Treat-to-Target Outcomes With Tapinarof Cream 1% in Phase 3 Trials for Plaque Psoriasis

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PRACTICE **POINTS**

- In clinical practice, many patients with psoriasis do not achieve treatment targets set forth by the National Psoriasis Foundation and the European Academy of Dermatology and Venereology, and topical treatments alone generally are insufficient in achieving treatment goals for psoriasis.
- Tapinarof cream 1% is a nonsteroidal aryl hydrocarbon receptor agonist approved by the US Food and Drug Administration for the treatment of plaque psoriasis in adults; it also is being studied for the treatment of plaque psoriasis in children 2 years and older.
- Tapinarof cream 1% is an effective topical treatment option for patients with plaque psoriasis of any severity, with no limitations on treatment duration, total extent of use, or application sites, including intertriginous skin and sensitive areas.

The National Psoriasis Foundation (NPF) treatment targets aim to achieve 1% or lower body surface area (BSA) affected after 3 months of treatment. European psoriasis treatment guidelines aim to achieve similar goals based on improvements in Psoriasis Area and Severity Index (PASI) scores. We performed pooled analyses of the PSOARING phase 3 program, which evaluated treat-to-target outcomes for patients treated with tapinarof cream 1% once daily (QD) for up to 52 weeks. Our analyses included 915 patients from PSOARING 1 and PSOARING 2 who had Physician Global Assessment (PGA) scores of 2 or higher before undergoing treatment with tapinarof, including those who received the vehicle in PSOARING 1 and PSOARING 2 and then tapinarof in PSOARING 3. The treatment targets we analyzed included the proportion of patients achieving an absolute BSA of 1% or lower or an absolute total PASI score of 3 or lower. In total, 40% of patients achieved the stringent NPF target of BSA of 1% or lower within 3 months, and 61% achieved a BSA of 1% or lower at any time (median, ~4 months). Furthermore, 75%, 67%, and 50% achieved PASI scores of 3, 2, and 1 or lower, respectively, at any time (median, ~2–6 months). Our results indicated that a high percentage of patients with mild to severe psoriasis can achieve and exceed ambitious treatment targets when treated with topical tapinarof monotherapy for up to 1 year.

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Trial registration with the following ClinicalTrials.gov identifiers: NCT03956355, NCT03983980, and NCT04053387.

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Psoriasis is a chronic inflammatory disease affecting approximately 8 million adults in the United States and 2% of the global population.[1,2] Psoriasis causes pain, itching, and disfigurement and is associated with a physical, psychological, and economic burden that substantially affects health-related quality of life.[3-5]

Setting treatment goals and treating to target are evidence-based approaches that have been successfully applied to several chronic diseases to improve patient outcomes, including diabetes, hypertension, and rheumatoid arthritis.[6-9] Treat-to-target strategies generally set low disease activity (or remission) as an overall goal and seek to achieve this using available therapeutic options as necessary. Introduced following the availability of biologics and targeted systemic therapies, treat-to-target strategies generally provide guidance on expectations of treatment but not specific treatments, as personalized treatment decisions depend on an assessment of individual patients and consider clinical and demographic features as well as preferences for available therapeutic options. If targets are not achieved in the assigned time span, adjustments can be made to the treatment approach in close consultation with the patient. If the target is reached, follow-up visits can be scheduled to ensure improvement is maintained or to establish if more aggressive goals could be selected.

Treat-to-target strategies for the management of psoriasis developed by the National Psoriasis Foundation (NPF) Medical Board include reducing the extent of psoriasis to 1% or lower total body surface area (BSA) after 3 months of treatment.[10] Treatment targets endorsed by the European Academy of Dermatology and Venereology (EADV) in guidelines on the use of systemic therapies in psoriasis include achieving a 75% or greater reduction in Psoriasis Area and Severity Index (PASI) score within 3 to 4 months of treatment.[11]

In clinical practice, many patients do not achieve these treatment targets, and topical treatments alone generally are insufficient in achieving treatment goals for psoriasis.[12,13] Moreover, conventional topical treatments (eg, topical corticosteroids) used by most patients with psoriasis regardless of disease severity are associated with adverse events that can limit their use. Most topical corticosteroids have US Food and Drug Administration label restrictions relating to sites of application, duration and extent of use, and frequency of administration.[14,15]

Tapinarof cream 1% (VTAMA [Dermavant Sciences, Inc]) is a first-in-class topical nonsteroidal aryl hydrocarbon receptor agonist that was approved by the US Food and Drug Administration for the treatment of plaque psoriasis in adults[16] and is being studied for the treatment of plaque psoriasis in children 2 years and older as well as for atopic dermatitis in adults and children 2 years and older. In PSOARING 1 (ClinicalTrials.gov identifier NCT03956355) and PSOARING 2 (NCT03983980)—identical 12-week pivotal phase 3 trials—monotherapy with tapinarof cream 1% once daily (QD) demonstrated statistically significant efficacy vs vehicle cream and was well tolerated in adults with mild to severe plaque psoriasis (Supplementary Figure S1).[17] Lebwohl et al[17] reported that significantly higher PASI75 responses were observed at week 12 with tapinarof cream vs vehicle in PSOARING 1 and PSOARING 2 (36% and 48% vs 10% and 7%, respectively; both $P<.0001$). A significantly higher PASI90 response of 19% and 21% at week 12 also was observed with tapinarof cream vs 2% and 3% with vehicle in PSOARING 1 and PSOARING 2, respectively ($P=.0005$ and $P<.0001$).[17]

In PSOARING 3 (NCT04053387)—the long-term extension trial (Supplementary Figure S1)—efficacy continued to improve or was maintained beyond the two 12-week trials, with improvements in total BSA affected and PASI scores for up to 52 weeks.[18] Tapinarof cream 1% QD demonstrated positive, rapid, and durable outcomes in PSOARING 3, including high rates of complete disease clearance (Physician Global Assessment [PGA] score=0 [clear])(40.9% [312/763]), durability of response on treatment with no evidence of tachyphylaxis, and a remittive effect of approximately 4 months when off therapy (defined as maintenance of a PGA score of 0 [clear] or 1 [almost clear] after first achieving a PGA score of 0).[18]

Herein, we report absolute treatment targets for patients with plaque psoriasis who received tapinarof cream 1% QD in the PSOARING trials that are at least as stringent as the corresponding NPF and EADV targets of achieving a total BSA affected of 1% or lower or a PASI75 response within 3 to 4 months, respectively.

METHODS

Study Design

The pooled efficacy analyses included all patients with a baseline PGA score of 2 or higher (mild or worse) before treatment with tapinarof cream 1% QD in the PSOARING trials. This included patients who received tapinarof cream 1% in PSOARING 1 and PSOARING 2 who may or may not have continued into PSOARING 3, as well as those who received the vehicle in PSOARING 1 and PSOARING 2 who enrolled in PSOARING 3 and had a PGA score of 2 or higher before receiving tapinarof cream 1%.

Trial Participants

Full methods, including inclusion and exclusion criteria, for the PSOARING trials have been previously reported.[17,18] Patients were aged 18 to 75 years and had chronic plaque psoriasis that was stable for at least 6 months before randomization; 3% to 20% total BSA affected (excluding the scalp, palms, fingernails, toenails, and soles); and a PGA score of 2 (mild), 3 (moderate), or 4 (severe) at baseline.

The clinical trials were conducted in compliance with the guidelines for Good Clinical Practice and the Declaration of Helsinki. Approval was obtained from local ethics committees or institutional review boards at each center. All patients provided written informed consent.

Trial Treatment

In PSOARING 1 and PSOARING 2, patients were randomized (2:1) to receive tapinarof cream 1% or vehicle QD for 12 weeks. In PSOARING 3 (the long-term extension trial), patients received up to 40 weeks of open-label tapinarof, followed by 4 weeks of follow-up off treatment. Patients received intermittent or continuous treatment with tapinarof cream 1% in PSOARING 3 based on PGA score: those entering the trial with a PGA score of 1 or higher received tapinarof cream 1% until complete disease clearance was achieved (defined as a PGA score of 0 [clear]). Those entering PSOARING 3 with or achieving a PGA score of 0 (clear) discontinued treatment and were observed for the duration of maintenance of a PGA score of 0 (clear) or 1 (almost clear) while off therapy (the protocol-defined "duration of remittive effect"). If disease worsening (defined as a PGA score 2 or higher) occurred, tapinarof cream 1% was restarted and continued until a PGA score of 0 (clear) was achieved. This pattern of treatment, discontinuation on achieving a PGA score of 0 (clear), and retreatment on disease worsening continued until the end of the trial. As a result, patients in PSOARING 3 could receive tapinarof cream 1% continuously or intermittently for 40 weeks.

Outcome Measures and Statistical Analyses

The assessment of total BSA affected by plaque psoriasis is an estimate of the total extent of disease as a percentage of total skin area. In the PSOARING trials, the skin surface of one hand (palm and digits) was assumed to be approximately equivalent to 1% BSA. The total BSA affected by psoriasis was evaluated from 0% to 100%, with greater total BSA affected being an indication of more extensive disease. The BSA efficacy outcomes used in these analyses were based post hoc on the proportion of patients who achieved a 1% or lower or 0.5% or lower total BSA affected. The smallest BSA affected increment that investigators were trained to measure and could record was 0.1%.

Psoriasis Area and Severity Index scores assess both the severity and extent of psoriasis. A PASI score lower than 5 often is considered indicative of mild psoriasis, a score of 5 to 10 indicates moderate disease, and a score higher than 10 indicates severe disease.[19] The maximum PASI score is 72. The PASI efficacy outcomes used in these analyses were based post hoc on the proportion of patients who achieved an absolute total PASI score of 3 or lower, 2 or lower, and 1 or lower.

Efficacy analyses were based on pooled data for all patients in the PSOARING trials who had a PGA score of 2 to 4 (mild to severe) before treatment with tapinarof cream 1% in the intention-to-treat population using observed cases. Time-to-target analyses were based on Kaplan-Meier (KM) estimates using observed cases.

Safety analyses included the incidence and frequency of adverse events and were based on all patients who received tapinarof cream 1% in the PSOARING trials.

RESULTS

Baseline Patient Demographics and Disease Characteristics

The pooled efficacy analyses included 915 eligible patients (Table). At baseline, the mean (SD) age was 50.2 (13.25) years, 58.7% were male, the mean (SD) weight was 92.2 (23.67) kg, and the mean (SD) body mass index was 31.6 (7.53) kg/m^2. The percentage of patients with a PGA score of 2 (mild), 3 (moderate), or 4 (severe) was 13.9%, 78.1%, and 8.0%, respectively. The mean (SD) PASI score was 8.7 (4.23) and mean (SD) total BSA affected was 7.8% (4.98).

Efficacy

Achievement of BSA-Affected Targets—The NPF-recommended target of 1% or lower total BSA affected within 3 months was achieved by 40% of patients (KM estimate [95% CI, 37%-43%])(Figure 1). Across the total trial period of up to 52 weeks, a total BSA affected of 1% or lower was achieved by 61% of patients (561/915), with the median time to target of approximately 4 months (KM estimate: 120 days [95% CI, 113-141])(Supplementary Figure S2a). Approximately 50% of patients (455/915) achieved a total BSA affected of 0.5% or lower, with a median time to target of 199 days (KM estimate [95% CI, 172-228)(Figure 1; Supplementary Figure S2b).

Baseline Patient Demographics and Disease Characteristics of Patients in the Pooled Analyses

Characteristic	Tapinarof cream 1% QD (N=915)
Mean (SD) age, y	50.2 (13.25)
Male sex, n (%)	537 (58.68)
Mean (SD) weight, kg	92.2 (23.67)
Mean (SD) BMI, kg/m^2	31.6 (7.53)
PGA score, n (%)	
0 (clear)	0 (0)
1 (almost clear)	0 (0)
2 (mild)	127 (13.88)
3 (moderate)	715 (78.14)
4 (severe)	73 (7.98)
Mean (SD) PASI score	8.7 (4.23)
Mean (SD) BSA affected, %	7.8 (4.98)

Abbreviations: BMI, body mass index; BSA, body surface area; PASI, Psoriasis Area and Severity Index; PGA, Physician Global Assessment; QD, once daily.

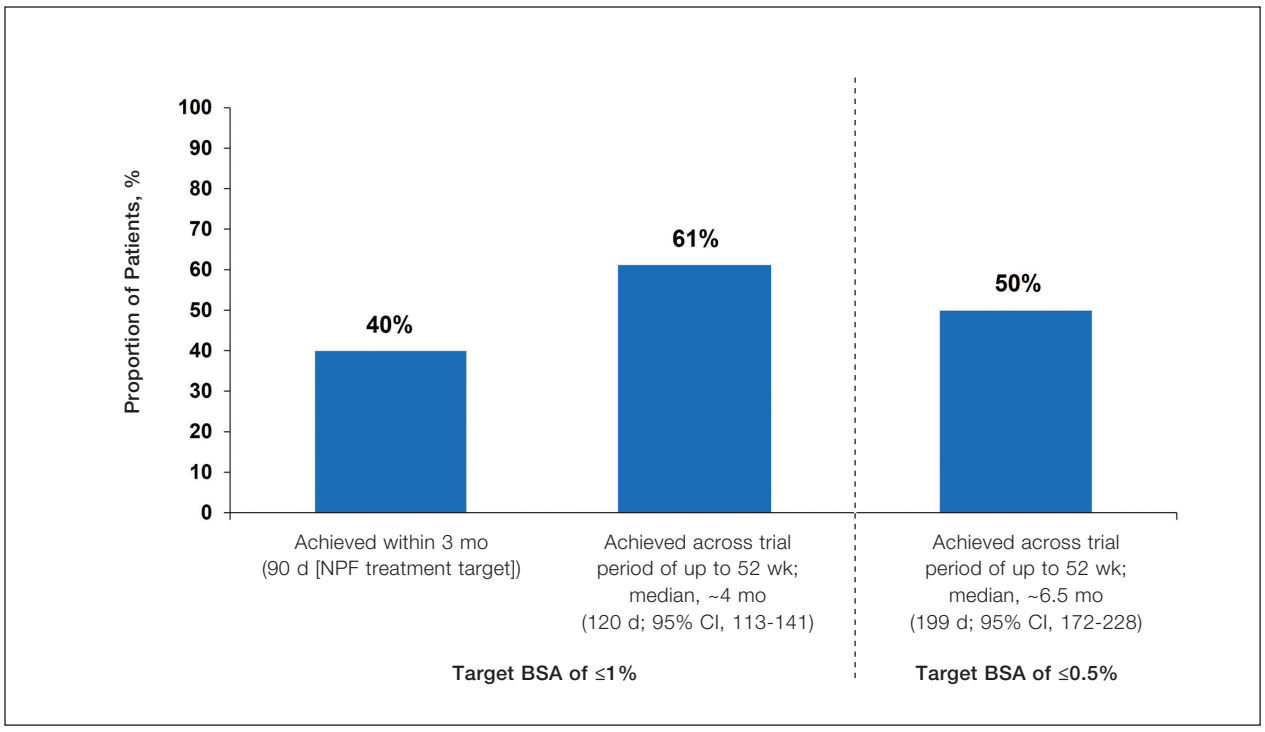

FIGURE 1. Pooled analysis of total body surface area (BSA) affected targets achieved by patients with mild to severe plaque psoriasis treated with tapinarof cream 1% once daily (QD) across a trial period up to 52 weeks in PSOARING 1, PSOARING 2, and PSOARING 3 (target total BSA affected, ≤1% [National Psoriasis Foundation [NPF]—recommended target]; target total BSA affected, ≤.5%)(N=915). These analyses included patients receiving continuous or intermittent tapinarof monotherapy in the 12-week pivotal trials (PSOARING 1 and PSOARING 2) and in the forced-withdrawal design of PSOARING 3 (treatment was stopped when patients achieved a Physician Global Assessment score of 0).

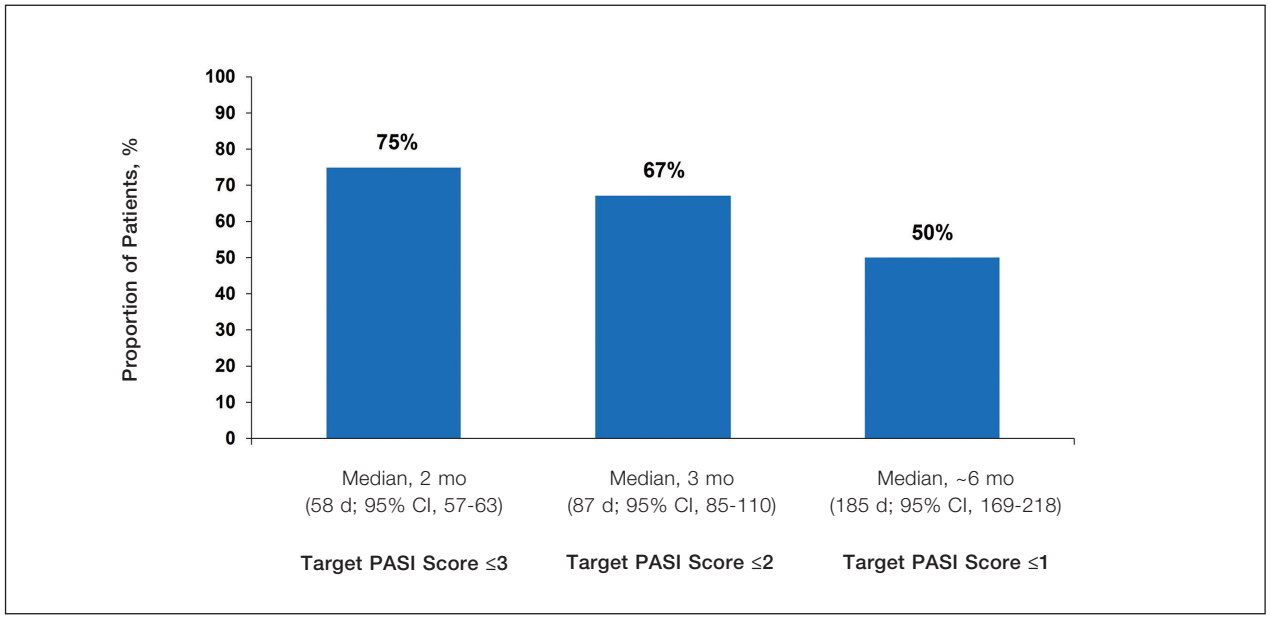

FIGURE 2. Total Psoriasis Area and Severity Index (PASI) score targets achieved by patients with mild to severe plaque psoriasis treated with tapinarof cream 1% once daily across a trial period up to 52 weeks in PSOARING 1, PSOARING 2 (target PASI score), and PSOARING 3 (target PASI score ≤3, ≤2, and ≤1)(N=915). These analyses included patients receiving continuous or intermittent tapinarof monotherapy in the 12-week pivotal trials (PSOARING 1 and PSOARING 2) and in the forced-withdrawal design of PSOARING 3 (treatment was stopped when patients achieved a Physician Global Assessment score of 0).

Achievement of Absolute PASI Targets—Across the total trial period (up to 52 weeks), an absolute total PASI score of 3 or lower was achieved by 75% of patients (686/915), with a median time to achieve this of 2 months (KM estimate: 58 days [95% CI, 57-63]); approximately 67% of patients (612/915) achieved a total PASI score of 2 or lower, with a median time to achieve of 3 months (KM estimate: 87 days [95% CI, 85-110])(Figure 2; Supplementary Figures S3a and S3b). A PASI score of 1 or lower was achieved by approximately 50% of patients (460/915), with a median time to achieve of approximately 6 months (KM estimate: 185 days [95% CI, 169-218])(Figure 2, Supplementary Figure S3c).

Illustrative Case—Case photography showing the clinical response in a 63-year-old man with moderate plaque psoriasis in PSOARING 2 is shown in Figure 3. After 12 weeks of treatment with tapinarof cream 1% QD, the patient achieved all primary and secondary efficacy end points. In addition to achieving the regulatory end point of a PGA score of 0 (clear) or 1 (almost clear) and a decrease from baseline of at least 2 points, achievement of 0% total BSA affected and a total PASI score of 0 at week 12 exceeded the NPF and EADV consensus treatment targets.[10,11] Targets were achieved as early as week 4, with a total BSA affected of 0.5% or lower and a total PASI score of 1 or lower, illustrated by marked skin clearing and only faint residual erythema that completely resolved at week 12, with the absence of postinflammatory hyperpigmentation.

Safety

Safety data for the PSOARING trials have been previously reported.[17,18] The most common treatment-emergent adverse events were folliculitis, contact dermatitis, upper respiratory tract infection, and nasopharyngitis. Treatment-emergent adverse events generally were mild or moderate in severity and did not lead to trial discontinuation.[17,18]

COMMENT

Treat-to-target management approaches aim to improve patient outcomes by striving to achieve optimal goals. The treat-to-target approach supports shared decision-making between clinicians and patients based on common expectations of what constitutes treatment success.

The findings of this analysis based on pooled data from a large cohort of patients demonstrate that a high proportion of patients can achieve or exceed recommended treatment targets with tapinarof cream 1% QD and maintain improvements long-term. The NPF-recommended treatment target of 1% or lower BSA affected within approximately 3 months (90 days) of treatment was achieved by 40% of tapinarof-treated patients. In addition, 1% or lower BSA affected at any time during the trials was achieved by 61% of patients (median, approximately 4 months). The analyses also indicated that PASI total scores of 3 or lower and 2 or

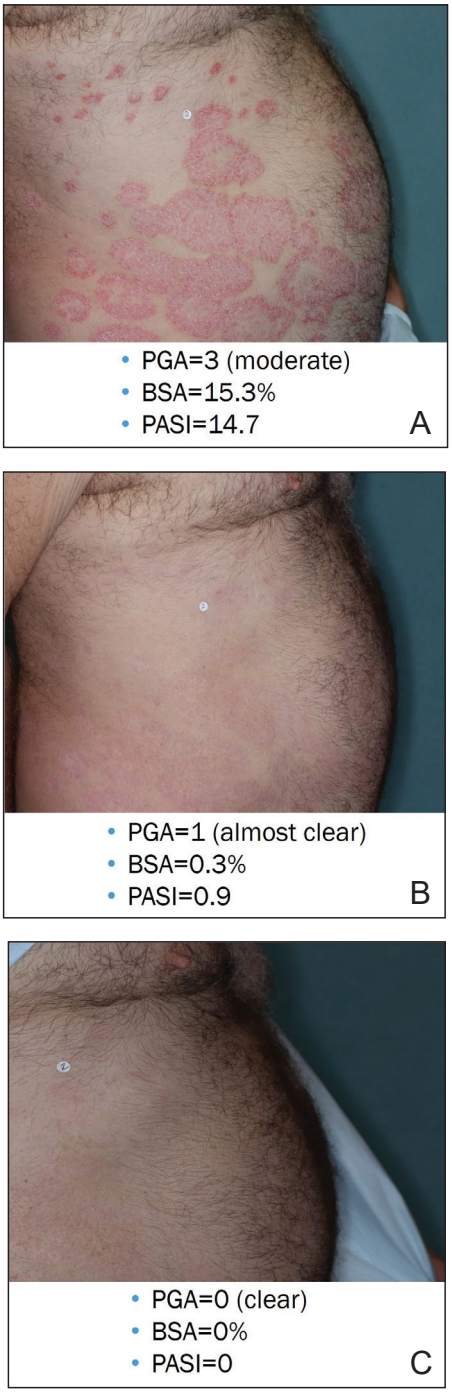

FIGURE 3. Moderate plaque psoriasis on the abdomen in a patient treated with tapinarof cream 1% once daily in PSOARING 2 who achieved the primary end point at week 4. A, At baseline, well-circumscribed erythematous patches, plaques, and scaling were visible. B, The patient achieved the primary end point and National Psoriasis Foundation (NPF) and European Academy of Dermatology and Venereology (EADV) treatment targets by week 4, at which point there was marked clearing with faint residual erythema C, By week 12, the patient had 0% total body surface area affected and a total Psoriasis Area and Severity Index score of 0, exceeding NPF/EADV consensus treatment targets. Faint residual erythema completely resolved with the absence of postinflammatory hyperpigmentation.

lower were achieved by 75% and 67% of tapinarof-treated patients, respectively, within 2 to 3 months.

These findings support the previously reported efficacy of tapinarof cream, including high rates of complete disease clearance (40.9% [312/763]), durable response following treatment interruption, an off-therapy remittive effect of approximately 4 months, and good disease control on therapy with no evidence of tachyphylaxis.[17,18]

CONCLUSION

Taken together with previously reported tapinarof efficacy and safety results, our findings demonstrate that a high proportion of patients treated with tapinarof cream as monotherapy can achieve aggressive treatment targets set by both US and European guidelines developed for systemic and biologic therapies. Tapinarof cream 1% QD is an effective topical treatment option for patients with plaque psoriasis that has been approved without restrictions relating to severity or extent of disease treated, duration of use, or application sites, including application to sensitive and intertriginous skin.

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APPENDIX

Dr. Armstrong is a research investigator and/or scientific advisor for AbbVie; Amgen; ASLAN; Boehringer Ingelheim; Bristol Myers Squibb; Dermavant Sciences, Inc; Dermira; Eli Lilly and Company; EPI; Galderma; Incyte; Janssen; LEO Pharma; Meiji; Mindera; Modmed; Nimbus; Novartis; Organon; Ortho Dermatologics; Pfizer; Regeneron; Sanofi; Sun Pharma; Takeda; UCB Biopharma; and Ventyx.

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Drs. Brown and Tallman are employees of Dermavant Sciences, Inc, with stock options.

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