Incidence and Management of Dermatologic Adverse Reactions With Intravenous Amivantamab in Combination With Lazertinib: Interim Analysis

Rationale: Dermatologic AEs Observed With Amivantamab + Lazertinib in MARIPOSA[1-3]

Click to learn more about dermatologic AEs observed in MARIPOSA

Incidence

Prevalence and Severity

Phase 2 COCOON Interim Analysis* Trial: Investigating Enhanced Dermatologic Management With IV Amivantamab + Lazertinib[4,5]

Key Eligibility Criteria

- Locally advanced or metastatic NSCLC
- Treatment-naïve for advanced disease
- Documented *EGFR* Ex19del or L858R
- ECOG PS score of 0 or 1

Stratification Factors

- Race (Asian vs non-Asian)
- Age (<65 years vs ≥65 years)

1:1 randomization (N=201)

COCOON DM:
Amivantamab + lazertinib + enhanced dermatologic management
(n=99)

SoC DM:
Amivantamab + lazertinib + standard dermatologic management
(n=102)

VTE prophylaxis was mandatory for the first 4 months

Primary Endpoint:

- Incidence of grade ≥2 dermatologic AEs in the first 12 weeks after initiation of amivantamab + lazertinib treatment

Key Secondary Endpoints:

- Number of grade ≥2 dermatologic AEs per participant
- Incidence and severity of paronychia
- Incidence and severity of scalp rash
- Frequency of dose reductions, interruptions, and discontinuations due to AEs

***Interim analysis planned for when ~70% of participants completed Week 12 assessments[a]**

COCOON DM Enhanced Dermatologic Regimen Resulted in Reduction in Incidence of Grade ≥2 DAEIs in the First 12 Weeks[5]

COCOON DM: Agents are widely available[b]

Antibiotic prophylaxis

Weeks 1–12
Oral minocycline or doxycycline 100 mg twice daily

Weeks 13+
1% Topical clindamycin lotion on the scalp daily

Nail cleaning agent

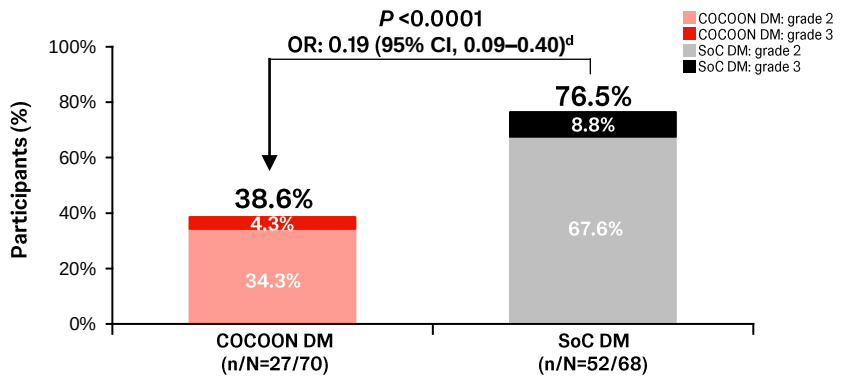
Weeks 1+
4% Chlorhexidine on the fingernails and toenails daily for 12 mos

Long-acting skin hydration

Weeks 1+
Ceramide-based moisturizer at least daily for 12 mos[c]

Both study arms received general skin prophylaxis instructions including minimizing sunlight exposure, wearing UV protective clothing, using SPF ≥30 sunscreen, and avoiding alcohol-based skin agents.

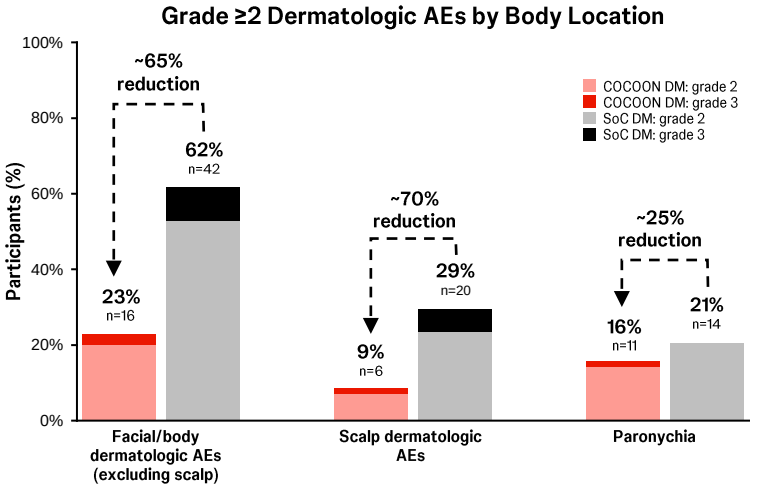
COCOON DM Reduced Grade ≥2 Dermatologic AEs by 50% vs SoC DM



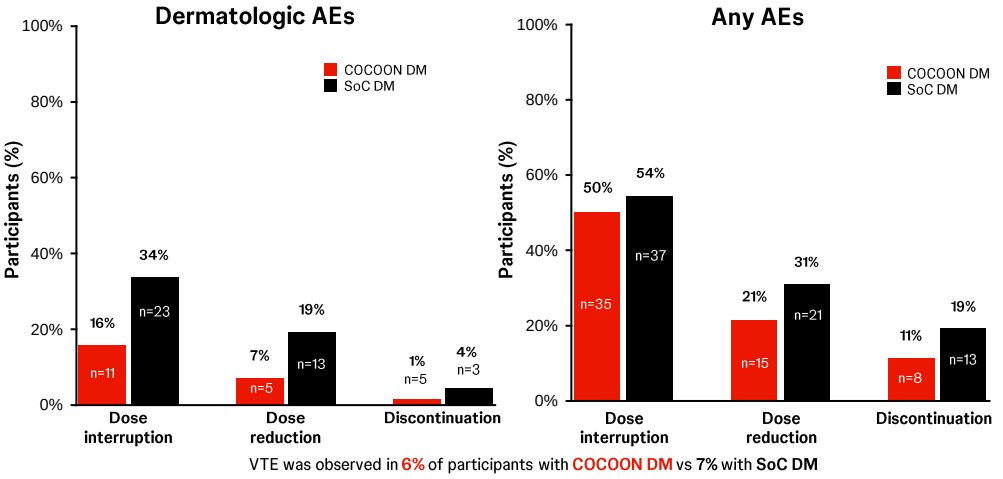
~70% Reduction in Moderate to Severe Scalp Dermatologic AEs and ~50% Reduction in Discontinuations Due to Any AEs Observed With COCOON DM Compared With SoC DM[5]

In the first 12 weeks, reductions in grade ≥2 dermatologic AEs were observed on different body locations with COCOON DM compared to SoC DM, including a 70% reduction in scalp dermatologic AEs

Grade ≥2 Dermatologic AEs by Body Location



Participants using the COCOON DM regimen had lower rates of amivantamab or lazertinib discontinuations due to any AEs (11% vs 19% for SoC)



VTE was observed in **6%** of participants with **COCOON DM** vs **7%** with **SoC DM**

Johnson & Johnson

AE, adverse event; BID, twice daily; CI, confidence interval; DAEI, dermatologic adverse event of interest; DM, dermatologic management; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; IV, intravenous; NSCLC, non-small cell lung cancer; mos, months; OR, odds ratio; QD, once daily; SoC, standard of care; VTE, venous thromboembolism.

[a]All analyses were performed using the safety analysis set. [b]Prophylactic antibiotics: oral doxycycline or minocycline 100 mg BID; topical clindamycin lotion 1% on scalp QD before bedtime. Paronychia prophylaxis: chlorhexidine 4% on the fingernails and toenails QD. Skin moisturization: La Roche Posay Lipikar AP+M moisturizer on the body and face at least QD. [c]La Roche Posay Lipikar AP+M moisturizer was used in COCOON. [d]OR was generated by a logistic model, adjusted by race and age (continuous).

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Rationale: Dermatologic AEs Observed With Amivantamab + Lazertinib in MARIPOSA[1-3]

Click to learn more about dermatologic AEs observed in MARIPOSA

Incidence

Prevalence and Severity

Incidence (n=421)[1,2]

Participant population: Adult participants with locally advanced or metastatic NSCLC and documented *EGFR* exon 19 deletion or exon 21 L858R mutations

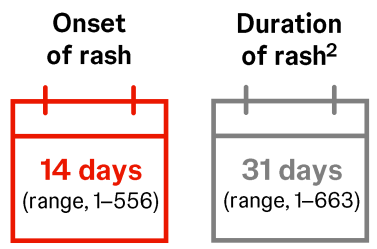
Median treatment duration:
18.5 months (range, 0.2–31.4)

Most common dermatologic AEs, %	All	Grade 3 or 4
Rash[a]	86	26
Nail toxicity/paronychia[a]	71	11
Dry skin[a]	25	1
Pruritus	24	0.5

Rash led to the following dose modifications of amivantamab in participants:

- Interruptions in **37%**
- Reductions in **23%**
- Discontinuations in **5%**

Median time to:



Note: Additional warnings and precautions associated with amivantamab and lazertinib include IRR, ILD/pneumonitis, VTE events, ocular toxicity, and embryo-fetal toxicity

[a]Grouped term. For rash, this includes the following preferred terms: rash, dermatitis acneiform, folliculitis, rash maculopapular, skin lesion, acne, erythema, rash pustular, dermatitis, rash pruritic, rash papular, rash erythematous, rash macular, dermatitis infected, erythema multiforme, papule, drug eruption, rash follicular, rash vesicular, skin exfoliation, and epidermolysis.
AE, adverse event; EGFR, epidermal growth factor receptor; ILD, interstitial lung disease; IRR, infusion-related reaction; NSCLC, non-small cell lung cancer; VTE, venous thromboembolism.

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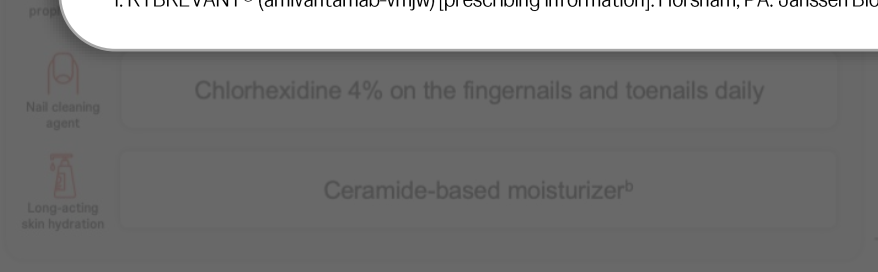
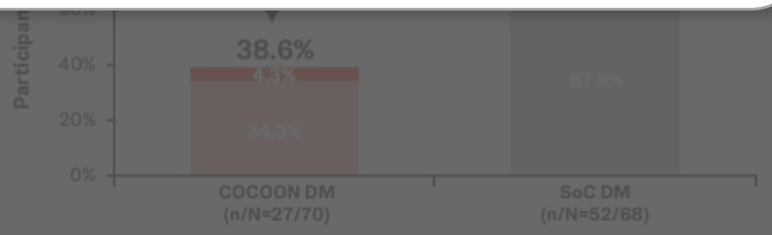
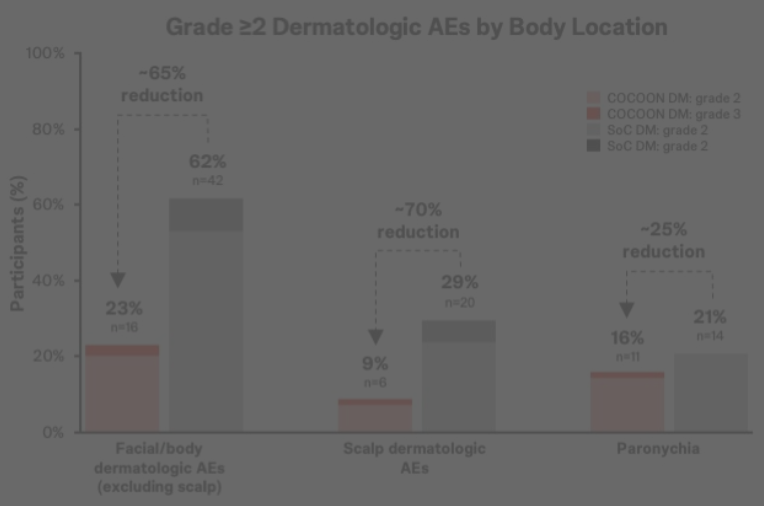




~70% Reduction in Moderate to Severe Scalp Rash and ~50% Reduction in Discontinuations Due to AEs Observed With COCOON DM Compared With SoC DM[5]

In the first 12 weeks, substantial reductions in grade ≥2 dermatologic AEs were observed on different body locations with COCOON DM compared to SoC DM, including a 70% reduction in scalp rash



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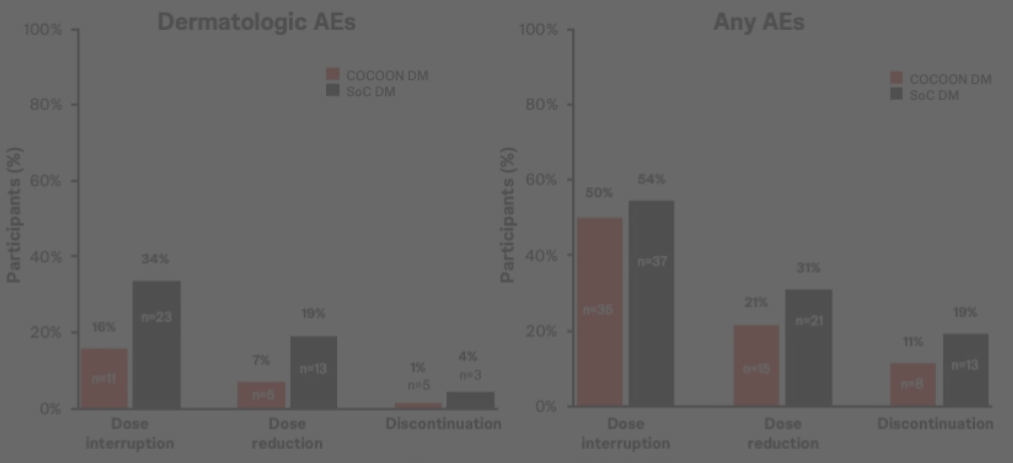

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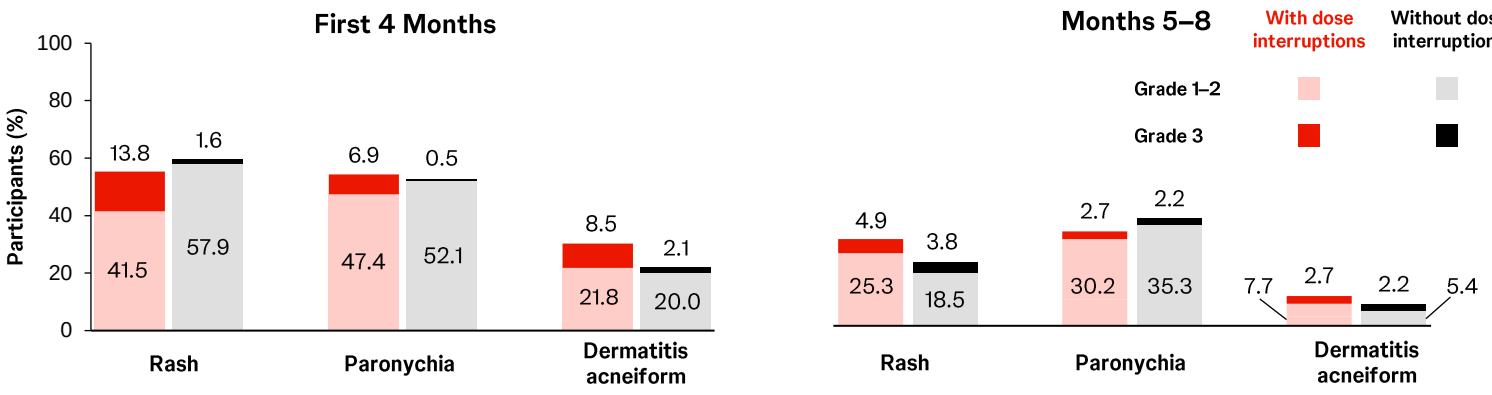
Prevalence and Severity Over Time[1]

Participant population: Adult participants with locally advanced or metastatic NSCLC and documented *EGFR* exon 19 deletion or exon 21 L858R mutations



This analysis is not included in the prescribing information for amivantamab and lazertinib. This was a post hoc exploratory analysis

Note: Additional warnings and precautions associated with amivantamab and lazertinib include IRR, ILD/pneumonitis, VTE events, ocular toxicity, and embryo-fetal toxicity

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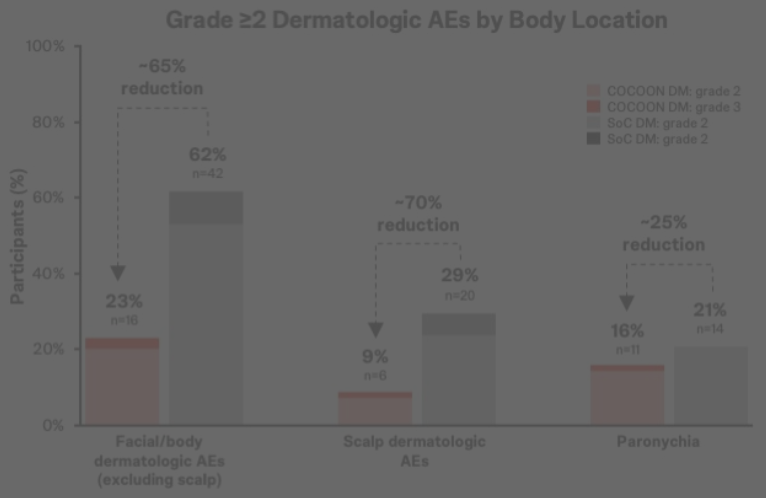

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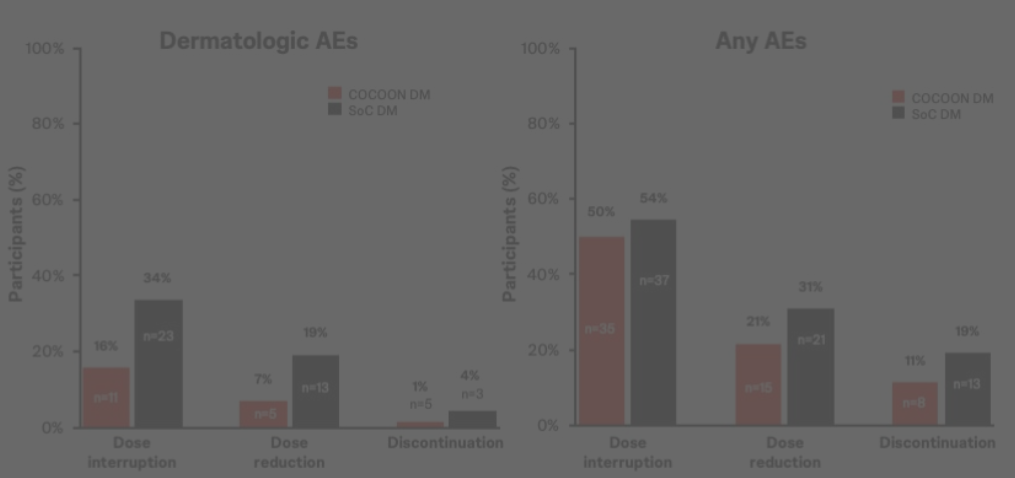

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