

Patient and Parent/Caregiver Satisfaction with Efficacy and Cosmetic Elegance of Tapinarof Cream 1% Once Daily in a Long-term Extension Trial in Adults and Children Down to Age 2 Years with Atopic Dermatitis

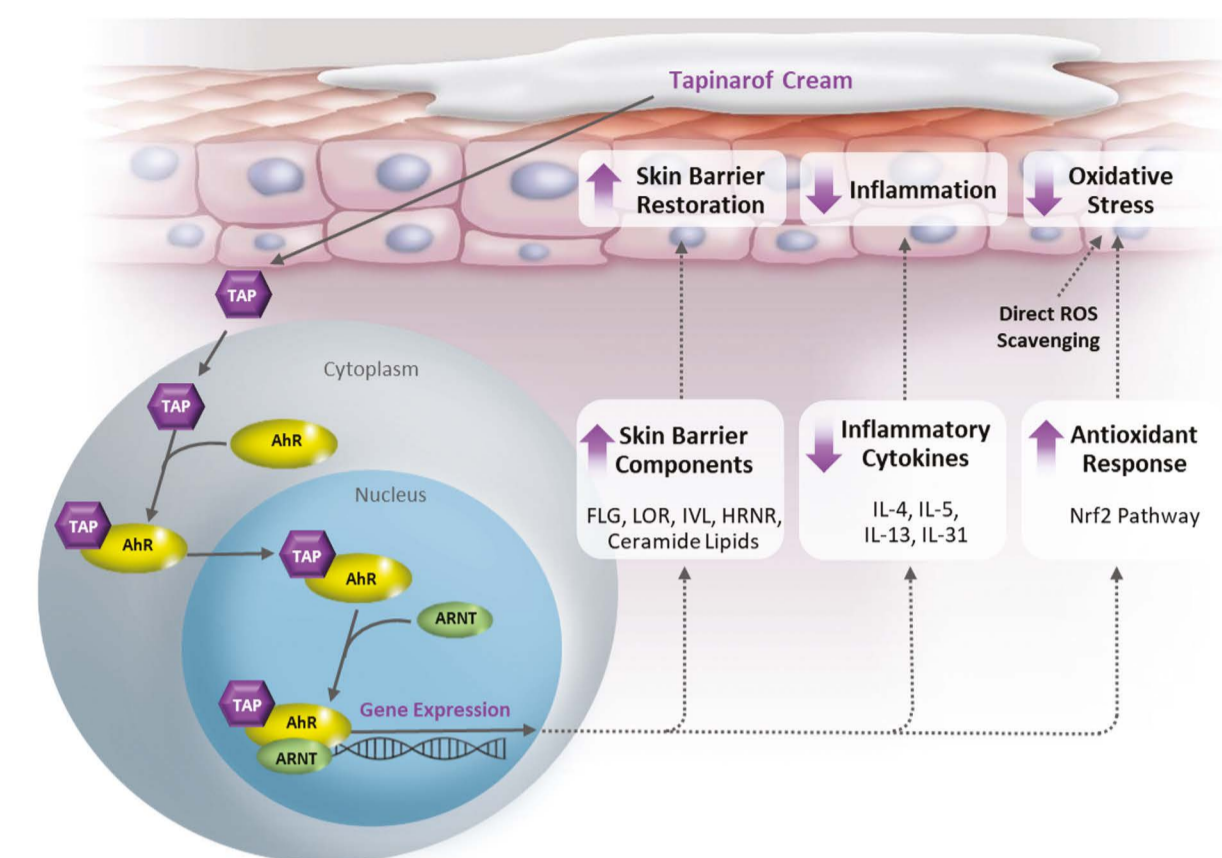
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INTRODUCTION

- Patients with atopic dermatitis (AD) report low treatment satisfaction with topical therapies¹
- Tapinarof 1% (VTAMA[®], Dermavant Sciences, Inc.) is a cosmetically elegant, once-daily (QD) topical cream that does not contain added fragrance and is free of petrolatum, para-aminobenzoic acid, phthalates, and parabens²
 - The vehicle is specifically designed to reduce skin irritation and optimize the delivery of tapinarof to the target site²
- Tapinarof is a non-steroidal, topical aryl hydrocarbon receptor (AhR) agonist, approved by the FDA for the treatment of plaque psoriasis in adults,³ with no warnings, contraindications, drug-drug interactions, or restrictions on duration, location, or extent of use
- Tapinarof binds to and activates AhR to restore the skin barrier through upregulation of skin barrier components, to downregulate pro-inflammatory cytokines associated with AD, and to reduce oxidative stress (Figure 1)⁴
- In two phase 3, randomized, double-blind, vehicle-controlled pivotal trials, ADORING 1 and 2 (NCT05014568, NCT05032859), tapinarof cream 1% QD demonstrated superior efficacy and was well tolerated in adults and children down to 2 years of age with AD⁵
- ADORING 3 was an open-label, long-term, multicenter extension trial that evaluated the efficacy, safety, and tolerability of tapinarof cream 1% QD⁶

Figure 1. Proposed Mechanism of Action of Tapinarof⁴



AhR, aryl hydrocarbon receptor; ARNT, aryl hydrocarbon receptor nuclear translocator; FLG, filaggrin; HRNR, hennipin; IL, interleukin; IVL, involucrin; LOR, loricrin; Nrf2, nuclear factor erythroid 2-related factor 2; ROS, reactive oxygen species; TAP, tapinarof.

OBJECTIVE

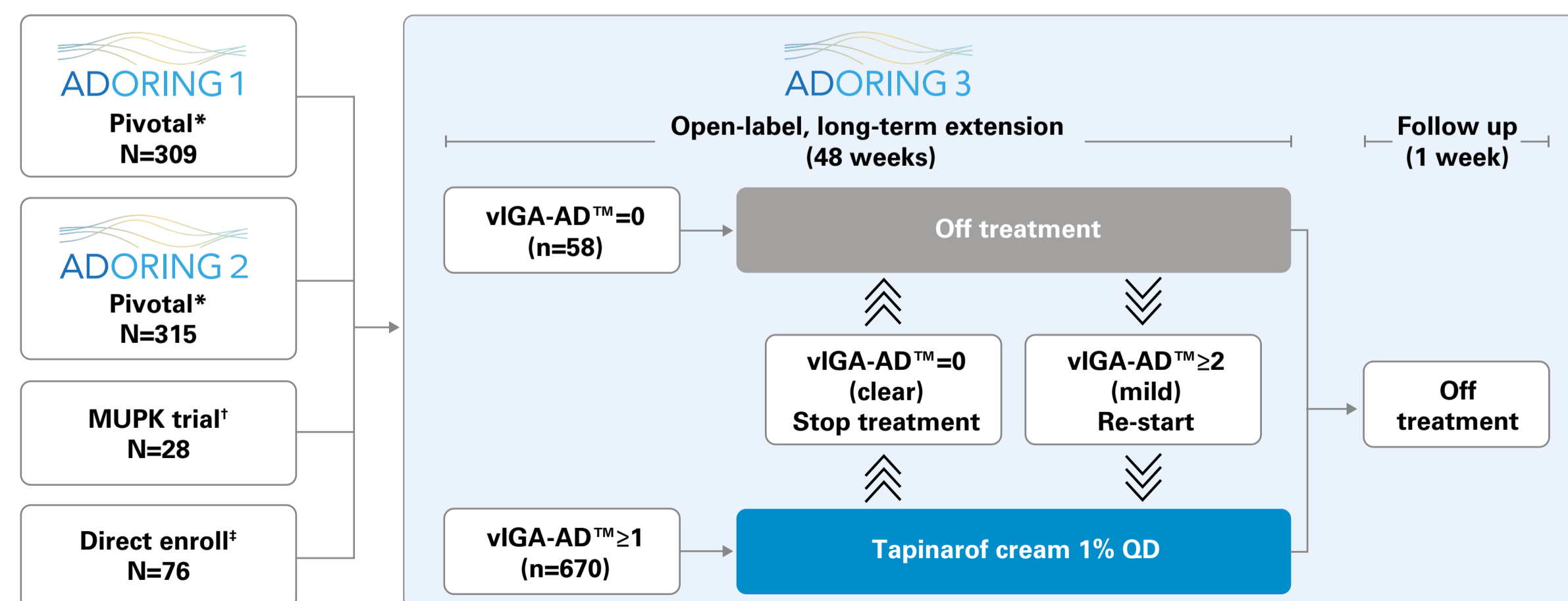
- To present Patient Satisfaction Questionnaire[®] data from ADORING 3, the 48-week, open-label extension trial

METHODS

Trial Design

- In the long-term extension trial, ADORING 3, eligible patients from ADORING 1 and 2, from a 4-week maximal usage pharmacokinetics trial, and tapinarof-naïve patients with mild AD, or moderate or severe AD, that did not meet inclusion criteria for ADORING 1 or 2, received up to 48 weeks of open-label tapinarof cream 1% QD, followed by a 1-week follow-up period off-treatment (Figure 2)
- The Patient Satisfaction Questionnaire was designed to assess patients' or parents'/caregivers' satisfaction with tapinarof efficacy, cosmetic elegance, application ease, impact on daily life, and preference versus prior AD therapies
 - The questionnaire comprised 18 questions with responses on a 5-point scale ("strongly agree", "agree", "neutral", "disagree", or "strongly disagree") and 2 questions on AD treatment history
 - Cosmetic elegance refers to the look and feel of tapinarof cream
 - Patients aged ≥16 years self-completed; parents/caregivers completed for children aged 2 to <16 years
- Responses to the Patient Satisfaction Questionnaire were assessed at Week 48 or at the early termination visit

Figure 2. ADORING 3 Trial Design



The vIGA-AD[™] scale is copyright ©2017 Eli Lilly and Company – Used with permission under a Creative Commons Attribution-NoDerivatives 4.0 International License. *Patients were adults and children down to 2 years of age with a clinical diagnosis of AD by Hanflin and Rajka criteria, a vIGA-AD[™] score of ≥3 (moderate or severe), an EASI score of ≥6, and BSA involvement of 5–35% at screening and baseline. †Patients were adolescents and children aged 2–17 years with a clinical diagnosis of AD by Hanflin and Rajka criteria, a vIGA-AD[™] score of ≥3 (moderate or severe) and BSA involvement of ≥35% for children aged 2–11 years or ≥25% for adolescents aged 12–17 years. ‡Pediatric patients aged 2–17 years with mild AD (vIGA-AD[™]=2, n=39), or moderate or severe AD, that did not meet the inclusion criteria to be enrolled in ADORING 1 or 2. AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; MUPK, maximal usage pharmacokinetics; QD, once daily; vIGA-AD[™], Validated Investigator Global Assessment for Atopic Dermatitis[™].

Efficacy, Safety, and Tolerability Outcomes from ADORING 3

- Overall, 51.9% (n=378/728) of patients entered with or achieved complete disease clearance (vIGA-AD[™]=0), and 81.6% entered with or achieved clear or almost clear skin (vIGA-AD[™]=0 or 1) on tapinarof monotherapy at least once⁶
- After first achieving complete clearance and then discontinuing treatment (n=378), patients experienced a treatment-free interval (remittive effect) of ~80 consecutive days off therapy⁶
- Tapinarof demonstrated maintenance of efficacy with either continuous or intermittent treatment, with no tachyphylaxis for up to 48 weeks of therapy⁶
- Adverse events were consistent with previous trials, with no new safety signals identified during long-term treatment⁶
 - The most frequent treatment-emergent adverse events (TEAEs) were folliculitis (12.1%), nasopharyngitis (6.9%), and upper respiratory tract infection (6.9%)
 - Trial discontinuations due to TEAEs were low (2.6%)
 - Adverse events of special interest, follicular events, contact dermatitis, and headache, were mostly mild or moderate and associated with low discontinuation rates (1.0%, 0.4%, and 0%, respectively)
- Long-term application of tapinarof cream demonstrated favorable local tolerability, even on sensitive skin areas⁶
 - At baseline in ADORING 3, 72.5% of patients had AD affecting the head and neck region

RESULTS

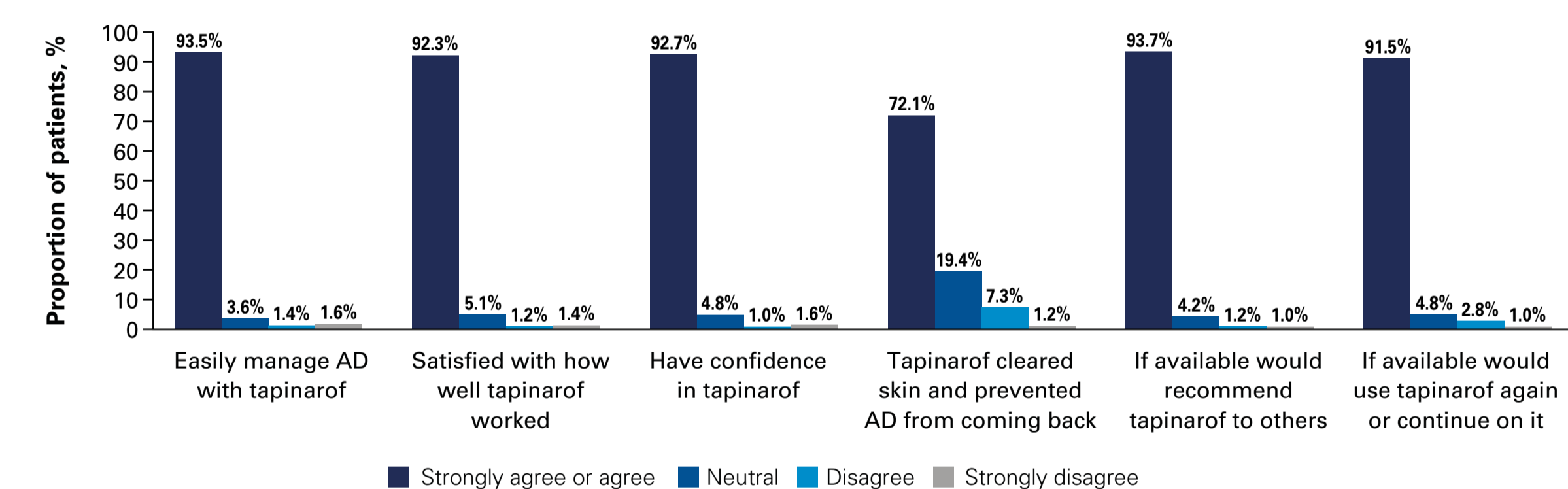
Patient Satisfaction Questionnaire

- Patient Satisfaction Questionnaires were completed by 505 patients or parents/caregivers in ADORING 3
- Patients consistently reported high satisfaction rates across all parameters, including patients' or parents'/caregivers' satisfaction with tapinarof efficacy, cosmetic elegance, application ease, impact on daily life, and preference for tapinarof cream versus prior AD 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)
- 93.5% felt they could easily manage their AD with tapinarof, and 92.3% were very satisfied with how well tapinarof worked
- 72.1% of patients either strongly agreed or agreed that tapinarof cleared their skin and kept AD from coming back
- 92.7% had confidence in tapinarof, 93.7% would recommend tapinarof to other patients with AD, and 91.5% of patients would use tapinarof again or continue on tapinarof if it were available

Figure 3. Confidence and Satisfaction with the Efficacy of Tapinarof Cream 1% QD (N=505)

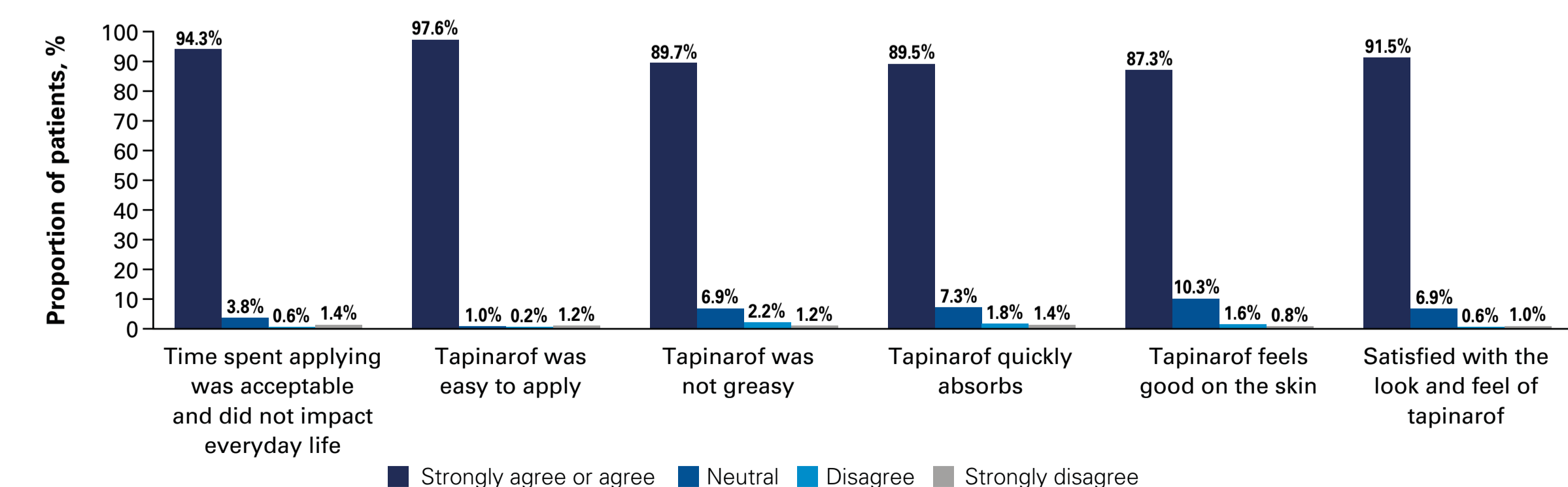


AD, atopic dermatitis; QD, once daily.

Ease of Application and Cosmetic Elegance of Tapinarof Cream

- Patients were consistently very satisfied with the tapinarof cream formulation and elegance (Figure 4)
- 94.3% were very satisfied with the time spent applying tapinarof, 97.6% considered it easy to apply, and 91.5% were very satisfied with the look and feel of tapinarof
- In addition, most patients either strongly agreed or agreed that tapinarof quickly absorbed (89.5%), felt good on their skin (87.3%), and was not greasy (89.7%)

Figure 4. Ease of Application and Cosmetic Elegance of Tapinarof Cream 1% QD (N=505)

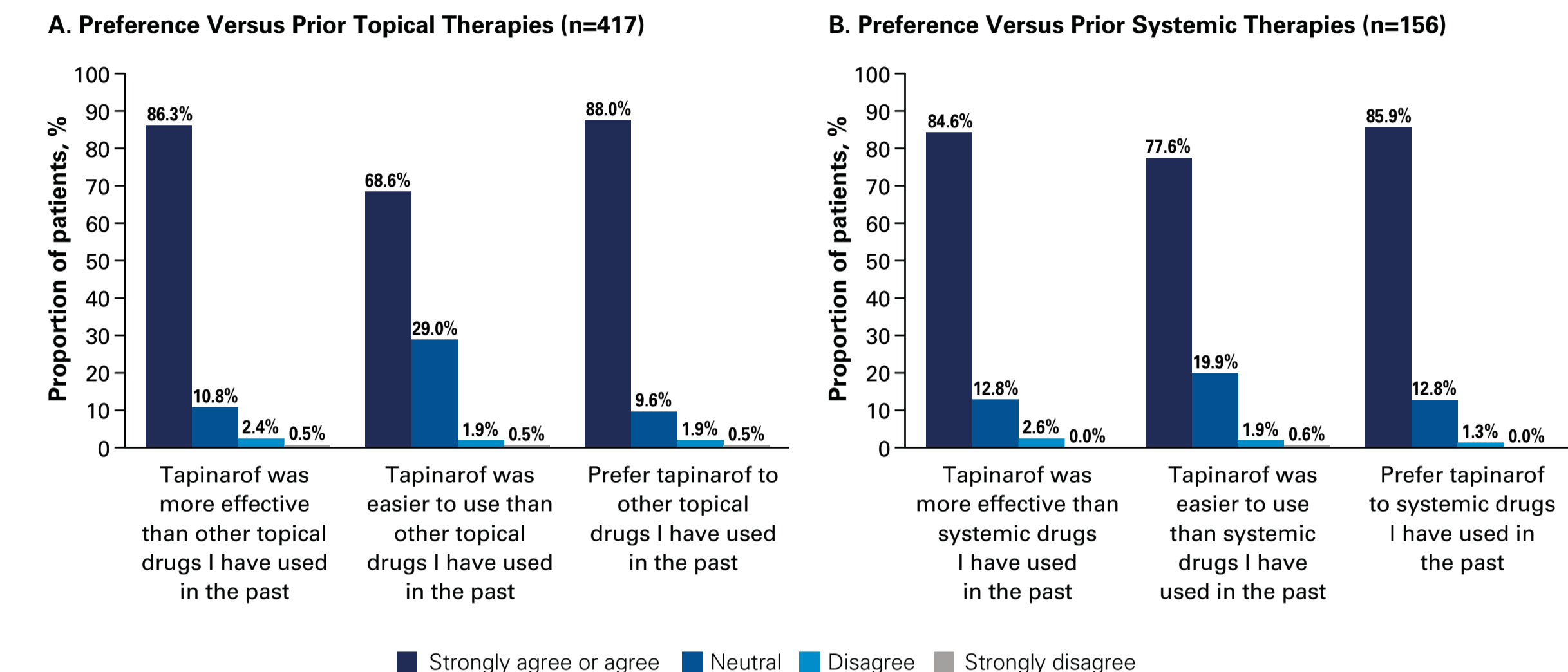


QD, once daily.

Preference for Tapinarof Cream Versus Prior AD Therapies

- For the 417 patients who had used other topical drugs to treat AD in the past, 86.3% strongly agreed or agreed that tapinarof cream was more effective than prior therapies, 68.6% considered tapinarof easier to use, and 88.0% preferred tapinarof (Figure 5A)
- For the 156 patients who had used systemic drugs to treat AD in the past, 84.6% strongly agreed or agreed that tapinarof cream was more effective than prior therapies, 77.6% considered tapinarof easier to use, and 85.9% preferred tapinarof (Figure 5B)

Figure 5. Patient Preference for Tapinarof Cream 1% QD Versus (A) Prior Topicals and (B) Systemic Therapies



QD, once daily.

CONCLUSIONS

- Patients and parents/caregivers reported consistent and highly positive perceptions of long-term use of tapinarof cream across all parameters in ADORING 3, including satisfaction with efficacy, cosmetic elegance, application ease, impact on daily life, and preference for tapinarof compared with prior AD therapies
- In ADORING 3, tapinarof cream 1% QD monotherapy was highly efficacious and well tolerated for up to 48 weeks in a diverse population of adults and children down to 2 years of age with AD⁶

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ACKNOWLEDGMENTS

This trial was funded by Dermavant Sciences, Inc. The authors thank the participating investigators, patients and their families, and colleagues involved in the conduct of the trial.

A.A.H. has received research support paid to the medical school from AbbVie, Arcutis, Dermavant Sciences, Inc., and Pfizer; has received honoraria from Arcutis, Dermavant Sciences, Inc., Galderma, Incyte, LEO Pharma, Novan, Ortho Dermatologics, Sun Pharma, and Verrica; and has received honoraria as part of Data Safety Monitoring Boards for Alphyn, GSK, Ortho Dermatologics, and Sanofi Regeneron. J.D.R. is a consultant and research investigator for Arcutis, Amgen, Bausch Health (Ortho Dermatologics), Bristol Myers Squibb, Dermavant Sciences, Inc., Galderma, Lilly, LEO Pharma, Pfizer, Sanofi/Regeneron, and UCB Pharma. S.M.J. is an advisor and/or speaker and/or editor and/or is involved in clinical trials for AbbVie, Acclaris, AFMC, Allergan, Amgen, Candela Syneron, Cassiopea, Celgene, Chemocentryx, Dermavant Sciences, Inc., Dermira, Foamix, Gage, Galderma, GSK, Journal of Arkansas Medical Society, LEO Pharma, Eli Lilly, National Psoriasis Foundation, Nielsen, Novartis, Practical Dermatology, Regeneron, Sanofi Genzyme, Skin Medical, TARGET Therapeutics, and the University of Pennsylvania. L.J.G. has served as an investigator, speaker, and/or advisor to Amgen, Apogee, Arcutis, Dermavant Sciences, Inc., Galderma, and Incyte. S.S. has served as a sub-investigator for clinical research trials for AbbVie, Acelvyrin, Alumis, AnaptysBio, Apogee, Arcutis, Asana BioSciences, Cara Therapeutics, Evmmune, Dermavant Sciences, Inc., Libertas Bio, Lilly, Q32 Bio, and Sun Pharma; and as an advisor for Incyte, Sun Pharma, and Verrica Pharmaceuticals. P.M.B., D.S.R., and A.M.T. are employees of Dermavant Sciences, Inc. with stock options. Editorial and medical writing support under the guidance of the authors was provided by ApotheCom, UK, and was funded by Dermavant Sciences, Inc., in accordance with Good Publication Practice (GPP) guidelines (*Ann Intern Med.* 2022;175:1298–1304).

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