Tapinarof Cream 1% Once Daily Improves Patient-reported Outcomes in the Treatment of Mild to Severe Plaque Psoriasis in the Head and Neck Region

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INTRODUCTION

- Up to 80% of patients with plaque psoriasis experience lesions in the head and neck region, with the scalp being one of the most commonly affected areas[1–3]
- Because of its location, psoriasis affecting the head and neck region has substantial impact on health-related quality of life (HRQoL), through pruritus, pain, and psychological distress[2,3]
  - The scalp, in particular, may be difficult to treat due to the presence of hair and challenges with cosmetic elegance of topical formulations[3]
- Topical corticosteroids (TCSs), although efficacious, are associated with dermatologic adverse events (AEs), including acne, atrophy, striae, and telangiectasia, which limit their use especially in the head and neck region[4]
- Over 50% of patients with psoriasis have reported dissatisfaction with their treatment[5]
  - Patients prefer topicals that are easy to apply, nongreasy, and absorb quickly[6,7]
- There remains a need for efficacious, cosmetically elegant, non-steroidal topical therapies that can be used without restrictions
- Tapinarof cream 1% (VTAMA®, Dermavant Sciences, Inc.) is a non-steroidal, topical aryl hydrocarbon receptor agonist approved for the treatment of plaque psoriasis in adults, with no restrictions on location, extent, or duration of use[8]
- In this 12-week, open-label, phase 4 trial (NCT05789576), tapinarof cream 1% QD demonstrated efficacy and was well tolerated in patients with mild to severe plaque psoriasis in the head and neck region[9]
  - The primary endpoint of a target lesion Physician's Global Assessment (tPGA) response (tPGA score of clear [0] or almost clear [1] and ≥2-grade improvement from baseline at Week 12) was achieved by 88.5% of patients at Week 12, and complete clearance was achieved by 80.8% of patients[9]

OBJECTIVE

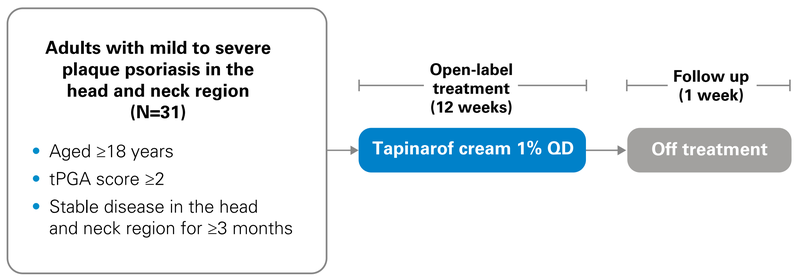
- To present patient-reported outcomes from the 12-week, open-label, phase 4 trial of tapinarof cream 1% QD for the treatment of adults with mild to severe plaque psoriasis affecting the head and neck region

MATERIALS AND METHODS

Trial Design

- In this open-label, multicenter trial, adults with mild to severe plaque psoriasis affecting the head and neck region received tapinarof cream 1% QD for 12 weeks, followed by 1 week of follow-up (**Figure 1**)

Figure 1. Plaque Psoriasis (Head and Neck Region) Trial Design



The tPGA is a target lesion assessment of efficacy for psoriasis affecting the head and neck region.
QD, once daily; tPGA, target lesion Physician's Global Assessment.

Patient-reported Outcomes and Statistical Analyses

- Patient-reported outcomes evaluated by visit (Weeks 1, 2, 4, 8, and 12) were:
  - Change in Peak Pruritus Numerical Rating Scale (PP-NRS) score for the head and neck region
    - The PP-NRS score is determined on an 11-point scale, where 0 indicates "no itch" and 10 indicates "worst imaginable itch" within the last 24 hours
  - Proportion of patients with a baseline PP-NRS score of ≥4 who achieved a ≥4-point reduction from baseline
  - Change in Dermatology Life Quality Index (DLQI) score
    - DLQI is a validated 10-item scale; each of the 10 items rate impact on HRQoL on a 4-point scale from 0 (not at all) to 3 (very much)
    - DLQI item scores are added to give a total score from 0–30, with lower scores indicating better HRQoL
- The Patient Satisfaction Questionnaire© is designed to assess patient satisfaction with tapinarof efficacy, formulation elegance, application ease, impact on daily life, and preference for tapinarof cream versus prior psoriasis therapies
  - The questionnaire includes 18 questions with responses of "strongly agree", "agree", "neutral", "disagree", or "strongly disagree"
  - Patient Satisfaction Questionnaire© responses were assessed at Week 12, or early termination
  - Data were summarized based on the number of responses to each question
- Patient-reported outcomes were summarized using observed cases based on the intention-to-treat population

RESULTS

Baseline Patient Demographics and Disease Characteristics

- Overall, 31 adults were enrolled at 8 sites in the US (**Table 1**)
  - Mean age was 55.5 years, and 51.6% were male
  - 54.8% (n=17/31) of patients had a tPGA score of 3 (moderate) and 58.1% had target lesion in the scalp
- Mean PP-NRS (head and neck region) score was 5.8, and 80.6% (n=25/31) had a PP-NRS (head and neck region) score of ≥4
- Mean DLQI total score was 9.7, indicating a moderate impact of disease on HRQoL

Table 1. Baseline Disease Characteristics

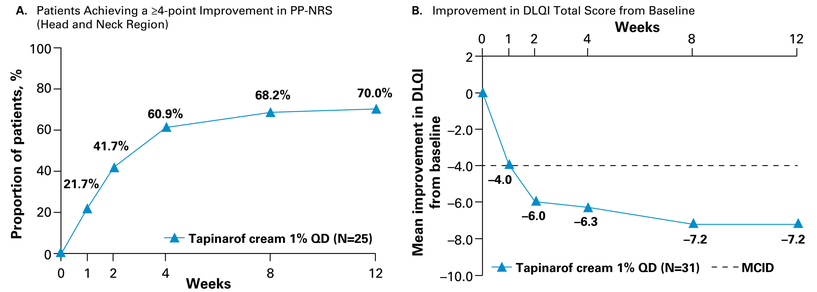
	Tapinarof cream 1% QD (N=31)
tPGA score, n (%)	
2 – Mild	12 (38.7)
3 – Moderate	17 (54.8)
4 – Severe	2 (6.5)
PP-NRS score (head and neck region), mean (SD)	5.8 (2.59)
Baseline PP-NRS (head and neck region) ≥4, n (%)	25 (80.6)
DLQI score, mean (SD)	9.7 (7.39)

DLQI, Dermatology Life Quality Index; PP-NRS, Peak Pruritus Numerical Rating Scale; QD, once daily; SD, standard deviation; tPGA, target lesion Physician's Global Assessment.

Mean Improvement in PP-NRS (Head and Neck Region) Score and at Least a 4-point Improvement in PP-NRS Score

- Rapid improvement in mean PP-NRS score was demonstrated as early as Week 1, the first assessment, (–1.6 [standard deviation (SD), 2.54]) and continued through Week 12 (–4.2 [3.35])
- At Week 12, 70% (n=14/20) of patients with a PP-NRS score ≥4 at baseline achieved the gold standard of a clinically meaningful ≥4-point reduction in PP-NRS score (**Figure 2A**)

Figure 2. (A) Proportion of Patients who Achieved >4-point Improvement in PP-NRS (Head and Neck Region), and (B) Mean Improvement in DLQI Total Score from Baseline, by Visit Through Week 12



Intention-to-treat, observed cases.
DLQI, Dermatology Life Quality Index; MCID, minimal clinically important difference; PP-NRS, Peak Pruritus Numerical Rating Scale; QD, once daily.

Mean Improvement in DLQI

- The mean DLQI minimal clinically important difference (MCID) of –4.0 was demonstrated as early as Week 1, the first assessment, improving to a mean difference of –7.2 at Week 12 (**Figure 2B**)

Achievement of the Primary Endpoint and Patient-reported Outcomes at Week 12

- The patient in **Figure 3** had moderate disease (tPGA=3) at baseline, with improvement in the visible target lesion and investigator-assessed global improvement as early as Week 1. There was continued improvement to achieve the primary efficacy endpoint of completely clear skin (tPGA=0) at Week 12
- At baseline, the patient reported an itch score of 10 (the highest possible score) that improved to an itch-free state at Week 12 (PP-NRS=0)
- This patient's baseline DLQI score was 24, indicating that psoriasis had a severe effect on HRQoL, and improvement surpassed the MCID as early as Week 1, with continued improvement to Week 12 (DLQI=0), indicating no effect on HRQoL

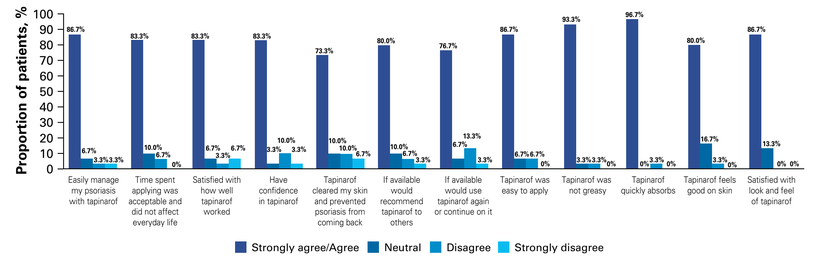
Patient Satisfaction Questionnaire©

- Most patients strongly agreed or agreed with questions assessing satisfaction with cosmetic elegance (93.3%) (not greasy), quick absorption (96.7%), application ease (86.7%), efficacy (83.3%), confidence in tapinarof (83.3%), and application time not impacting everyday life (83.3%) (**Figure 4**)
- For patients who had used other topical drugs to treat psoriasis in the past (n=26), 76.9% considered tapinarof to be more effective than prior therapies, 76.9% considered tapinarof easier to use, and 69.2% preferred tapinarof
- For patients who had used systemic drugs to treat psoriasis in the past (n=14), 57.1% considered tapinarof to be more effective than prior therapies, 78.6% considered tapinarof easier to use, and 71.4% preferred tapinarof

Figure 3. Achievement of MCID in DLQI as early as Week 1, and tPGA and PP-NRS Success at Week 12 in a Patient with Plaque Psoriasis Affecting the Head and Neck Region Treated with Tapinarof Cream 1% QD

Example of one representative target lesion in a tapinarof-treated patient from the open-label phase 4 trial. Individual results may vary.
DLQI, Dermatology Life Quality Index; MCID, minimal clinically important difference; PP-NRS, Peak Pruritus Numerical Rating Scale; tPGA, target lesion Physician's Global Assessment; QD, once daily.

Figure 4. High Confidence and Satisfaction with Cosmetic Elegance, Ease of Application, and Efficacy of Tapinarof Cream 1% QD (N=31)



Intention-to-treat, observed cases.
QD, once daily.

Safety

- Most treatment-emergent adverse events (TEAEs) were mild or moderate, consistent with previous trials
- The most frequent TEAEs were contact dermatitis, folliculitis, and headache

CONCLUSIONS

- Tapinarof cream 1% QD demonstrated rapid and clinically meaningful improvements in patient-reported pruritus and disease impact on HRQoL in patients with psoriasis in the head and neck region, including on the scalp, from the earliest visit at Week 1, through Week 12
- Patient satisfaction data showed a consistent and highly positive perception of tapinarof cream across all relevant parameters, including satisfaction with tapinarof efficacy, formulation elegance, application ease, impact on daily life, and preference for tapinarof cream compared with prior psoriasis therapies
- Tapinarof cream is a cosmetically elegant, well-tolerated, non-steroidal treatment option in adults with mild to severe plaque psoriasis, including in the head and neck region

REFERENCES

1. National Psoriasis Foundation. Available at: https://www.psoriasis.org/locations-and-types/. Accessed November 2023. 2. Kragballe K, et al. *Curr Probl Dermatol.* 2009;38:160–171. 3. Mosca M, et al. *Dermatol Ther.* 2021;11:769–797. 4. Yasir M, et al. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023. https://www.ncbi.nlm.nih.gov/books/NBK531462/. Accessed November 2023. 5. Armstrong AW, et al. *JAMA Dermatol.* 2013;149:1180–1185. 6. Fouéré S, et al. *J Eur Acad Dermatol Venereol.* 2005;19(Suppl 3):2–6. 7. Eastman WJ, et al. *Cutis.* 2014;94:46–53. 8. Dermavant Sciences. VTAMA (tapinarof) cream, 1%: US prescribing information. 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/215272s000lbl.pdf. Accessed November 2023. 9. Stein Gold L, et al. Poster presented at Winter Clinical Dermatology Conference-Hawaii, January 11–17, 2024. Lahaina, Hawaii, USA.

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