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Original research

Subcutaneous versus intravenous amivantamab, both in combination with lazertinib, in refractory *EGFR*-mutated non-small cell lung cancer: Patient satisfaction and resource utilization results from the PALOMA-3 study

Mariam Alexander [a,*], Ying Cheng [b], Se-Hoon Lee [c], Antonio Passaro [d], Alexander I. Spira [e], Byoung Chul Cho [f], Sun Min Lim [f], Yuichiro Ohe [g], Adnan Nagrial [h], Jiunn Liang Tan [i], Vanina Wainsztein [j], Elisa Ramos [k], Maria del Rosario Garcia Campelo [l], Hiroaki Akamatsu [m], Danny Nguyen [n], Alexis B. Cortot [o], Alona Zer [p], Dilek Erdem [q,1], Rachel E. Sanborn [r], Till-Oliver Emde [s], Anna R. Minchom [t], Bogdan Zurawski [u], Maria Lurdes Ferreira [v], James Chih-Hsin Yang [w], Melina E. Marmarelis [x], Julia Schuchard [y], Jefferson Alves [z], Debopriya Ghosh [z], Gregor Balaburski [aa], Remy B. Verheijen [ab], Liliana Ribeiro [ac], Mohamed Gamil [aa], Joshua M. Bauml [aa], Mahadi Baig [z], Natasha B. Leighl [ad]

[a] *Hollings Cancer Center, Medical University of South Carolina, Charleston, SC, United States*
[b] *Jilin Cancer Hospital, Changchun, China*
[c] *Samsung Medical Center, Sungkyunkwan University Medical School, Seoul, Republic of Korea*
[d] *Division of Thoracic Oncology, European Institute of Oncology, Milan, Italy*
[e] *Virginia Cancer Specialists, Fairfax, VA, United States*
[f] *Division of Medical Oncology, Yonsei Cancer Center, Yonsei University College of Medicine, Seoul, Republic of Korea*
[g] *National Cancer Center Hospital, Tokyo, Japan*
[h] *Westmead Hospital, Westmead, Australia*
[i] *Department of Medicine, University of Malaya, Kuala Lumpur, Malaysia*
[j] *CEMIC, Buenos Aires, Argentina*
[k] *Cetus Oncologia, Belo Horizonte, Brazil*
[l] *Medical Oncology, Hospital Universitario A Coruña, Coruña, Spain*
[m] *Internal Medicine III, Wakayama Medical University Hospital, Wakayama, Japan*
[n] *City of Hope National Medical Center, Duarte, CA, United States*
[o] *Université de Lille, CHU Lille, Thoracic Oncology Department, Centre National de la Recherche Scientifique, INSERM, Institut Pasteur de Lille, UMR9020-UMR-S 1277-Canther, Lille, France*
[p] *Rambam Health Care Campus, Haifa, Israel*
[q] *VM Medical Park Samsun Hastanesi, Samsun, Turkey*
[r] *Earle A. Chiles Research Institute, Providence Cancer Institute, Portland, OR, United States*
[s] *Oncologianova GmbH, Recklinghausen, Germany*
[t] *Drug Development Unit, The Royal Marsden Hospital and The Institute of Cancer Research, Sutton, United Kingdom*
[u] *Centrum Onkologii im. prof. Franciszka Łukaszczyka w Bydgoszczy, Bydgoszcz, Poland*
[v] *Division of Pulmonology, Hospital de Braga, Braga, Portugal*
[w] *Department of Medical Oncology, National Taiwan University Cancer Center, Taipei, Taiwan*
[x] *Division of Hematology and Oncology, Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, United States*
[y] *Johnson & Johnson, Horsham, PA, United States*
[z] *Johnson & Johnson, Raritan, NJ, United States*
[aa] *Johnson & Johnson, Spring House, PA, United States*
[ab] *Janssen Research & Development, a Johnson & Johnson company, Leiden, the Netherlands*
[ac] *Janssen-Cilag Farmacêutica, a Johnson & Johnson company, Porto Salvo, Portugal*
[ad] *Princess Margaret Cancer Centre, Toronto, ON, Canada*

* Correspondence to: Hollings Cancer Center, Medical University of South Carolina, 86 Jonathan Lucas Street, Charleston, SC 29425, USA.
E-mail address: alexanma@musc.edu (M. Alexander).

[1] Current affiliation: Istinye University Medical Faculty, Istanbul, Turkey

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ABSTRACT

Introduction: Intravenous anticancer treatments present challenges for patients and healthcare professionals (HCPs), prompting the development of subcutaneous formulations. In the phase 3 PALOMA-3 study, subcutaneous amivantamab demonstrated noninferior pharmacokinetics and response rates versus intravenous amivantamab (both with lazertinib), with substantially faster administration, a 5-fold reduction in infusion-related reactions, reduced venous thromboembolism, and numerically prolonged survival.

Methods: Participants with *EGFR*-mutated NSCLC and progression on osimertinib and chemotherapy were randomized to subcutaneous (n = 206) or intravenous amivantamab (n = 212), plus lazertinib. Resource utilization and participant-reported treatment satisfaction were evaluated at cycle (C) 1 day (D) 1 and C3D1.

Results: Time-in-chair was substantially lower for subcutaneous versus intravenous amivantamab (C1D1: median [range], 23 min or 0.4 h [0–12.0 h] vs 6.5 h [0–24.0 h]; C3D1: 35 min or 0.6 h [0–6.6 h] vs 3.4 h [0.5–9.0 h]), as were HCP time and participant time-in-room.

More participants who received subcutaneous versus intravenous amivantamab reported feeling unrestricted (C1D1, 66 % vs 29 %; C3D1, 60 % vs 42 %) or unbothered (C1D1, 69 % vs 30 %; C3D1, 71 % vs 45 %) by administration, and reported gaining time for other activities (C1D1, 36 % vs 7 %; C3D1, 37 % vs 6 %). Few participants who received subcutaneous amivantamab reported moderate-to-very severe injection-site pain (C1D1, 14 %; C3D1, 16 %), swelling (C1D1, 5 %; C3D1, 6 %), or redness (C1D1, 5 %; C3D1, 6 %). Most subcutaneous amivantamab recipients preferred and were more satisfied with its administration versus historical experience with intravenous therapies and would recommend it.

Conclusions: In PALOMA-3, subcutaneous amivantamab, which simplifies and shortens administration, reduces resource utilization, and enhances treatment experience, was a preferred option for patients who received amivantamab-lazertinib.

1. Introduction

Amivantamab is an epidermal growth factor receptor (EGFR)-MET bispecific antibody with immune cell–directing activity [1–4]. In the phase 3 MARIPOSA trial, intravenous amivantamab combined with lazertinib, a central nervous system–penetrant, third-generation EGFR tyrosine kinase inhibitor (EGFR TKI), demonstrated superior progression-free survival (hazard ratio, 0.70; $P < 0.001$) versus osimertinib in patients with treatment-naïve *EGFR*-mutated advanced non-small cell lung cancer (NSCLC) [5,6]. Based on these results, intravenous amivantamab with lazertinib was recently approved in the United States and European Union as a first-line treatment for patients with advanced NSCLC with *EGFR* exon 19 deletion (Ex19del) or exon 21 L858R substitution mutations [6,7]. Intravenous amivantamab is also approved in multiple geographies (eg, Brazil, the European Union, the United Kingdom, and the United States) combined with platinum-based chemotherapy for patients with *EGFR* Ex19del- or L858R-mutant advanced NSCLC after disease progression on a third-generation EGFR TKI [6,8–10]. Additionally, for patients with locally advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations, intravenous amivantamab is approved as a first-line combination treatment with chemotherapy and as monotherapy after disease progression on chemotherapy [6].

A subcutaneous formulation of amivantamab has been developed that aims to enhance patient and provider treatment experience, reduce administration time and healthcare costs, and lower the incidence of adverse events, consistent with other intravenous to subcutaneous formulation transitions in oncology [11–13]. In the phase 3 PALOMA-3 study (ClinicalTrials.gov Identifier: NCT05388669), subcutaneous amivantamab plus oral lazertinib demonstrated pharmacokinetic noninferiority and a comparable objective response rate with intravenous amivantamab plus oral lazertinib. Furthermore, subcutaneous administration showed promising results over intravenous administration for progression-free survival, duration of response, and overall survival, and a significant advantage in administration time (<5 min vs 2–5 h). Subcutaneous amivantamab was also associated with a substantial reduction in infusion-related reactions and venous thromboembolism rates [14].

These data support a noninferior or numerically improved efficacy and favorable safety profile for subcutaneous amivantamab in *EGFR*-mutated NSCLC. The subcutaneous amivantamab formulation containing recombinant human hyaluronidase PH20 (rHuPH20; Halozyme, Inc.) is currently under review by several health authorities.

Here, the prespecified analyses of the secondary endpoints of medical resource utilization and patient treatment satisfaction are reported from the PALOMA-3 study, comparing subcutaneous with intravenous administration of amivantamab (both with oral lazertinib) and providing further insights into its benefits.

2. Materials and methods

2.1. Study participants

PALOMA-3 enrolled participants aged ≥18 years with locally advanced or metastatic NSCLC harboring documented common *EGFR* mutations (Ex19del/L858R) with disease progression on or after osimertinib (or another approved third-generation EGFR TKI) and platinum-based chemotherapy, irrespective of sequence. Details of the trial design, methodology, and primary results have been previously reported [14].

2.2. Study design and treatment

In total, 418 participants were randomized 1:1 to receive subcutaneous amivantamab-lazertinib (n = 206) or intravenous amivantamab-lazertinib (n = 212). Subcutaneous amivantamab was administered at a dose of 1600 mg (2240 mg for ≥ 80 kg weight) by manual injection to the abdomen, lasting approximately 5 min, once weekly for 4 weeks and biweekly thereafter. Intravenous amivantamab was administered at a dose of 1050 mg (1400 mg for ≥ 80 kg weight) on the same schedule. The first dose of intravenous amivantamab was administered over 2 days, with 350 mg on cycle (C) 1 day (D) 1 and the remainder on C1D2. Oral lazertinib was administered at a dose of 240 mg once daily.

2.3. Protocol approval

The trial was conducted in accordance with the provisions of the Declaration of Helsinki, Good Clinical Practice guidelines, applicable regulatory requirements, and the policy on bioethics and human biologic samples of the trial sponsor, Johnson & Johnson. All participants provided written informed consent, and the study protocol received

approval from an independent ethics committee or institutional review board.

2.4. Endpoints and assessments

Medical resource utilization was assessed in the following predefined secondary endpoints: participant chair time (time between entry and exit from chair), participant time in treatment room (time between entry and exit from treatment room), and active healthcare professional (HCP) time (measured by stopwatch for prespecified tasks related to drug preparation, treatment administration, and post-treatment monitoring) on C1D1 (study day 1) and C3D1 (study day 57; Supplemental Table 1). In the intravenous amivantamab-lazertinib group, participant chair time included the time required to administer the first 350 mg dose of amivantamab on C1D1 only. Median HCP time and participant time in treatment room included a 4-hour observation period for participants who received subcutaneous amivantamab, which was mandatory on C1D1 and recommended at subsequent infusions. HCPs included nurses, pharmacists, pharmacy technicians/assistant staff, and physicians. To determine administration impact, participant comfort, ease of use, and to identify potential issues, endpoints were assessed at C1D1 (immediate feedback) and C3D1 (experience-based feedback following multiple administrations).

Cancer therapy satisfaction was assessed using a modified version of the Therapy Administration Satisfaction Questionnaire (mTASQ), which was completed by participants following drug administration on C1D1 (C1D2 for the intravenous arm), C3D1, and end-of-treatment (EOT). The unmodified TASQ is a validated 12-item administration satisfaction questionnaire designed for adults and validated in rituximab studies [15]. Question 11 of the TASQ form was modified (mTASQ) for use in PALOMA-3 to reflect that the subcutaneous injection would occur in the "skin," instead of "thigh." The mTASQ measured the impact of the mode of treatment administration in 9 items across 5 domains: physical impact (3 items), psychological impact (1 item), impact on activities of daily living (1 item), convenience (2 items), and satisfaction (2 items; Supplemental Table 2). Each domain was scored on a scale of 0–100, with higher scores indicative of more positive feelings toward therapy. The recall/observation period was based on participants' most recent subcutaneous injection or intravenous infusion. Participants were asked to report on their current/most recent treatment experience with subcutaneous or intravenous amivantamab. Participants had prior experience receiving other anticancer drugs intravenously but were not instructed to compare current with prior treatments. For participants with multiple records at the same visit, the one closest to the visit date was selected as the scheduled assessment.

The mTASQ was provided in the local language in accordance with local guidelines.

2.5. Statistical methods

Descriptive statistics were used to summarize results of medical resource utilization by treatment arm in the safety analysis set. No formal statistical hypothesis testing was conducted.

mTASQ domain scores and single symptom items were evaluated at baseline, C3D1, and EOT for absolute values using descriptive statistics in the full analysis set. A Pearson's chi-squared test was performed to compare the proportion of participants who selected certain responses on the mTASQ between arms; *P*-values were nominal.

Additional information on statistical methods can be found in the study protocol, which was published with the primary analysis of PALOMA-3 [14].

3. Results

3.1. Participants

A total of 418 participants were randomized to receive subcutaneous (n = 206) or intravenous amivantamab (n = 212), both in combination with oral lazertinib. Before randomization to a study treatment, all participants were previously treated with systemic therapies for NSCLC, including platinum-based chemotherapy (subcutaneous arm, n = 191; intravenous arm, n = 192) and/or osimertinib (subcutaneous arm, n = 193; intravenous arm, n = 203), irrespective of sequence [14]. The proportion of participants with ≥3 months of cumulative lazertinib treatment was comparable between arms (subcutaneous, 68 % [140/206]; intravenous, 61 % [127/210]).

Overall, data collection rates were high for all endpoints presented here. Active HCP time was collected for 98 % (202/206) of participants in the subcutaneous arm and 97 % (203/210) of participants in the intravenous arm at C1D1 (C3D1 rates were 98 % [163/166] and 93 % [147/158], respectively). Correspondingly, duration of amivantamab treatment administration was collected from 100 % (206/206) and 99 % (207/210) of participants at C1D1 (C3D1 rates, 98 % [162/166] and 93 % [147/158]), participant time-in-chair was collected from 96 % (198/206) and 94 % (198/210) of participants at C1D1 (C3D1 rates, 98 % [163/166] and 93 % [147/158]), and participant time in treatment room was collected from 98 % (201/206) and 96 % (201/210) of participants at C1D1 (C3D1 rates, 98 % [162/166] and 94 % [148/158]).

Among participants who were undergoing treatment at the time of assessment, 94 % (193/206) in the subcutaneous arm and 92 % (195/212) in the intravenous arm completed the mTASQ at C1D1; corresponding completion rates at C3D1 were 88 % (146/166) and 79 % (125/158), respectively. Compliance at EOT was 86 % (61/71) in the subcutaneous arm and 71 % (55/77) in the intravenous arm. The most common reasons for missing mTASQ data included failure of the electronic clinical outcome assessment data-collection device (C1D1, 4 subcutaneous amivantamab recipients vs 13 intravenous amivantamab recipients; C3D1, 4 vs 6; EOT, 2 vs none), sites failing to administer the questionnaire (C1D1, 3 vs 9 participants; C3D1, 6 vs 7; EOT, 2 vs 1), or participants being too ill to complete the questionnaire (C1D1, 1 vs 5 participants; C3D1, none; EOT, 3 vs 8). Given the smaller sample sizes at EOT, this analysis focuses on results for C1D1 and C3D1; data from EOT can be found in the Supplemental Data **Section.**

3.2. Medical resource utilization

Median (range) participant time in the treatment chair at C1D1 was 23 min, or 0.4 h (0–12.0 h) in the subcutaneous arm and 6.5 h (0–24.0 h) in the intravenous arm. Corresponding values for C3D1 were 35 min, or 0.6 h (0–6.6 h) in the subcutaneous arm and 3.4 h (0.5–9.0 h) in the intravenous arm (Fig. 1A and Supplemental Table 3). Median (range) active HCP time at C1D1 was 5.6 h (0.4–11.4 h) in the subcutaneous arm (including the mandatory observation time of 4 h) and 7.6 h (1.6–19.2 h) in the intravenous arm. At C3D1, when the 4-hour observation time for subcutaneous administration was optional, active HCP time was 2.3 h (0.2–8.6 h) and 4.4 h (2.5–9.5 h) in the subcutaneous and intravenous arms, respectively (Fig. 1B). Similarly, median (range) participant time in treatment room at C1D1 was 4.7 h (0.1–23.7) and 7.0 h (1.2–24.0 h) in the subcutaneous and intravenous arms, respectively; at C3D1, the values were 1.5 h (0.1–6.6 h) and 3.9 h (0.5–8.5 h; Fig. 1C).

3.3. Patient-reported outcomes

Mean mTASQ scores were better (higher values) among participants who received subcutaneous versus intravenous amivantamab in the domains for convenience, impact on daily activities, psychological impact, and treatment satisfaction (Fig. 2).

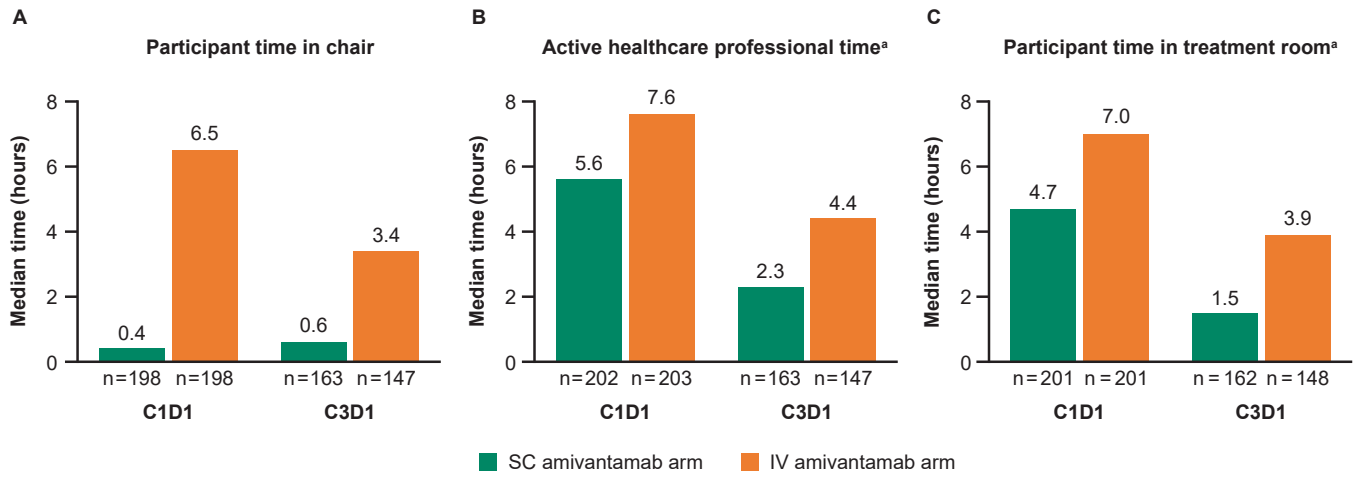

Fig. 1. Medical Resource Utilization. [a]C1D1 values include 4 h of mandatory observation time after amivantamab SC injection, resulting in extended active healthcare professional time and prolonged participant time in the treatment room; the infusion time in the IV arm was considered adequate for observation. C, cycle; D, day; IV, intravenous; SC, subcutaneous.

In the subcutaneous arm, 66 % of participants reported feeling unrestricted by their injection compared with 29 % in the intravenous arm at C1D1 (nominal $P < 0.001$); corresponding values at C3D1 were 60 % and 42 %, respectively (nominal $P = 0.004$; Fig. 3A). Rates at EOT are shown in Supplemental Table 4. Similarly, more participants who received subcutaneous versus intravenous amivantamab reported feeling unbothered by the amount of time needed for their injection or infusion (C1D1, 69 % vs 30 %, respectively; nominal $P < 0.001$; C3D1, 71 % vs 45 %; nominal $P < 0.001$; Fig. 3B), and felt that they gained time for other things (C1D1, 36 % vs 7 %; nominal $P < 0.001$; C3D1, 37 % vs 6 %; nominal $P < 0.001$; Fig. 3C). Only a minority of participants who received subcutaneous amivantamab reported moderate-to-very severe injection-related symptoms such as pain (C1D1, 14 %; C3D1, 16 %), swelling (C1D1, 5 %; C3D1, 6 %), or redness (C1D1, 5 %; C3D1, 6 %) at the injection site (Fig. 4).

In the subcutaneous arm, 77 % of participants preferred the subcutaneous injection over their historical experience with intravenous treatments; similar results were seen at C3D1 (81 %; Fig. 5A). Most participants in the subcutaneous arm were satisfied with their administration route (C1D1, 86 %; C3D1, 90 %; Fig. 5B) and would recommend subcutaneous administration to others (C1D1, 78 %; C3D1, 81 %; Fig. 5C). Other items that were assessed using the mTASQ form are shown in Supplemental Table 4.

4. Discussion

The prospective, randomized, phase 3 PALOMA-3 study provided a head-to-head comparison between subcutaneous and intravenous amivantamab, both combined with lazertinib. This study demonstrated that the pharmacokinetic properties and objective response rate of the subcutaneous formulation were noninferior to intravenous amivantamab, with an added benefit of a 5-fold reduction in infusion-related reactions, lower risk of venous thromboembolism, and numerically prolonged survival. Additionally, 85 % of participants found subcutaneous administration to be “very convenient” or “convenient” compared with about one-third of participants who received the intravenous formulation [14]. A key advantage of transitioning from intravenous to subcutaneous formulations is potentially improving overall treatment experiences while also reducing infusion-related reactions [11–13,16]. The findings from PALOMA-3 are notable, as an enhanced patient experience may improve adherence to treatment regimens, particularly for long-term therapies like those for advanced NSCLC.

Subcutaneous amivantamab administration was feasible and demonstrated several practical advantages over intravenous amivantamab, such as significantly reducing participant chair time, time in the treatment room, and HCP time spent on drug preparation and administration. This overall reduction in medical resource utilization was observed despite the mandatory 4-hour observation period in C1D1, which may indicate that the benefit could be even higher in non-clinical

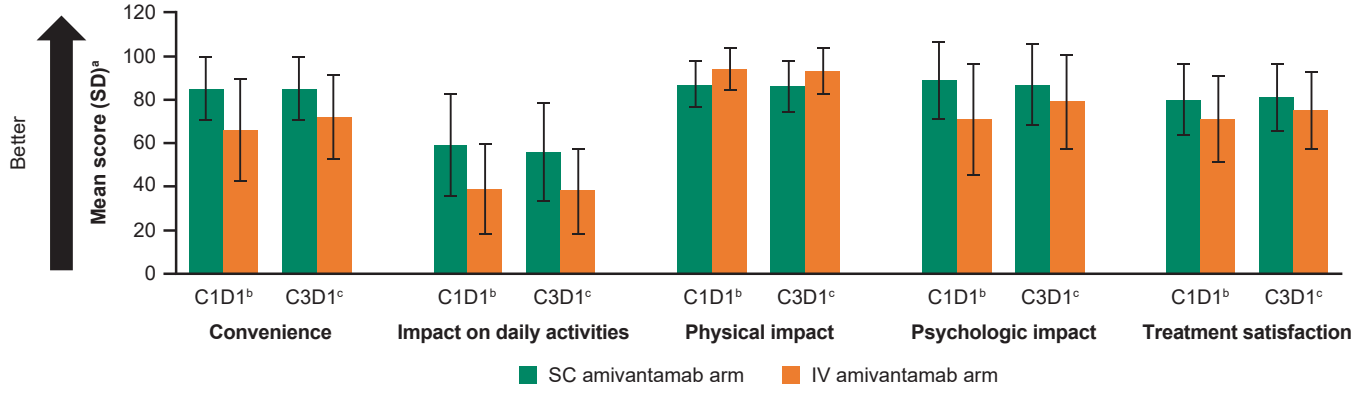

Fig. 2. Summary of Patient-Reported Outcome Scores Assessed Using the mTASQ Form. [a]Each domain was measured using a 100-point scale. [b]SC, n = 193; IV, n = 195. [c]SC, n = 146; IV, n = 125. C, cycle; D, day; IV, intravenous; mTASQ, modified Therapy Administration Satisfaction Questionnaire; SC, subcutaneous; SD, standard deviation.

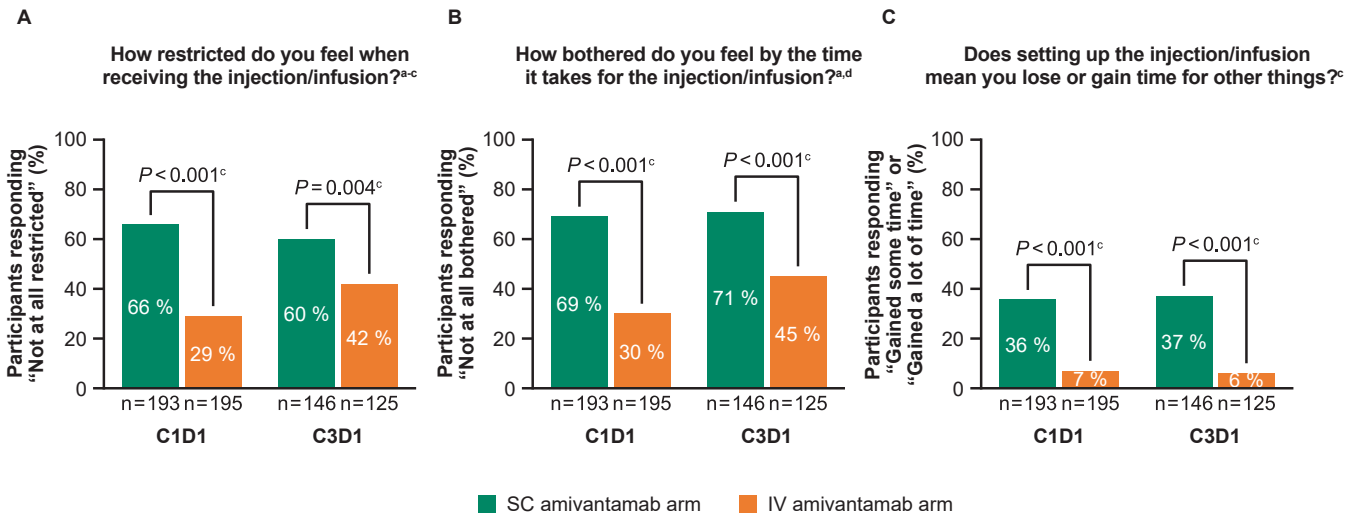

Fig. 3. Treatment Convenience and Impact on Daily Activities. [a]Questions rephrased for easier graph interpretation. [b]Question asked in the questionnaire was "When receiving the injection/infusion, how restricted do you feel?" [c]Nominal *P*-value obtained via Pearson's chi-squared test. [d]Question 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; SC, subcutaneous.

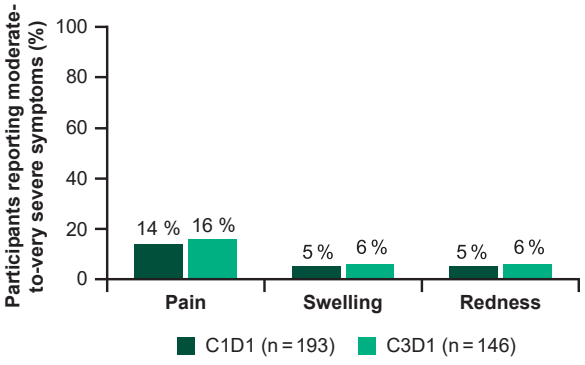

Fig. 4. Physical Impact in the Subcutaneous Arm. C, cycle; D, day.

trial settings where this observation period will not be a requirement. These results reflect similar findings in studies of other successful transitions from intravenous to subcutaneous formulations that contain rHuPH20, such as rituximab [17–19] and daratumumab [13], where transitioning from an intravenous to a subcutaneous formulation also led to meaningful time savings and more efficient use of medical resources. Decreases in medical resource utilization can substantially benefit patients, who often dedicate considerable time to cancer treatments, disrupting their schedules and daily lives [20–22]. Furthermore, the HCP activity and patient chair time required for intravenous cancer treatments place a strain on medical centers and HCPs themselves, which may be mitigated through the successful development of subcutaneous formulations that require far less time to administer [11].

Additionally, mean overall mTASQ scores were markedly better for subcutaneous versus intravenous amivantamab across nearly all evaluated domains. A small proportion of participants in the subcutaneous arm reported feeling moderate-to-very severe pain (~16 %), swelling

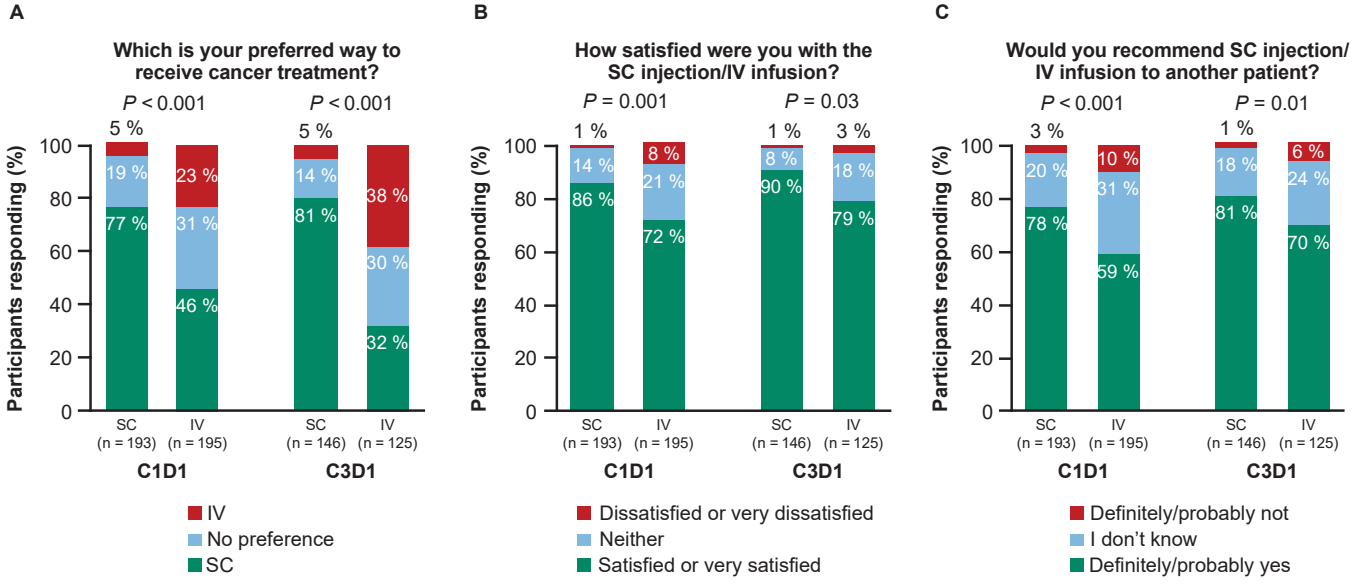

Fig. 5. Participant Preference, Satisfaction, and Recommended Treatment. Percentages may not sum up to 100 % due to rounding. Participants in the SC arm compared SC amivantamab with other IV treatments they have received historically; these participants did not receive IV amivantamab. *P*-values are nominal and obtained via Pearson's chi-squared test. C, cycle; D, day; IV, intravenous; SC, subcutaneous.

(~6 %), or redness (~6 %) at the injection site on both C1D1 and C3D1, indicating that the physical impact was minimal. These findings are aligned with earlier studies using the Rituximab Administration Satisfaction Questionnaire (RASQ; the tool on which the TASQ is based) to assess subcutaneous versus intravenous rituximab, where the subcutaneous formulation showed improved participant satisfaction across most domains [23,24]. Whereas the RASQ assessed satisfaction with subcutaneous rituximab given in the thigh, the mTASQ assessed satisfaction with subcutaneous amivantamab administration anywhere in the skin. This flexibility in injection-site location may have allowed participants to receive subcutaneous amivantamab even if they could not or did not wish to have an injection in their thigh. While compliance was generally reasonable, one potential limitation of the mTASQ is the potential for gaps in data collection, which in our study was influenced by device failures, sites failing to collect data, and participant illness. Smaller sample sizes at the EOT time point were due to few participants having completed an EOT visit at the time of the analysis because most participants were still on study treatment, or had died or withdrawn from the study without an EOT visit. Furthermore, EOT was defined by the investigator's decision to end treatment, which could occur after the last study treatment administration (eg, to allow for observation of adverse event recovery or other clinical assessments prior to formal withdrawal), and may have further contributed to missing data or reduced response rates at EOT.

Patient preference is a key driver in treatment decision-making and was intentionally incorporated into the PALOMA-3 study design. Participants who received subcutaneous amivantamab reported higher satisfaction compared with participants who received intravenous amivantamab, with the majority (≥77 %) expressing a preference for subcutaneous administration over previous experiences with intravenous anticancer drugs. While detailed treatment adherence data were not presented, we note that cumulative lazertinib treatment of ≥ 3 months was comparable between study arms, suggesting that the higher participant satisfaction with subcutaneous amivantamab compared with intravenous amivantamab was driven by the administration route of amivantamab. The higher participant satisfaction with subcutaneous administration reflects tolerability and participant preference, which are important contributors to clinical outcomes and treatment experience.

Results from the current study also showed that, among participants who received intravenous amivantamab, the preference for intravenous administration compared with subcutaneous administration transiently increased at C3, but decreased by EOT (C1D1, 23 %; C3D1, 38 %; EOT, 29 %), which may have been related to increased familiarity with and adaptation to the administration route over time. Furthermore, the change in sample size over time (n = 195 at C1D1 vs n = 125 at C3D1) in the intravenous amivantamab arm should also be considered when interpreting preference shifts, as this may reflect response variability and retention dynamics.

Our study does not directly compare participant preferences between intravenous and subcutaneous amivantamab, as those in the subcutaneous arm never received intravenous amivantamab (and those in the intravenous arm did not receive subcutaneous amivantamab). Furthermore, the prior experience with intravenous treatment in the subcutaneous arm was limited to platinum-based chemotherapy, which differs from intravenous amivantamab in mechanism of action, safety profile, and duration of treatment. Similarly, participants in the intravenous arm were unlikely to have prior experience with subcutaneous treatment, which makes direct comparisons with subcutaneous amivantamab challenging. However, most enrolled participants received intravenous chemotherapy prior to randomization and thus may have had recent experience with intravenous treatments [14].

Participant preference for subcutaneous amivantamab over intravenous treatments indicates that convenience is a significant factor during a patient's lung cancer experience. These results underscore the importance of shared decision-making with consideration given to individual patient priorities. Convenience and ease of treatment administration are both important aspects to consider.

The findings from PALOMA-3 have the potential to influence clinical practice by offering a safer, more efficient, and patient-preferred option for administering amivantamab. Considering recent evidence showing significant overall survival improvement with first-line intravenous amivantamab-lazertinib versus osimertinib [25], and the pharmacokinetic noninferiority of the subcutaneous formulation versus the intravenous formulation [14], the enhanced patient experience and efficacy offered by subcutaneous amivantamab-lazertinib could provide substantial benefit when compared with EGFR TKIs alone for patients with first-line *EGFR*-mutated NSCLC.

Additionally, the ongoing PALOMA-2 trial is further evaluating subcutaneous amivantamab across multiple settings and treatment combinations, including treatment-naïve *EGFR* Ex19del- or L858R-mutant NSCLC (subcutaneous amivantamab plus lazertinib), second-line *EGFR* Ex19del- or L858R-mutant NSCLC (subcutaneous amivantamab plus chemotherapy with or without lazertinib), treatment-naïve NSCLC with exon 20 insertion mutations (subcutaneous amivantamab plus chemotherapy), and extended dosing intervals of every 3 or 4 weeks [26]. These longer intervals may further reduce the number of clinic visits required, offering additional convenience for both patients and providers.

5. Conclusion

Subcutaneous amivantamab plus lazertinib in PALOMA-3 enhanced participant convenience and reduced medical resource utilization compared with intravenous amivantamab plus lazertinib, while improving safety and numerically increasing some efficacy measures. These findings highlight the potential for subcutaneous administration of amivantamab to become a preferred option in treating patients with *EGFR*-mutant NSCLC, improving both clinical outcomes and the patient experience, potentially leading to wider adoption and increased quality of life.

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CRediT authorship contribution statement

Mariam Alexander: Writing – review & editing, Writing – original draft, Investigation, Data curation. **Ying Cheng:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Se-Hoon Lee:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Antonio Passaro:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Alexander I. Spira:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Byoung Chul Cho:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Sun Min Lim:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Yuichiro Ohe:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Adnan Nagrial:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Jiunn Liang Tan:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Vanina Wainsztein:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Elisa Ramos:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Maria del Rosario Garcia Campelo:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Hiroaki Akamatsu:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Danny Nguyen:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Alexis B. Cortot:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Alona**

Zer: Writing – review & editing, Writing – original draft, Investigation, Data curation. **Dilek Erdem:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Rachel E. Sanborn:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Till-Oliver Emde:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Anna R. Minchom:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Bogdan Zurawski:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Maria Lurdes Ferreira:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **James Chih-Hsin Yang:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Melina E. Marmarelis:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Julia Schuchard:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Methodology, Investigation, Funding acquisition, Data curation. **Jefferson Alves:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Methodology, Investigation, Funding acquisition, Data curation. **Debopriya Ghosh:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Software, Resources, Investigation, Funding acquisition, Formal analysis, Data curation. **Gregor Balaburski:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Investigation, Funding acquisition, Data curation. **Remy B. Verheijen:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Liliana Ribeiro:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Project administration, Investigation, Funding acquisition, Data curation. **Mohamed Gamil:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization. **Joshua M. Bauml:** Writing – review & editing, Writing – original draft, Supervision, Resources, Investigation, Funding acquisition, Data curation. **Mahadi Baig:** Writing – review & editing, Writing – original draft, Visualization, Supervision, Resources, Investigation, Funding acquisition, Data curation. **Natasha B. Leighl:** Writing – review & editing, Writing – original draft, Investigation, Data curation.

Prior presentation

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships that may be considered as potential competing interests:

Mariam Alexander: **consulting or advisory role** for AbbVie, Amgen, BioAtla, Catalym.

Ying Cheng: Nothing to disclose.

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Antonio Passaro: **consulting or advisory role** for Roche/Genentech, Bristol Myers Squibb, AstraZeneca, MSD, Pfizer, Boehringer Ingelheim, Johnson & Johnson, Novartis, Daiichi Sankyo Europe GmbH, Bayer; **speakers bureau member** for AstraZeneca, Johnson & Johnson, Boehringer Ingelheim, Daiichi Sankyo Europe GmbH, MSD.

Alexander I. Spira: **consulting or advisory role** for Array BioPharma, Incyte, Amgen, Novartis, Mirati Therapeutics, Gritstone bio, Jazz Pharmaceuticals, Merck, Bristol Myers Squibb, Takeda, Johnson & Johnson, Mersana, Blueprint Medicines, Daiichi Sankyo, AstraZeneca, Regeneron, Eli Lilly, Black Diamond Therapeutics, Sanofi; **consulting fees to institution** from AstraZeneca/MedImmune; **leadership role** for NEXT Oncology; **stock and ownership interests** in Eli Lilly; **honoraria** from CytomX Therapeutics, AstraZeneca/MedImmune, Merck, Takeda, Amgen, Johnson & Johnson, Novartis, Bristol Myers Squibb, Bayer; **research funding of institution** from Roche, AstraZeneca, Boehringer Ingelheim, Astellas, MedImmune, Novartis, Incyte, AbbVie, Ignyta, Takeda, MacroGenics, CytomX Therapeutics, Astex Pharmaceuticals, Bristol Myers Squibb, Loxo Oncology, Arch Therapeutics, Gritstone bio, Plexxikon, Amgen, Daiichi Sankyo, ADC Therapeutics, Johnson & Johnson, Mirati Therapeutics, Rubius Therapeutics, Synthekine, Mersana, Blueprint Medicines, Regeneron, Alkermes, Revolution Medicines, Medikine, Black Diamond Therapeutics, BluPrint Oncology, NALO Therapeutics, Scorpion Therapeutics, Arrivent Biopharma.

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Yuichiro Ohe: **grants/contracts** with AstraZeneca, Chugai, Eli Lilly, Ono Pharmaceutical, Bristol Myers Squibb, Kyorin, Dainippon Sumitomo, Pfizer, Taiho Pharma, Novartis, Takeda, Kissei, Daiichi Sankyo, Johnson & Johnson.

Adnan Nagrial: **consulting or advisory role** for MSD, Gilead, Bristol Myers Squibb, Johnson & Johnson, AstraZeneca, Roche.

Jiunn Liang Tan: **payment or honoraria** from MSD, Boehringer Ingelheim, Pfizer, AstraZeneca, Roche, Novartis; **travel, accommodations, and expenses** from MSD, Pfizer.

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Elisa Ramos: Nothing to disclose.

Maria del Rosario Garcia Campelo: **payment or honoraria** from Pfizer, Novartis, Roche, Eli Lilly, AstraZeneca, Takeda, MSD; **consulting or advisory role** for Pfizer, Novartis, Roche, Eli Lilly, AstraZeneca, Takeda, MSD; **speakers bureau** for Pfizer, Novartis, Roche, Eli Lilly, AstraZeneca, Takeda, MSD.

Hiroaki Akamatsu: **consulting or advisory role** for Amgen, Johnson & Johnson, Sandoz; **honoraria** from AstraZeneca, Daiichi Sankyo, Eli Lilly, Pfizer, MSD, Bristol Myers Squibb Japan, Taiho Pharma, Chugai, Boehringer Ingelheim, Ono Pharmaceutical, Amgen, Merck, Nippon Kayaku, Novartis, Takeda; **research funding of institution** from Amgen, Chugai, MSD.

Danny Nguyen: **payment or honoraria** from Johnson & Johnson; **leadership or fiduciary role** for Gryt Health; **consulting or advisory role** for Black Diamond Therapeutics.

Alexis B. Cortot: **grants/contracts** from Exeliom; **consulting or advisory role** for Novartis, AbbVie, Roche, Exeliom, Pfizer, Johnson &

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Alona Zer: **consulting or advisory role** for MSD, Takeda, AstraZeneca, AbbVie; **payment or honoraria** from MSD, Takeda, AstraZeneca; **travel, accommodations, and expenses** from Roche; **participation on a data safety monitoring/advisory board** for Beyond Cancer; **stock or stock options** in Nixio.

Dilek Erdem: Nothing to disclose.

Rachel E. Sanborn: **advisory board member** for AbbVie, Amgen, AstraZeneca, Daiichi Sankyo, Eli Lilly, GE HealthCare, Gilead, IDEOlogy Health, Inhibrx, Johnson & Johnson, Sanofi-Aventis, Regeneron, GSK, G1 Therapeutics; **invited speaker** for Illumina, OncLive, PRIME Education; **steering committee member** at AstraZeneca, BeiGene, GSK, Johnson & Johnson; **research funding** from Merck, AstraZeneca; **research funding of institution** from Bristol Myers Squibb, Jounce Therapeutics.

Till-Oliver Emde: **grants/contracts** from Janssen-Cilag, a Johnson & Johnson company, Roche, Eli Lilly, Daiichi Sankyo, GBG Forschungs, WSG Laboratories, iOMEDICO, Bristol Myers Squibb, Sanofi; **honoraria** from AbbVie; **travel, accommodations, and expenses** from Janssen-Cilag, a Johnson & Johnson company, BeiGene; **participation on a data safety monitoring/advisory board** for AstraZeneca, BeiGene, Bristol Myers Squibb GmbH & Co. KGaA, Daiichi Sankyo Deutschland GmbH, Pfizer Pharma GmbH, AbbVie.

Anna R. Minchom: **advisory board member** for Johnson & Johnson, Merck, Takeda, MSD, Genmab, Pfizer, AstraZeneca, Immutep; **honoraria** from Chugai, Faron Pharmaceuticals, Merck, GSK, Seagen, Takeda, Johnson & Johnson; **research funding of institution** from Merck, MSD, Astex Pharmaceuticals; **travel, accommodations, and expenses** from Amgen, Johnson & Johnson.

Bogdan Zurawski: **honoraria** from Roche, Astellas; **employment** with MSD, Johnson & Johnson, Bristol Myers Squibb, Roche, Novartis, GSK, Merck Serono.

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James Chih-Hsin Yang: **honoraria** from AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly, MSD, Novartis, Ono Pharmaceutical, Pfizer, Roche, Takeda; **consulting or advisory role** for AbbVie, Amgen, AstraZeneca, Bayer, Blueprint Medicines, Boehringer Ingelheim, Bristol Myers Squibb/Celgene, Clovis Oncology, Daiichi Sankyo, G1 Therapeutics, Hansoh Pharma, Incyte, Eli Lilly, Merck Serono, MSD, Novartis, Ono Pharmaceutical, Pfizer, Takeda, Yuhan Corporation; **consulting fees to institution** from Amgen, AstraZeneca, Boehringer Ingelheim, Daiichi Sankyo, GSK, Johnson & Johnson, Merck Serono, MSD, Novartis, Takeda; **travel, accommodations, and expenses** from Pfizer.

Melina E. Marmarelis: **stock and other ownership interests** in Johnson & Johnson, Merck; **honoraria** from AstraZeneca, Blueprint Medicines, Johnson & Johnson, Novocure, Takeda, Targeted Oncology, Thermo Fisher Scientific; **honoraria for institution** from Health Advances; **consulting or advisory role** for AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb/Celgene, Ikena Oncology, Regeneron, Daiichi Sankyo; **research funding of institution** from AstraZeneca, Eli Lilly, Merck, Genentech, Trizell; **travel, accommodations, and expenses** from Boehringer Ingelheim, Novocure.

Julia Schuchard: **employee** of Johnson & Johnson and **may hold stock** in Johnson & Johnson.

Jefferson Alves: **employee** of Johnson & Johnson and **may hold stock** in Johnson & Johnson.

Debopriya Ghosh: **employee** of Johnson & Johnson and **may hold stock** in Johnson & Johnson.

Gregor Balaburski: **employee** of Johnson & Johnson and **may hold stock** in Johnson & Johnson.

Remy B. Verheijen: **employee** of Janssen Research and Development, a Johnson & Johnson company, and **may hold stock** in Johnson & Johnson.

Liliana Ribeiro: **employee** of Janssen-Cilag Farmacêutica, a Johnson & Johnson company and **may hold stock** in Johnson & Johnson.

Mohamed Gamil: **employee** of Johnson & Johnson and **may hold stock** in Johnson & Johnson.

Joshua M. Bauml: **employee** of Johnson & Johnson and may **hold stock** in Johnson & Johnson.

Mahadi Baig: employee of Johnson & Johnson and may hold stock in Johnson & Johnson.

Natasha B. Leighl: **grants or contracts (institution)** from AstraZeneca, Eli Lilly, Johnson & Johnson, MSD, Novartis, Pfizer, Guardant Health, NeoGenomics; **travel, accommodations**, **expenses (independent CME lectures)** from AstraZeneca, Eisai, Guardant Health, Johnson & Johnson, MSD, Roche, Sanofi; **participation on data safety monitoring board (uncompensated)** for Daiichi Sankyo.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ejca.2025.115624.

Data availability

The data sharing policy of Janssen Pharmaceutical Companies of Johnson & Johnson is available at https://www.janssen.com/clinical-trials/transparency. As noted on this site, requests for access to the study data can be submitted through Yale Open Data Access (YODA) Project site at http://yoda.yale.edu.

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