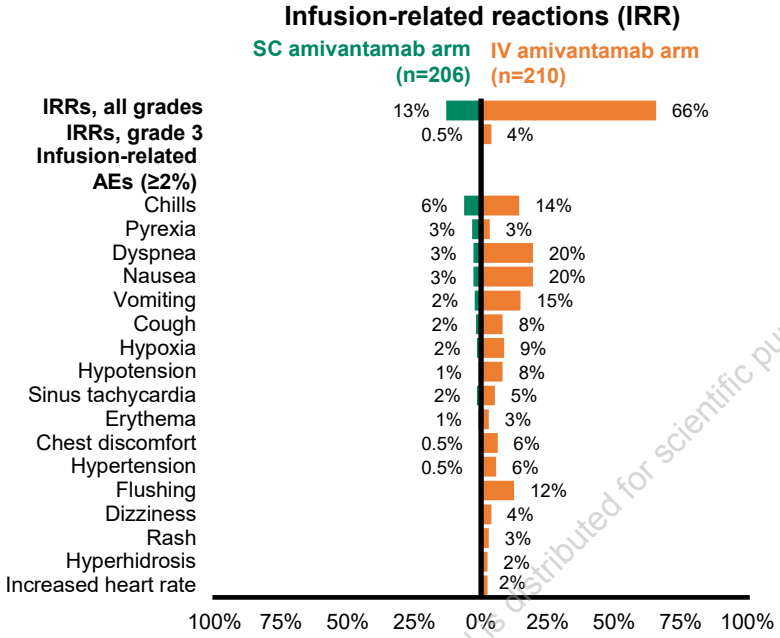
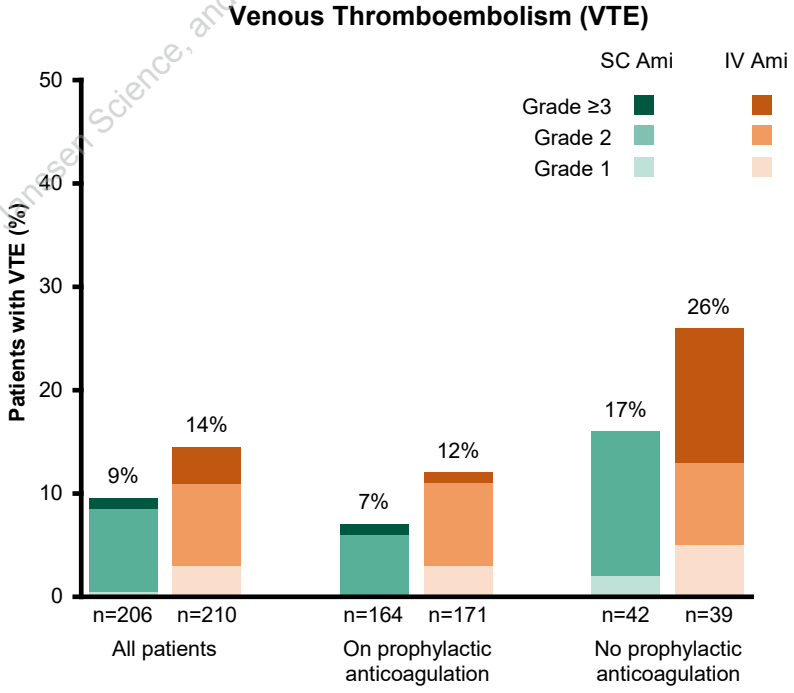
The safety profile of SC amivantamab was consistent with IV, with fewer IRRs and VTEs





Ami, amivantamab; IV, intravenous; IRR, infusion-related reaction; VTE, venous thromboembolism; SC, subcutaneous.

1. Leighl NB, et al. Presented at the American Society of Clinical Oncology (ASCO) Congress; May 31–June 4; Chicago, USA.

Patient Time in Chair[a]

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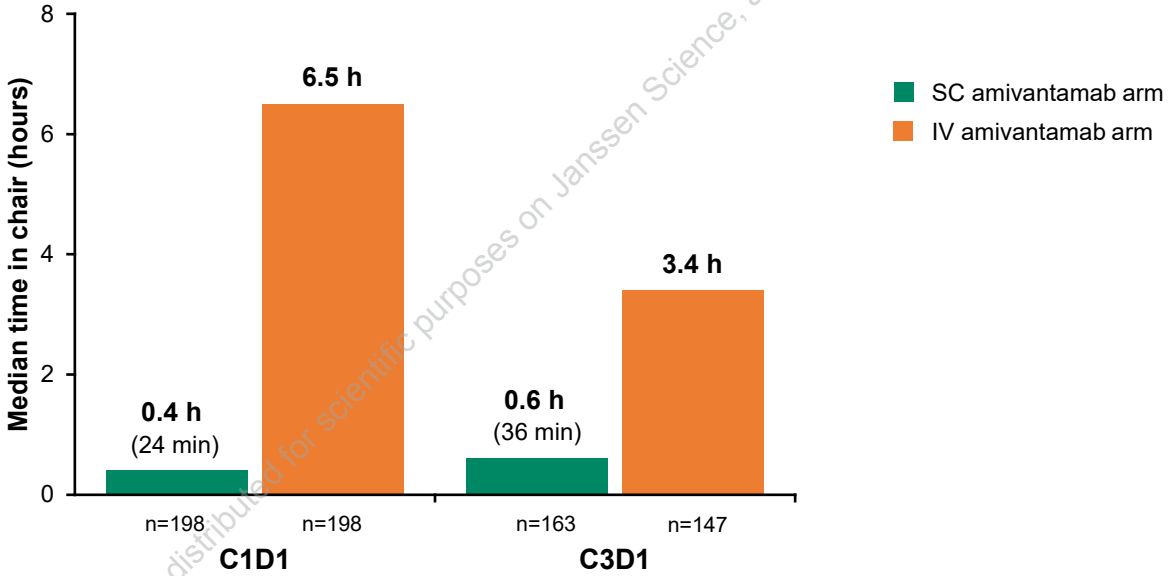
Patient time in chair was substantially lower with SC vs IV amivantamab on C1D1 and C3D1



[a]Time between entry and exit from patient chair.

C, cycle; D, day; IV, intravenous; SC, subcutaneous.

Healthcare Resource Utilization

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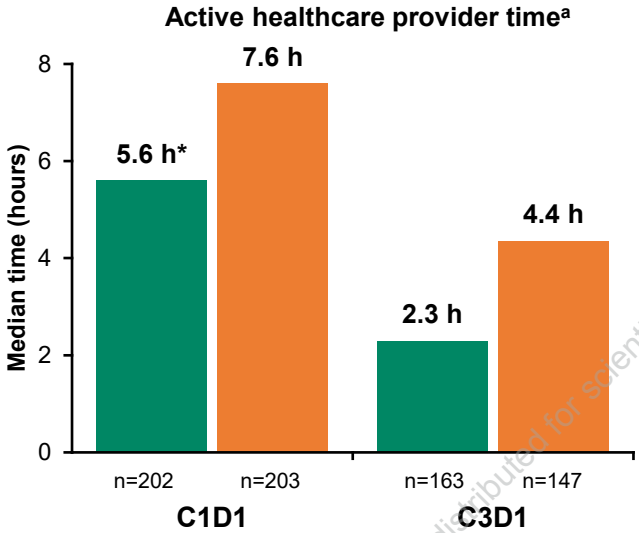
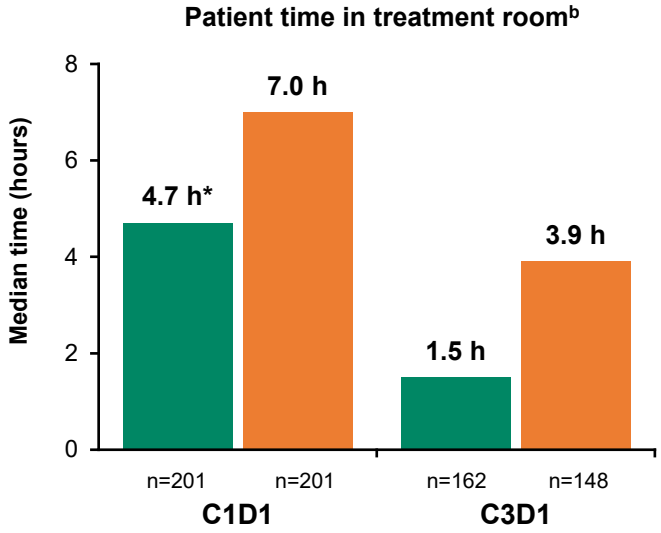
Healthcare resource utilization was substantially improved with SC vs IV amivantamab on C1D1 and C3D1

*Trial required mandatory observation period of 4 hours for SC amivantamab on C1D1





SC amivantamab arm
IV amivantamab arm

[a]Time collected through stopwatch measurement for prespecified tasks related to drug preparation (IV reconstitution or SC syringe filling and dispensing), treatment administration, and post treatment monitoring. HCPs include nurses, pharmacists, pharmacy technicians/assistant staff and physicians. [b]Time between entry in the treatment room for receiving therapy and exit from the treatment room.

C, cycle; D, day; HCP, healthcare provider; IV, intravenous; SC, subcutaneous.

Patient Convenience

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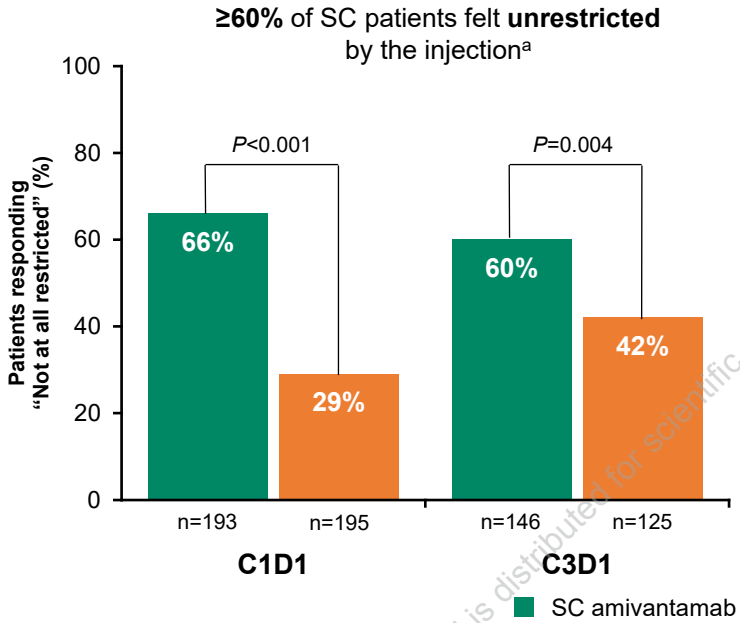
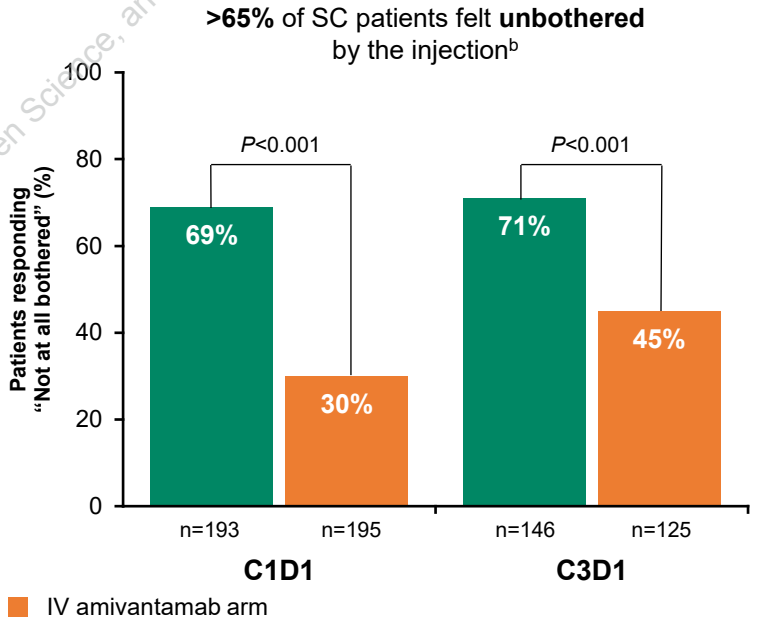
Patient convenience as measured by mTASQ was substantially improved with SC vs IV amivantamab on C1D1 and C3D1





SC amivantamab arm
IV amivantamab arm

Note: P values were nominal and obtained by Pearson's chi-squared test. [a]Question asked in the questionnaire was "When receiving the injection/infusion, do you feel restricted?" [b]Question asked in the questionnaire was "How bothered are you by the amount of time it takes to have the infusion/injection?"

C, cycle; D, day; IV, intravenous; mTASQ, modified Therapy Administration Satisfaction Questionnaire; SC, subcutaneous.

Injection Site Symptoms in the SC Arm

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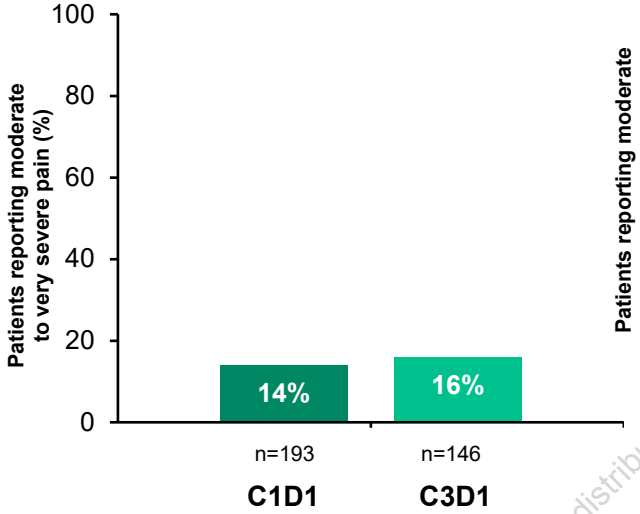
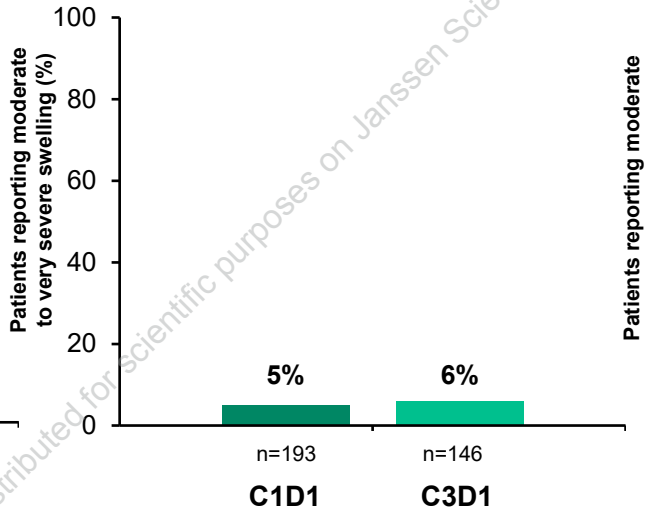
Patients receiving SC amivantamab reported minimal injection site symptoms

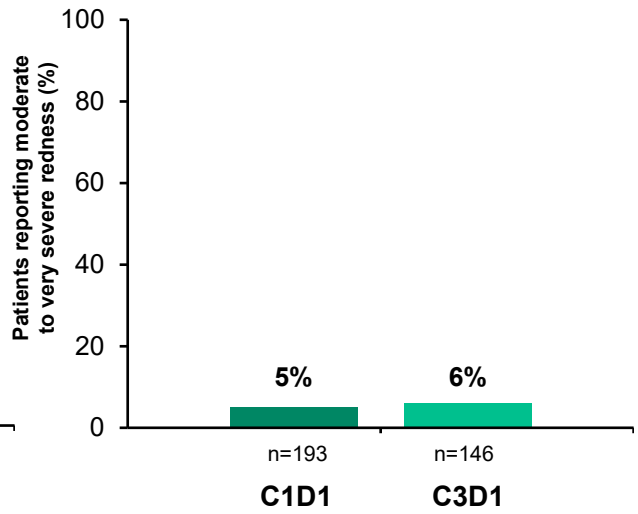
How much pain did you experience at the injection site?



How much swelling did you experience at the injection site?



How much redness did you experience at the injection site?



C, cycle; D, day; IV, intravenous; SC, subcutaneous.

Patient Satisfaction, Preference and Recommendation in the SC Arm

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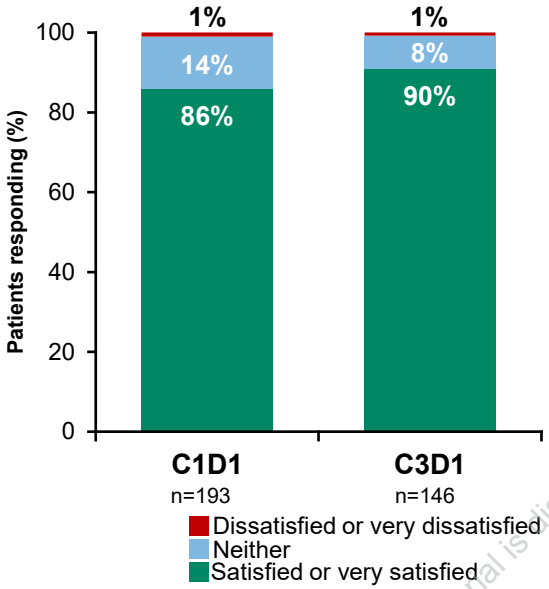
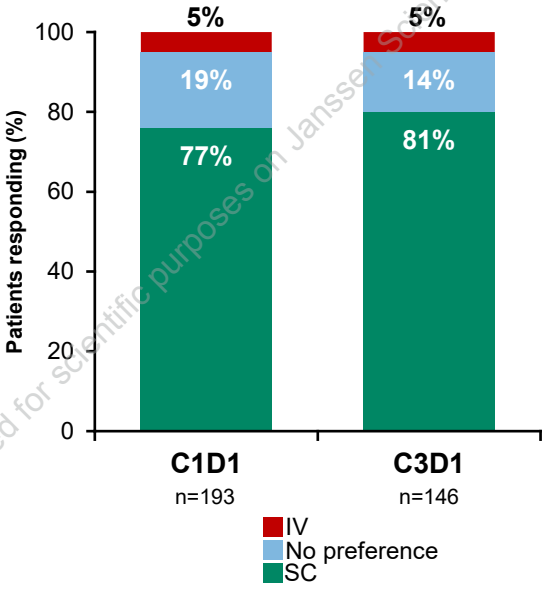
Patients were satisfied with SC administration and were likely to prefer it over IV and recommend it to other patients

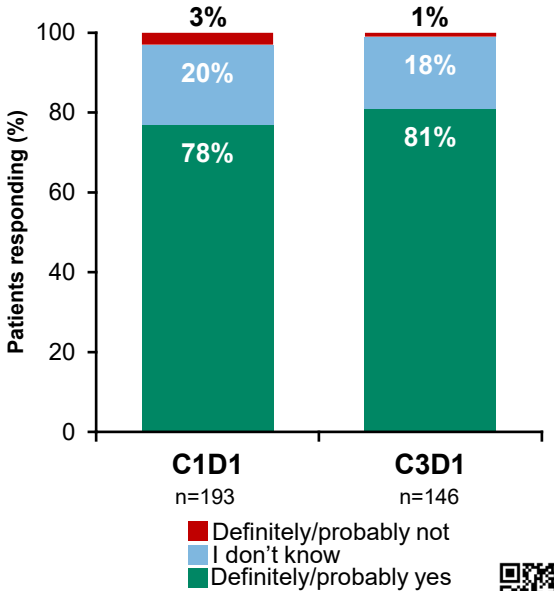
How **satisfied** were you with the SC injection?[a]



Which is your **preferred** way to receive cancer treatment?[a,b]



Would you **recommend** SC injection to another patient?[a]



[a]Percentages may not add up due to rounding. [b]Patients in the SC arm compared SC amivantamab to other IV treatments they have received; these patients did not receive IV amivantamab. C, cycle; D, day; IV, intravenous; SC, subcutaneous.

Conclusions

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- In the randomized, phase 3 PALOMA-3 study, **SC amivantamab** had lower rates of IRR and VTE, administration time of <5 minutes while maintaining the efficacy of the IV formulation (non-inferior PK and ORR)[1]
- SC amivantamab provides additional benefits by reducing healthcare resource utilization compared to the IV formulation
  - Patient time in chair: 0.4 vs 6.5 hours at C1D1 and 0.6 vs 3.4 hours at C3D1
- By cycle 3, patient satisfaction was higher with SC administration compared to IV for the following domains: patient convenience, psychological impact, and overall treatment satisfaction
- By cycle 3, a substantial majority of patients (>80%) were satisfied with SC amivantamab and would recommend it to others
- SC amivantamab has been submitted for registration in the US and the EU, based on these data and supportive data from PALOMA-2, and was granted priority review by the US FDA

SC administration simplifies the delivery of amivantamab, reduces healthcare burden, and is preferred by patients

C, cycle; D, day; EGFR, epidermal growth factor receptor; FDA, Food and Drug Administration; IRR, infusion-related reaction; IV, intravenous; ORR, objective response rate; PK, pharmacokinetics; SC, subcutaneous; VTE, venous thromboembolism.

1. Leighl NB, et al. *J Clin Oncol*. 2024. doi:10.1200/JCO.24.01001.

Other Amivantamab Presentations at WCLC 2024

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MARIPOSA

Longer follow-up of amivantamab + lazertinib vs osimertinib in first-line *EGFR*-mutant advanced NSCLC

Sunday, Sep 8 10:47-10:57am
(OA02.03; Gadgeel)

MARIPOSA

Patient-relevant outcomes of amivantamab + lazertinib vs osimertinib in first-line *EGFR*-mutant advanced NSCLC

Tuesday, Sep 10 1:55-2:00pm
(MA12.07; Nguyen)

MARIPOSA

Lazertinib vs osimertinib in first-line *EGFR*-mutant advanced NSCLC

Sunday, Sep 8 11:07-11:17am
(OA02.05; Lee)

PAPILLON

High-risk biomarker subpopulations from patients with *EGFR* Ex20ins in PAPILLON

Tuesday, Sep 10 1:50-1:55pm
(MA12.06; Goldman)

SKIPPirr

Preventing infusion-related reactions with intravenous amivantamab: primary results

Tuesday, Sep 10 2:00-2:05pm
(MA12.08; Lopes)

EGFR esisters

Development of a **patient-friendly lung cancer lexicon**:
Sunday, Sep 8 6:15-7:45pm
(P2.16F.03; Feldman)
Poster tour: Monday, Sep 9 6:45-6:53pm

Additional posters:

- **COCOON TiP:** Enhanced vs standard dermatologic management with amivantamab + lazertinib in advanced NSCLC**:** Monday, Sep 9 12:00-2:00pm (P3.12D.04; Cho)
- **PolyDamas TiP:** Amivantamab + cetrelimab in advanced NSCLC: Virtual ePoster (EP.12H.02; Voon)
- 5-year survival estimates with 1L osimertinib for *EGFR*-mutant advanced NSCLC in the US: Virtual ePoster (EP.12A.03; Sabari)

Acknowledgments

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- Patients who participated in the study and their families and caregivers
- Physicians and nurses who cared for patients and staff members who supported this clinical trial
- Staff members at the study sites and involved in data collection/analyses
- Medical writing assistance was provided by Lumanity Communications Inc., and funded by Janssen Global Services, LLC

A total of 418 patients from 20 countries were randomized in the PALOMA-3 study