

Patient Satisfaction with Tapinarof Cream 1% Once Daily for Plaque Psoriasis in a Long-Term Extension Trial

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BACKGROUND

- Patient dissatisfaction with current therapies is an important barrier to optimal care of psoriasis (52% of psoriasis patients have reported dissatisfaction with their treatment¹) and there is a need for efficacious, tolerable, easy-to-use topical therapies that can be used long term, including on sensitive skin areas
- Tapinarof 1% is a cosmetically elegant, once daily (QD) topical cream that does not contain added fragrance and is free of petrolatum, parabens, and gluten. The vehicle is specifically designed to reduce skin irritation and optimize the delivery of tapinarof to the target site
- Tapinarof cream 1% QD demonstrated significant efficacy and was well tolerated in two 12-week pivotal phase 3 trials of 1,025 adults with mild-to-severe plaque psoriasis, PSOARING 1 (NCT03956355) and PSOARING 2 (NCT03983980), and demonstrated favorable patient-reported local tolerability and investigator-assessed irritation scores including sensitive skin areas^{2,3}
- PSOARING 3 (NCT04053387) was a 40-week, long-term, open-label extension trial to assess the efficacy, durability of response on therapy, duration of remittive effect off therapy, safety, and tolerability of tapinarof cream 1% QD
- **Figure 1** displays photographs of the clinical response of a patient treated with tapinarof 1% QD who achieved primary and secondary efficacy, and patient-reported outcome (PRO) endpoints

Figure 1. Clinical Response of a Patient with Plaque Psoriasis who Achieved Primary and Secondary Efficacy, and PRO Endpoints

BASELINE	WEEK 8	WEEK 12
<ul style="list-style-type: none"> • PGA=4 • PASI=18.4 • DLQI=16 • PP-NRS=6 	<ul style="list-style-type: none"> • PGA=2 • PASI=0.9 • DLQI=4* • PP-NRS=0 	<ul style="list-style-type: none"> • PGA=1 • PASI=0.6 • DLQI=1 • PP-NRS=0

PGA and PASI are global efficacy assessments. Example of one representative target lesion of one tapinarof-treated patient from PSOARING 1 clinical trial.

*DLQI was assessed at baseline, Week 4 (no evaluation at Week 8), and Week 12.

DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; PGA, Physician Global Assessment; PP-NRS, Peak Pruritus Numeric Rating Scale.

OBJECTIVE

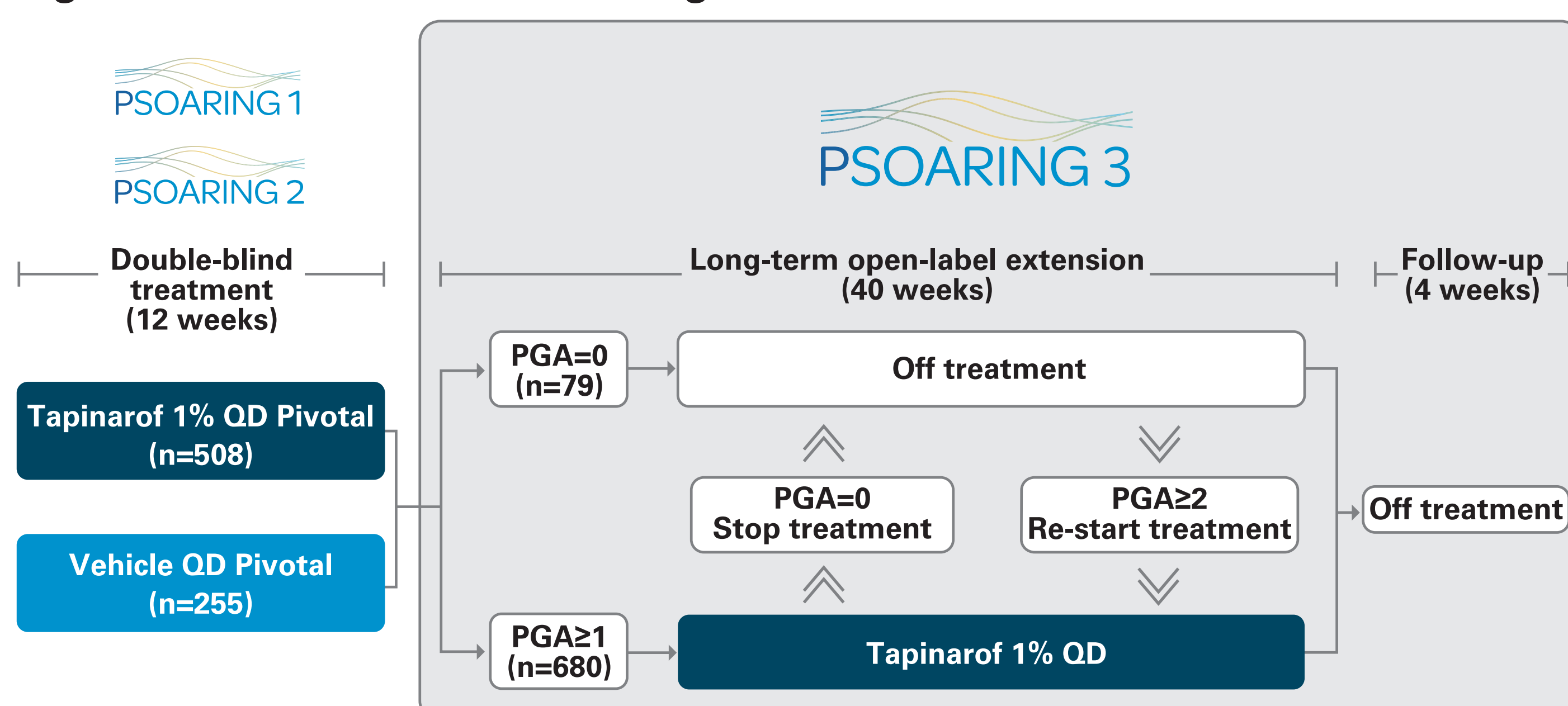
- Given that patient dissatisfaction with current therapies has a significant impact on disease management, we assessed patient satisfaction using a Patient Satisfaction Questionnaire; here we present the results from PSOARING 3, a long-term, open-label extension trial of tapinarof cream 1% QD

METHODS

Trial Design

- Patients completing PSOARING 1 and PSOARING 2 were eligible to enroll in PSOARING 3 for up to 40 weeks of open-label treatment with tapinarof cream 1% QD, followed by 4 weeks of follow-up (**Figure 2**)
- The Patient Satisfaction Questionnaire was designed to assess patients' satisfaction with tapinarof efficacy, formulation elegance, application ease, impact on daily life, and preference for tapinarof cream versus prior psoriasis therapies
 - The questionnaire included a series of 18 questions with responses on a scale of strongly agree, agree, neutral, disagree, or strongly disagree
- Patient Satisfaction Questionnaire responses were assessed at Week 40 (or Early Termination Visit) and summarized overall

Figure 2. PSOARING 3 Trial Design



Four patients (3 tapinarof, 1 vehicle) did not have a baseline PGA and are listed as missing. PGA, Physician Global Assessment; QD, once daily.

Previously Reported Efficacy Outcomes from PSOARING 3

- Tapinarof cream 1% QD demonstrated continued and substantial improvement in efficacy with long-term use, beyond the improvements already observed in the 12-week pivotal trials, PSOARING 1 and 2⁴

- Overall, 40.9% (312/763) of patients achieved complete disease clearance at least once during the trial; this included 233 patients who entered the trial with a Physician Global Assessment (PGA) score of ≥ 1 and 79 patients who entered with a PGA of 0⁴
- The median duration of remittive effect while off therapy for patients who entered the trial with a PGA of 0 was 115 days, and the mean total duration of remittive effect off therapy for patients who entered with, or achieved, a PGA of 0 was 130 days⁴
- Durability of response of up to 52 weeks was demonstrated with intermittent use of tapinarof cream 1% QD, indicating no observation of tachyphylaxis (defined as loss of response) while on therapy⁴
- Tapinarof cream 1% QD was well tolerated with long-term use and had a safety profile consistent with previous trials^{2,5}

RESULTS

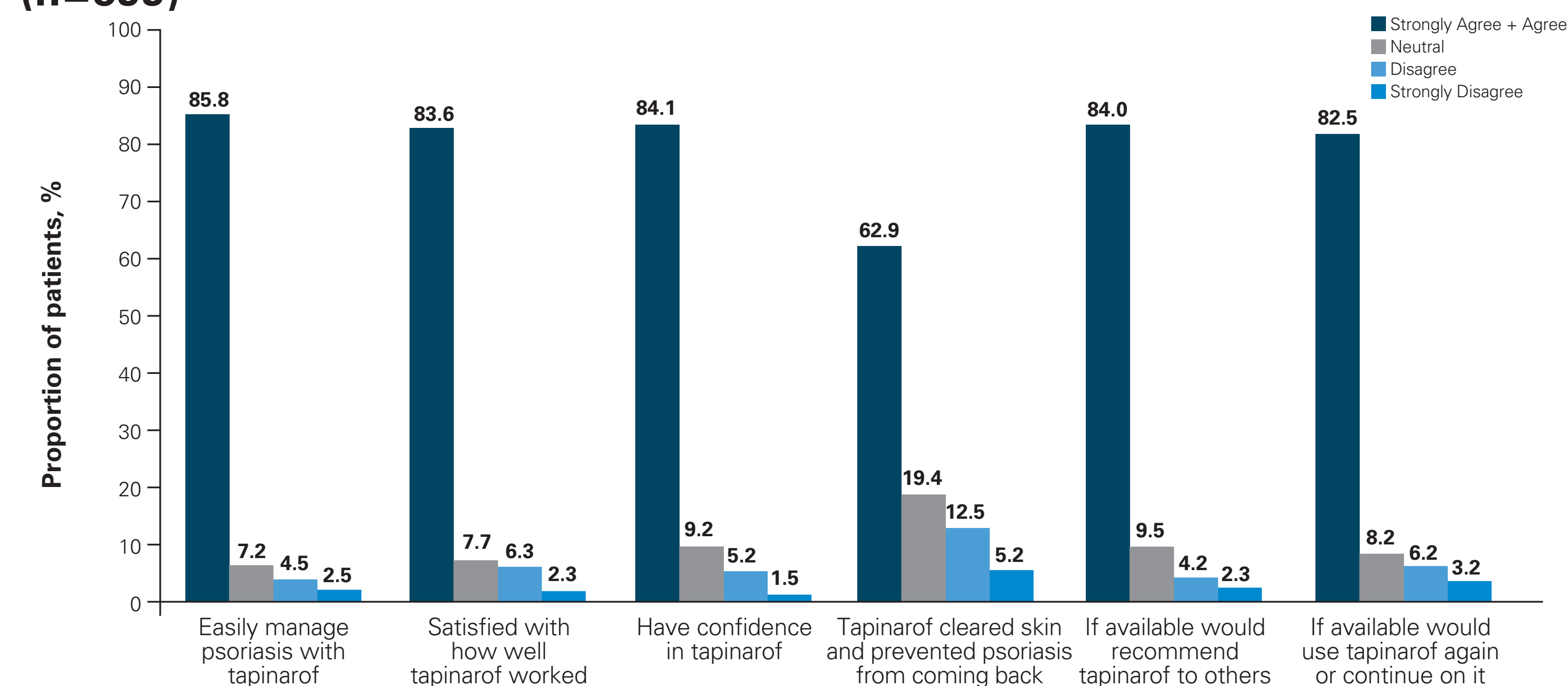
Patient Satisfaction Questionnaire

- 91.6% of eligible patients (n=763) completing PSOARING 1 and 2 elected to enroll in PSOARING 3
- Patient Satisfaction Questionnaires were completed by 78.5% (599/763) of patients in PSOARING 3
- Patients consistently reported high satisfaction rates across all parameters, including patients' satisfaction with tapinarof efficacy, formulation elegance, application ease, impact on daily life, and preference for tapinarof cream versus prior psoriasis therapies

Confidence and Satisfaction with the Efficacy of Tapinarof Cream

- Most patients either strongly agreed or agreed with all questions on confidence and satisfaction with the efficacy of tapinarof cream (**Figure 3**)
- 85.8% felt they could easily manage their psoriasis with tapinarof, and 83.6% were satisfied with how well tapinarof worked
- In addition to the 40.9% of patients who achieved complete disease clearance and the observed remittive effect of ~4 months, 62.9% of patients either strongly agreed or agreed that tapinarof cleared their skin and kept psoriasis from coming back
- 84.1% had confidence in tapinarof, and 84.0% would recommend tapinarof to other patients with psoriasis
- 82.5% of patients would use tapinarof again or continue on tapinarof if it was available

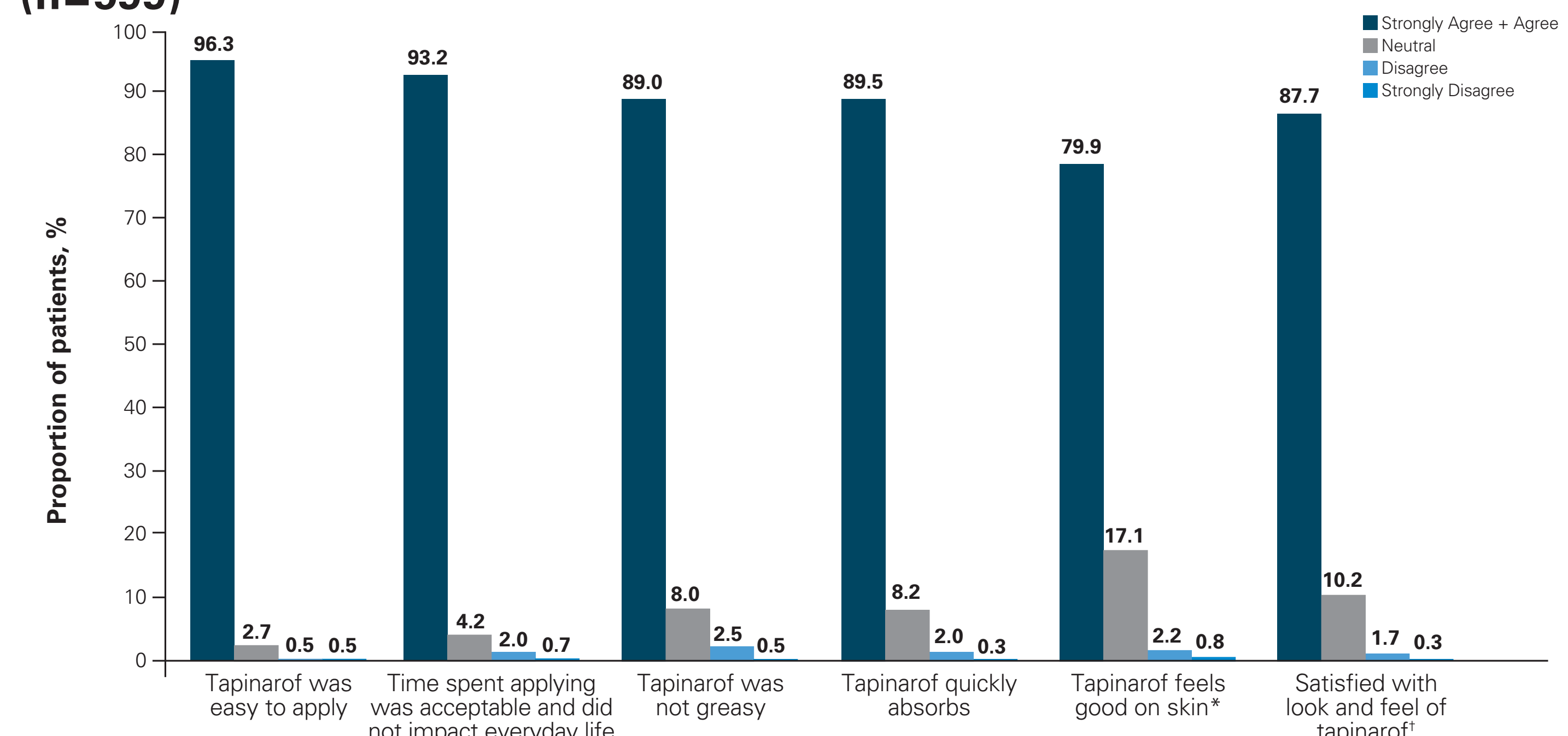
Figure 3. Confidence and Satisfaction with the Efficacy of Tapinarof Cream (n=599)



Ease of Application and Cosmetic Elegance of Tapinarof Cream

- Patients were consistently very satisfied with the tapinarof cream formulation and elegance (**Figure 4**)
- 93.2% were satisfied with the time spent applying tapinarof, and 96.3% considered it easy to apply
- In addition, most patients either strongly agreed or agreed that tapinarof was quickly absorbed (89.5%), felt good on their skin (79.9%), and was not greasy (89.0%)
- 87.7% were very satisfied with the look and feel of tapinarof

Figure 4. Ease of Application and Cosmetic Elegance of Tapinarof Cream (n=599)



*n number for question is 598. †n number for question is 587.

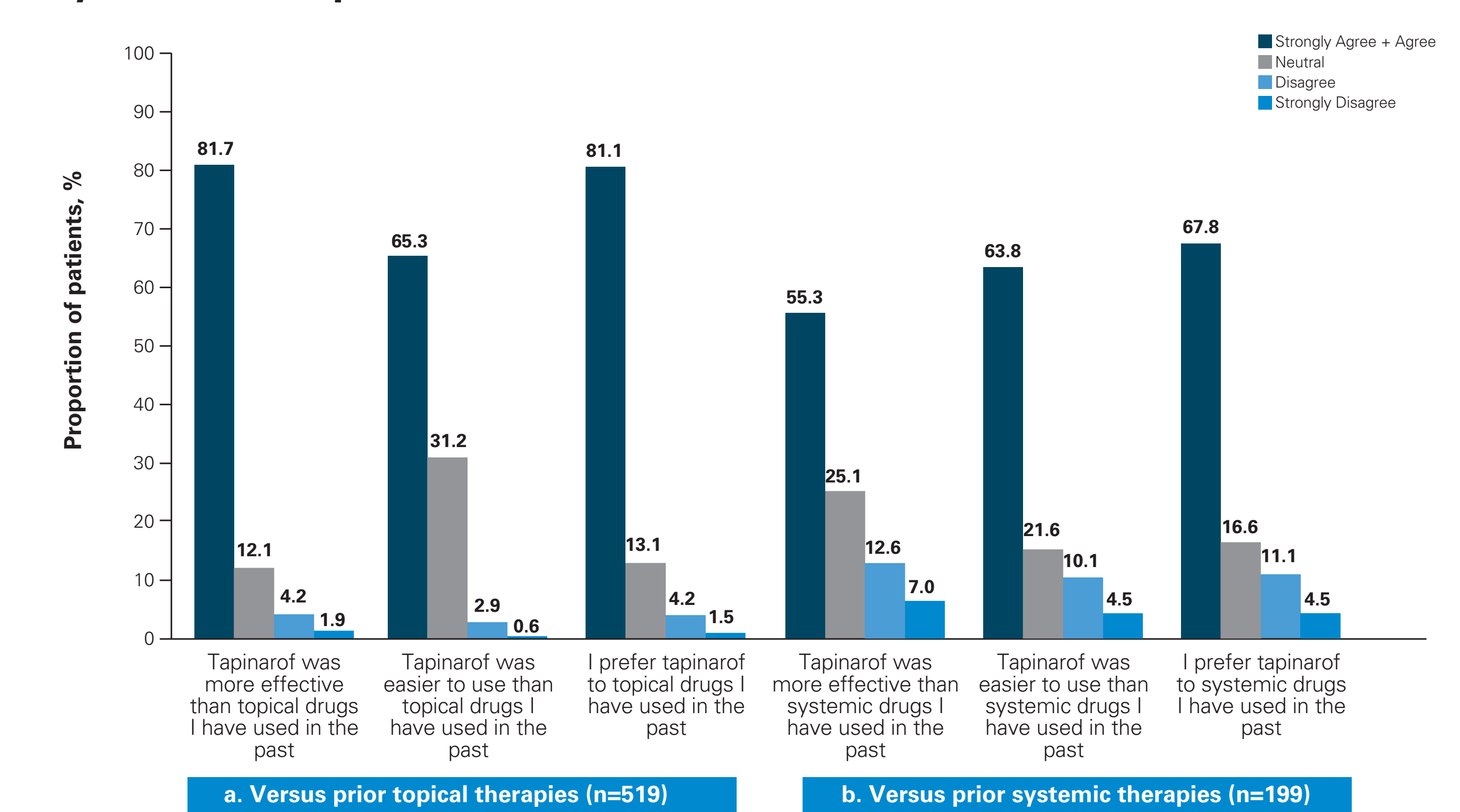
Preference for Tapinarof Cream Versus Prior Topical Psoriasis Therapies

- For patients who reported having used other topical drugs to treat psoriasis in the past, 81.7% considered tapinarof to be more effective than prior therapies, and 65.3% considered tapinarof easier to use (**Figure 5a**)
- 81.1% of patients preferred tapinarof to other topical drugs used to treat their psoriasis in the past

Preference for Tapinarof Cream Versus Prior Systemic Psoriasis Therapies

- For patients who reported having used systemic drugs to treat psoriasis in the past, 55.3% considered tapinarof to be more effective than prior therapies, and 63.8% considered tapinarof to be easier to use (**Figure 5b**)
- Most patients (67.8%) also preferred tapinarof to systemic drugs used to treat their psoriasis in the past

Figure 5. Patient Preference for Tapinarof Cream Versus Prior Topical and Systemic Therapies



CONCLUSION

- Patient satisfaction data from PSOARING 3 demonstrate a consistent and highly positive perception of tapinarof cream 1% QD across all patient relevant parameters, including satisfaction with tapinarof efficacy, formulation elegance, application ease, impact on daily life, and preference for tapinarof cream versus prior psoriasis therapies

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