

Tapinarof Cream 1% Once Daily: Consistent Efficacy Across Age Groups for Children Down to 2 Years of Age with Atopic Dermatitis in Two Pivotal Phase 3 Trials

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OBJECTIVE

- To report efficacy of tapinarof monotherapy in children aged 2–17 years with AD in ADORING 1 and 2, two phase 3, randomized, vehicle-controlled trials

CONCLUSIONS

- Tapinarof cream 1% QD monotherapy demonstrated significant and clinically meaningful efficacy in children aged 2–17 years with AD across multiple clinical measures – Efficacy was consistent across age groups
- Tapinarof was well tolerated; TEAEs were consistent with those seen in previous trials, and trial discontinuation rates were lower with tapinarof than vehicle
- Tapinarof is a once-daily, non-steroidal cream with no restrictions on duration, extent, or location of use, and without the need for long-term maintenance therapy^{1,6}

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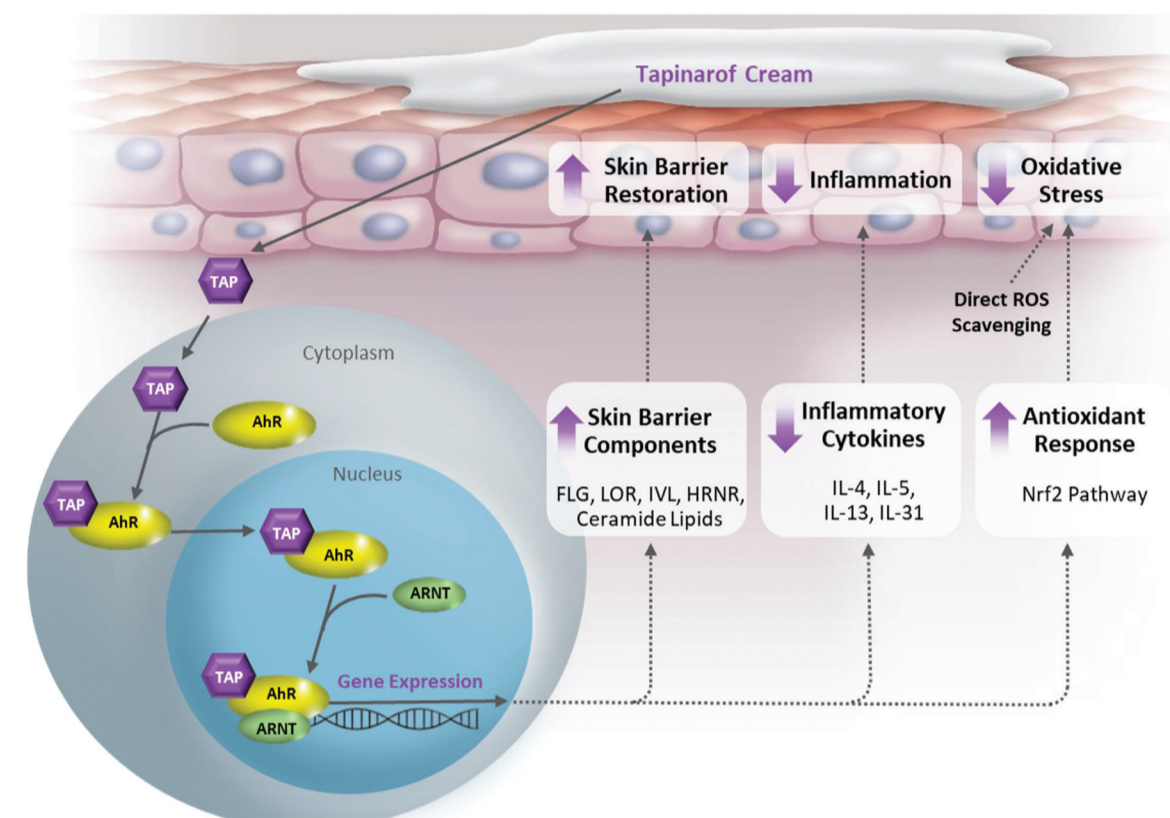
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INTRODUCTION

- Tapinarof (VTAMA®, Dermavant Sciences, an Organon Company) is a non-steroidal, topical aryl hydrocarbon receptor (AhR) agonist approved by the FDA for the treatment of atopic dermatitis (AD) in adults and children down to 2 years of age, and for the treatment of plaque psoriasis in adults, with no warnings, contraindications, drug–drug interactions, or restrictions on duration, location, or extent of use¹
- Tapinarof cream is cosmetically elegant, easily applied, quickly absorbed, and not greasy or sticky²
- Tapinarof binds to and activates AhR to restore the skin barrier by upregulating key barrier components, downregulating pro-inflammatory cytokines associated with AD, and reducing oxidative stress (Figure 1)³
- In ADORING 1 and 2, two pivotal phase 3, randomized, double-blind, vehicle-controlled trials, tapinarof cream 1% once daily (QD) demonstrated statistically significant efficacy and was well tolerated in adults and children down to 2 years of age with AD⁴

Figure 1. Proposed Mechanism of Action of Tapinarof³



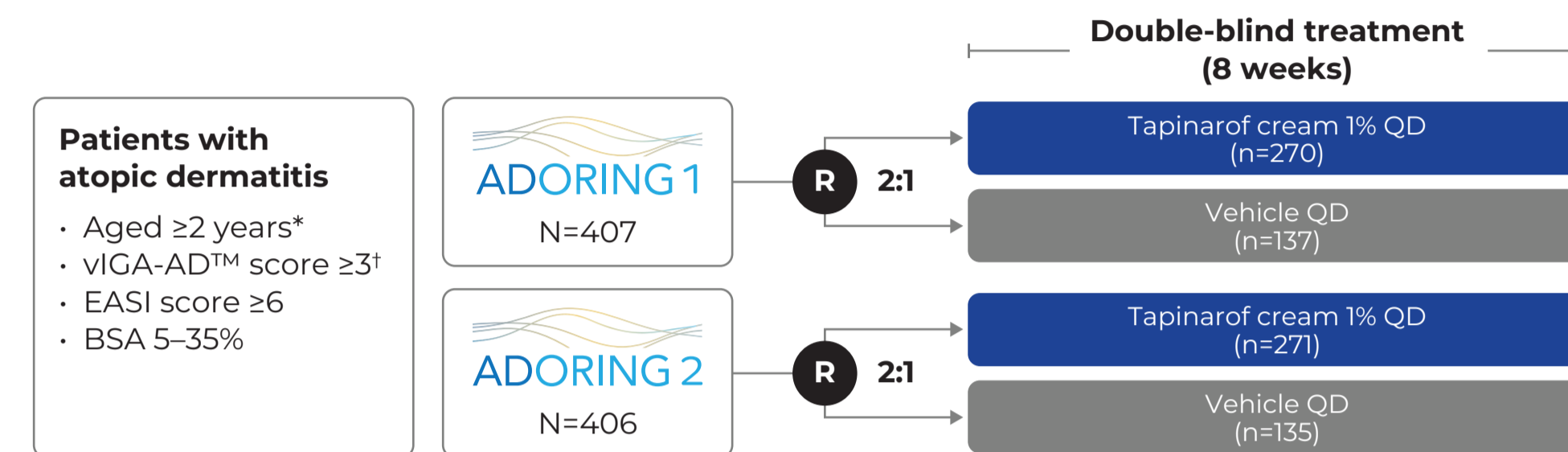
AhR, aryl hydrocarbon receptor; ARNT, aryl hydrocarbon receptor nuclear translocator; FLG, filaggrin; HRNR, hornerin; IL, interleukin; IVL, involucrin; LOR, lorixin; Nrf2, nuclear factor erythroid 2-related factor 2; ROS, reactive oxygen species; TAP, tapinarof.

METHODS

Trial Design

- In ADORING 1 and 2, adults and children with AD were randomized 2:1 to tapinarof cream 1% or vehicle QD for 8 weeks (Figure 2)

Figure 2. ADORING 1 and 2 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.
 *A minimum of ~15% of patients were enrolled into the following age groups: 2–6 years, 7–11 years, 12–17 years, and ≥18 years. Adults (≥18 years) comprised a maximum of approximately 20% of enrolled patients. †Patients with a vIGA-AD™ score of 4 (severe) represented a minimum of ~10% of the total randomized population; the remainder had a vIGA-AD™ score of 3 (moderate). BSA, body surface area; EASI, Eczema Area and Severity Index; QD, once daily; R, randomized; vIGA-AD™, Validated Investigator Global Assessment for Atopic Dermatitis™.

Endpoints

- The primary efficacy endpoint was Validated Investigator Global Assessment for Atopic Dermatitis™ (vIGA-AD™) response (vIGA-AD™ score of clear [0] or almost clear [1] and ≥2-grade improvement) from baseline at Week 8
- Secondary efficacy endpoints included ≥75% improvement in Eczema Area and Severity Index (EASI) score (EASI75) and the percent change in body surface area (%BSA) affected
- Safety assessments included the incidence and frequency of treatment-emergent adverse events (TEAEs)
- Efficacy outcomes in children (aged 2–17) were stratified by age group: 2–6 years, 7–11 years, and 12–17 years

RESULTS (CONT.)

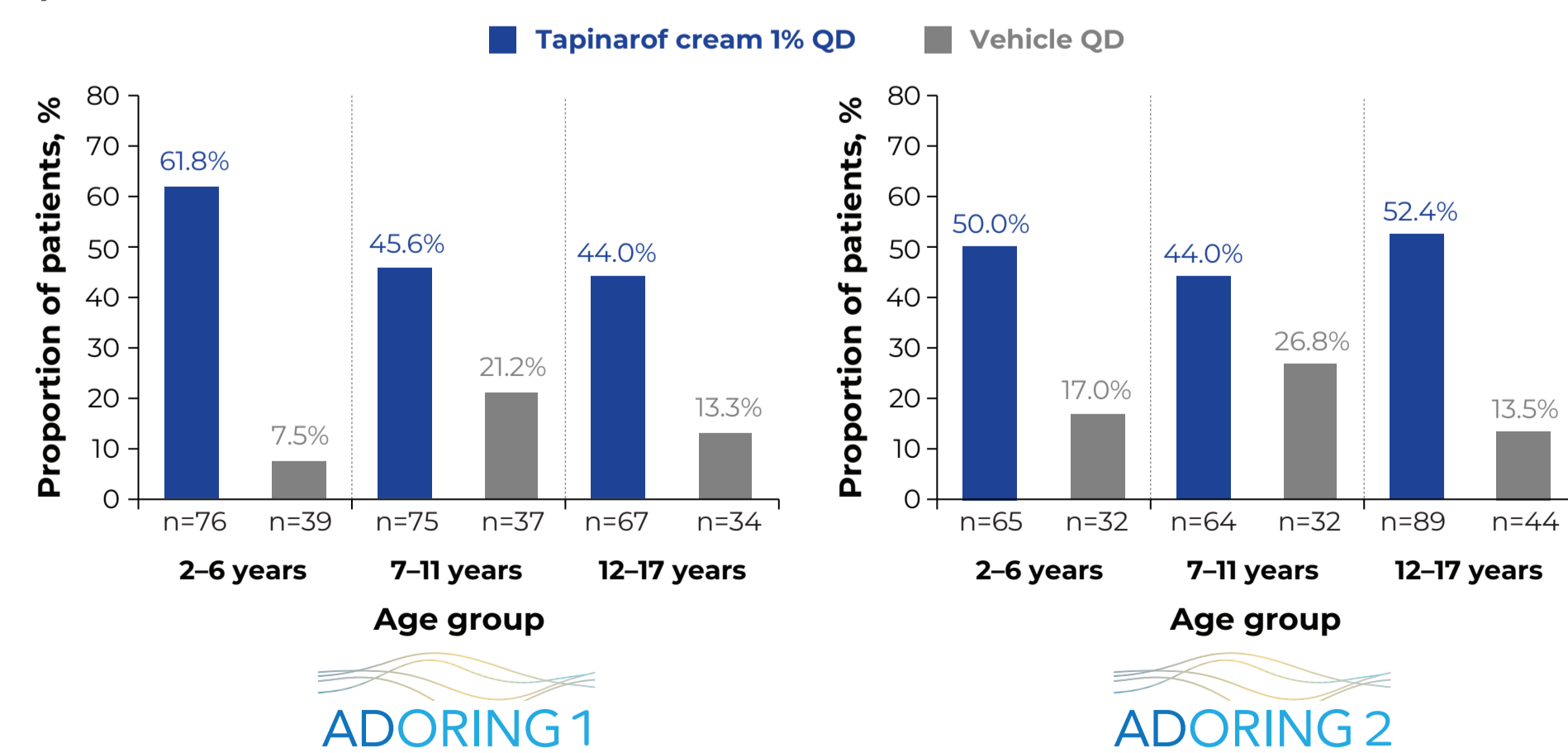
Achievement of vIGA-AD™ Response at Week 8 (Adults and Children)

- Overall, a significantly higher proportion of patients achieved a vIGA-AD™ response at Week 8 with tapinarof versus vehicle in both trials, respectively: 45.4% vs 13.9% and 46.4% vs 18.0% (both $P < 0.0001$)⁴

Achievement of vIGA-AD™ Response in Children by Age Group at Week 8

- vIGA-AD™ response rates with tapinarof compared with vehicle were consistent in both trials across all pediatric age groups (Figure 3)

Figure 3. Consistent vIGA-AD™ Response* Rates in Children by Age Group at Week 8 with Tapinarof Cream 1% QD



*vIGA-AD™ score of clear (0) or almost clear (1) and ≥2-grade improvement from baseline. Intention-to-treat, multiple imputation (non-estimand). QD, once daily; vIGA-AD™, Validated Investigator Global Assessment for Atopic Dermatitis™.

Safety and Tolerability

- Overall, most TEAEs were mild or moderate in ADORING 1 and 2; the most frequent (≥5% in any group) were folliculitis, headache, and nasopharyngitis⁴
- Trial discontinuation rates due to TEAEs were low and were lower with tapinarof versus vehicle (ADORING 1: 1.9% vs 3.6%; ADORING 2: 1.5% vs 3.0%, respectively)⁴
- Tapinarof cream 1% QD demonstrated favorable local tolerability, including on sensitive skin, in adults and children down to 2 years of age, as reported by patients or parents/caregivers and when assessed by investigators⁵

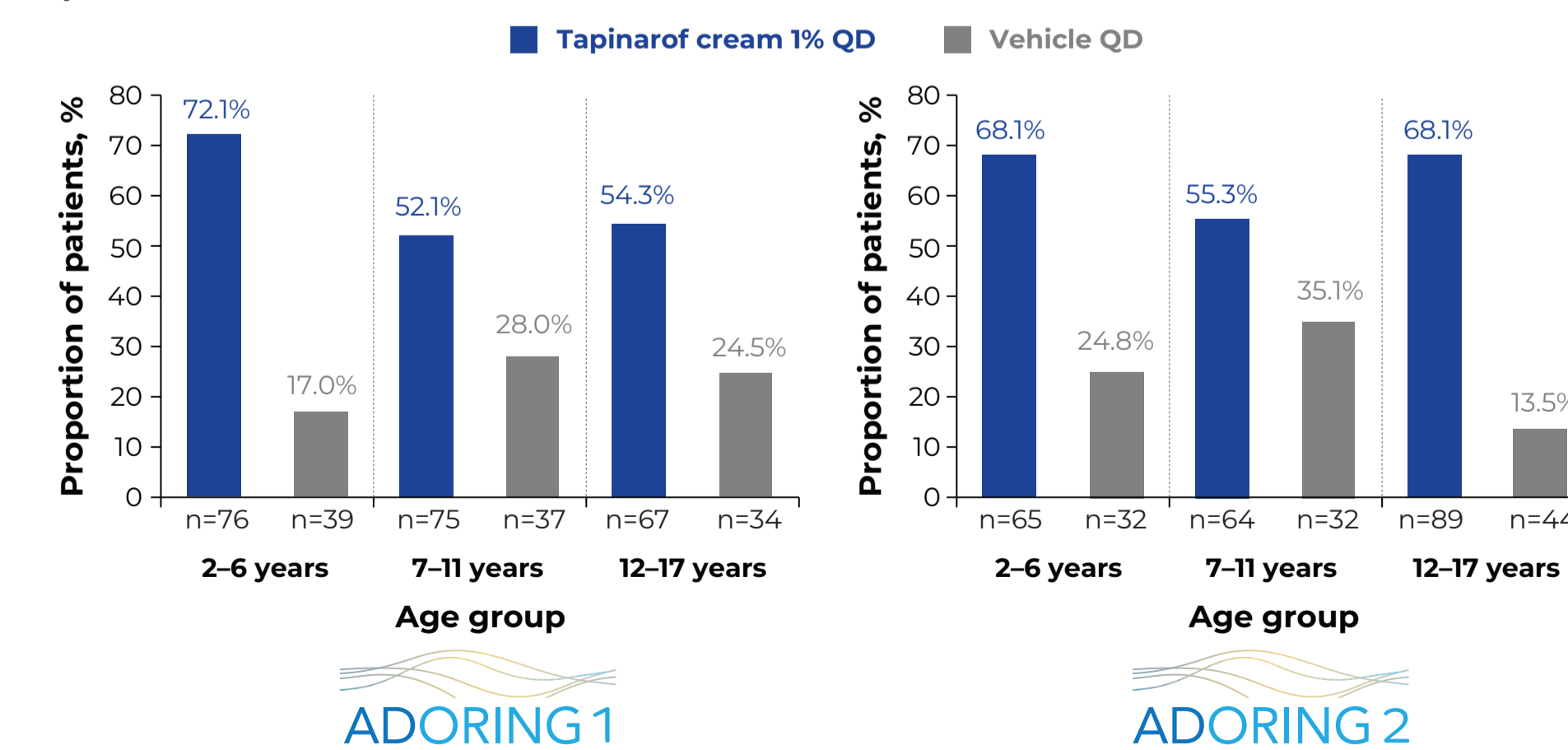
Achievement of EASI75 Responses at Week 8 (Adults and Children)

- EASI75 response was statistically significant with tapinarof groups compared with vehicle at Week 8 in ADORING 1 and 2: 55.8% vs 22.9% and 59.1% vs 21.2% (both $P < 0.0001$), respectively⁴

Achievement of EASI75 Responses in Children by Age Group at Week 8

- EASI75 response rates with tapinarof versus vehicle were consistent in both trials across all pediatric age groups (Figure 4)

Figure 4. Consistent EASI75 Response* Rates in Children by Age Group at Week 8 with Tapinarof Cream 1% QD



*≥75% improvement in Eczema Area and Severity Index score from baseline. Intention-to-treat, multiple imputation (non-estimand). EASI75, ≥75% improvement in Eczema Area and Severity Index score; QD, once daily.

RESULTS

- 407 and 406 patients in the US and Canada were enrolled in ADORING 1 and 2, respectively (Table 1)
- 328 (80.6%) and 326 (80.3%) were children (2–17 years)
- At baseline, 89.9% and 84.0% of patients had a vIGA-AD™ score of 3 (moderate)
- Mean baseline EASI scores were 12.5 and 13.3, indicating moderate to severe disease

Table 1. ADORING 1 and 2 Baseline Patient Demographics and Disease Characteristics (Adults and Children)

	ADORING 1		ADORING 2	
	Tapinarof cream 1% QD (n=270)	Vehicle QD (n=137)	Tapinarof cream 1% QD (n=271)	Vehicle QD (n=135)
Age, years, mean (SD)	15.6 (16.6)	15.6 (16.5)	16.4 (16.2)	16.7 (16.1)
Male, n (%)	130 (48.1)	66 (48.2)	117 (43.2)	58 (43.0)
vIGA-AD™, n (%)				
3 – Moderate	244 (90.4)	122 (89.1)	228 (84.1)	113 (83.7)
4 – Severe	26 (9.6)	15 (10.9)	43 (15.9)	22 (16.3)
EASI, mean (SD)	12.2 (5.0)	12.9 (5.6)	13.5 (5.6)	13.1 (4.7)
BSA affected, %, mean (SD)	16.5 (8.7)	17.7 (9.5)	17.1 (8.7)	15.8 (7.9)
PP-NRS (all), mean (SD)	6.8 (2.3)	6.5 (2.4)	6.7 (2.4)	6.9 (2.1)

BSA, body surface area; EASI, Eczema Area and Severity Index; PP-NRS, Peak Pruritus Numerical Rating Scale; QD, once daily; SD, standard deviation; vIGA-AD™, Validated Investigator Global Assessment for Atopic Dermatitis™.

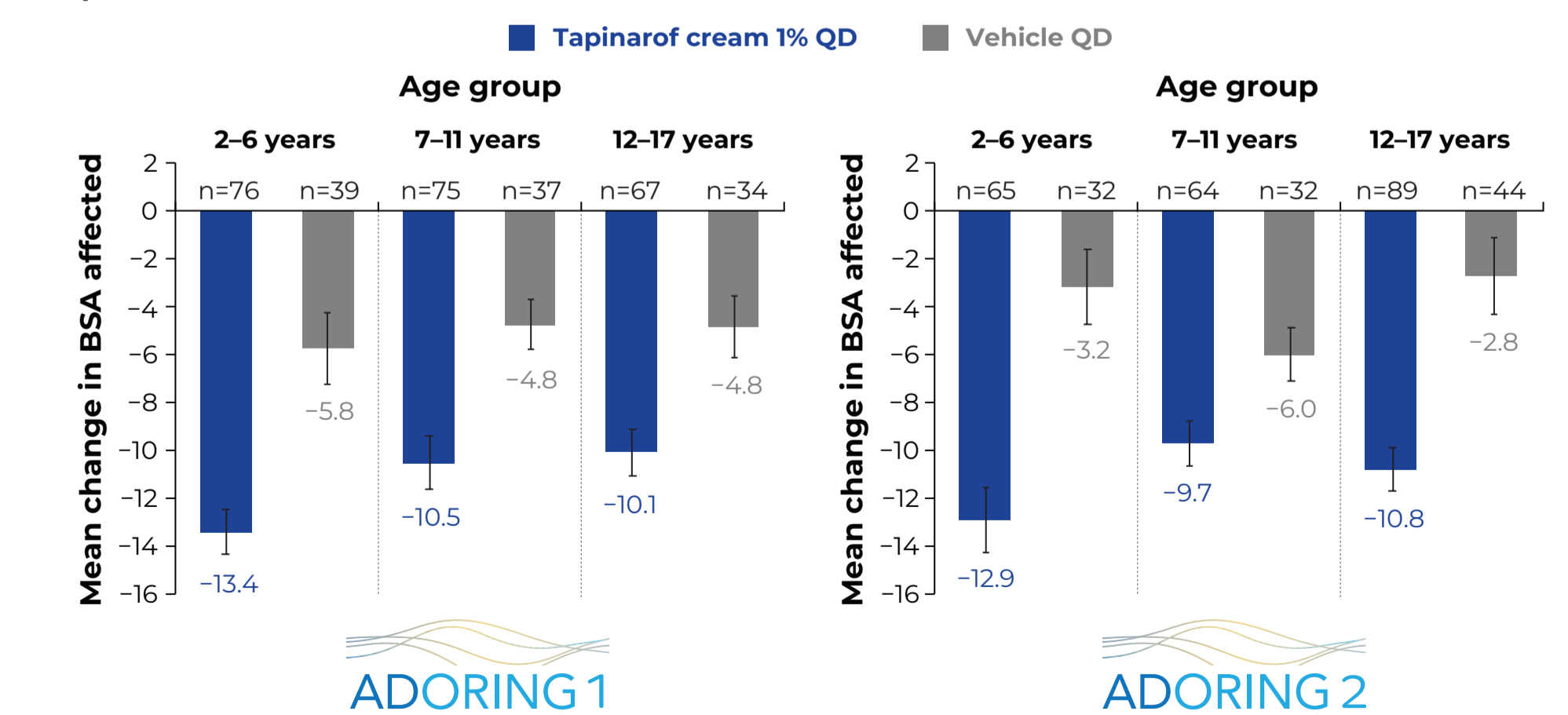
Mean Change in BSA Affected at Week 8 (Adults and Children)

- Significant improvements in mean BSA affected were reported with tapinarof versus vehicle at Week 8: –9.4 vs –3.2 ($P < 0.0001$) and –10.0 vs –3.4 ($P < 0.0001$), in ADORING 1 and 2, respectively

Mean Change in BSA Affected in Children by Age Group at Week 8

- Mean change in BSA affected with tapinarof compared with vehicle was consistent across age groups in both trials (Figure 5)

Figure 5. Consistent Improvement in BSA Affected in Children by Age Group at Week 8 with Tapinarof Cream 1% QD



Intention-to-treat, multiple imputation (non-estimand). BSA, body surface area; QD, once daily.