Treating moderate-to-severe atopic dermatitis in children and adolescents: Insights from the experts

Data updates
April 2025

Date of preparation: 15 April 2025

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AAAAI/WAO 2025: Dupilumab and vertical growth attainment

Growth analysis in children aged 6 to 11 years with severe AD, and impact of dupilumab treatment on height

Objective(s)	• To report the proportion of children aged 6 to 11 years with severe AD and reduced stature who reach a ≥5-percentile improvement in height following 16 weeks' treatment with **DUP** vs children in the **PBO** group
Study cohort and methods	• Height and weight were recorded for children aged 6 to 11 years who participated in: — **LIBERTY AD PEDS** (PEDS; NCT03345914; severe AD): a phase III, placebo-controlled 16-week trial — **LIBERTY AD PED-OLE** (PED-OLE; NCT02612454; moderate-to-severe AD): all eligible patients received **DUP** • Change from baseline in height percentile ≥5 was reported at week 16 (PEDS) and week 52 (PED-OLE)*
Results	• 54.2% (83/153) girls and 57.6% (87/151) boys aged 6 to 11 years with severe AD in lower height percentiles (<50th percentile) at baseline • **At week 16 (PEDS):** — Proportion of patients with reduced stature at baseline (<40th percentile) achieving a ≥5 percentile height improvement was significantly increased in **DUP**-treated vs **PBO**-treated patients (**~31%** vs **~11–15%**) • **At week 52 (PED-OLE):** — Proportion of **DUP**-treated patients with a ≥5 percentile height in the parent study (PEDS) rose to **~48–50%** — **PBO**-treated patients in PEDS transitioning to **DUP** in PEDS-OLE increased by ≥5 percentiles in height in similar or greater proportions at week 52 (~33–44%) compared with **DUP**-treated children in PED parent study at week 16
Conclusions	• **Data supports RWE suggesting severe AD during childhood carries risk of reduced stature** • **Prompt and effective DUP initiation may benefit those who are below expected height, by improving vertical growth** • **The catch-up growth phenomenon observed with DUP was repeated in PBO recipients who switched to DUP at week 16, with ~33–44% achieving ≥5 percentiles in height improvement at week 52**

*All height percentiles derived from CDC growth charts.

AAAAI, American Academy of Allergy, Asthma & Immunology; AD, atopic dermatitis; CDC, Centers for Disease Control and Prevention; DUP, dupilumab; OLE, open-label extension; PBO, placebo; RWE, real-world evidence; WAO, World Allergy Organization.

Irvine AD, et al. *J Clin Immunol.* 2025;155:AB208.

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AAAAI/WAO 2025: Lebrikizumab and mental-health outcomes

Lebrikizumab improves anxiety and depression symptoms of adolescents with moderate-to-severe AD: Results from the ADore 52-week open-label phase III study	
Objective(s)	• To report 52-week PROMIS anxiety and depression scores from ADore
Study cohort and methods	• Adolescent patients with moderate-to-severe AD treated with lebrikizumab — At baseline and week 2: 500 mg loading dose administered, then 250 mg Q2W • 52-week endpoints assessed included observed % change in: — PROMIS scores for anxiety and depression symptoms — PROMIS-anxiety and PROMIS-depression symptom scores from baseline
Results	• 206 patients were analysed 52-week endpoints assessed included observed % change in: — Female: 52.4%; mean age: 12.4 years — Mean average time experienced AD: 14.6 years • **At week 52:** Patients with baseline PROMIS scores >60 (deemed moderate-to-severe) had average improvements in their PROMIS-**anxiety score** (**19.0%**; n=43) and PROMIS-**depression score** (**12.6%**; n=34) — 68.6% (n=35) and 52.4% (n=22) achieved PROMIS-anxiety and PROMIS-depression scores of <60 (mild or less) by week 52
Conclusions	• **Moderate-to-severe PROMIS-anxiety and depression symptoms improved in adolescents with AD following lebrikizumab treatment** • **Many adolescent patients with moderate-to-severe baseline PROMIS-anxiety and PROMIS-depression symptoms showed improvement to mild scores or less at week 52**

AAAAI, American Academy of Allergy, Asthma & Immunology; AD, atopic dermatitis; PROMIS, Patient-Reported Outcomes Information System; Q2W, every 2 weeks; WAO, World Allergy Organization.

Geng B, et al. *J Clin Immunol.* 2025;155:AB200.

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AAAAI/WAO 2025: Abrocitinib in adolescent patients

Impact of baseline disease severity on long-term efficacy and safety of abrocitinib treatment in adolescent patients with moderate-to-severe AD: Interim analysis of the long-term extension JADE-EXTEND Study

Objective(s)	• Planned interim analysis evaluating the impact of baseline disease severity on abrocitinib efficacy and safety in adolescents with moderate-to-severe AD, with up to 112 weeks of treatment
Study cohort and methods	• Adolescents (aged 12 to <18 years) who received abrocitinib in either of two parent studies before enrolling in EXTEND: — JADE-MONO-1 (NCT03349060), -MONO-2 (NCT03575871) and -TEEN (NCT03796676): QD 200 mg/100 mg — EXTEND enrolment data cut-off: 5 September 2022 • Baseline AD severity was assessed by EASI and IGA scores (moderate: EASI 16-25+IGA 3; severe: EASI >25+IGA 4) • Week 112 assessments included proportion of patients achieving: — **IGA 0/1**; **EASI-75**; **PP-NRS4**
Results	• 254 patients with **moderate** AD (n=130) or **severe** AD (n=124) at baseline • **Week 112 efficacy** responses were comparable in patients with moderate vs severe AD for: — IGA 0/1: 200 mg: **61%** vs **48%**; 100 mg: **64%** vs **57%** — EASI-75: 200 mg: **89%** vs **86%**; 100 mg: **84%** vs **84%** — PP-NRS4: 200 mg: **71%** vs **69%**; 100 mg: **48%** vs **48%** • **Safety profile** showed AEs were more frequent in **severe** vs **moderate** AD — 200 mg: **98%** vs **86%** — 100 mg: **85%** vs **66%**
Conclusions	**Week 112 efficacy responses were consistent across AD severities, with higher AE frequency in more severe cases**

AAAAI, American Academy of Allergy, Asthma & Immunology; AD, atopic dermatitis; AE, adverse event; EASI, Eczema Area and Severity Index; EASI-75, >75% improvement in EASI score; IGA, Investigator's Global Assessment; IGA 0/1, achieved IGA of 0 (clear) or 1 (almost clear) with >2-grade improvement; PP-NRS4, >4-point improvement in Peak Pruritus Numerical Rating Scale; QD, once daily; WAO, World Allergy Organization.

Spergel J, et al. *J Clin Immunol.* 2025;155:AB590.

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AAD 2025: Dupilumab data in children aged 6 months to 11 years

Dupilumab safety and efficacy up to 3 years in children aged 6 months to 11 years with AD	
Objective(s)	• Evaluate the impact of dupilumab treatment low-potency TCS for 3 years on safety and efficacy measures in children aged 6 months to 11 years with moderate-to-severe AD
Study cohort and methods	• Children dosed in two 16-week parent studies before entering OLE phase: — **6 months to 5 years (n=180)** (NCT03346434) DUP dosing schedule: 5 to <15 kg 200 mg Q4W; 15 to <30 kg 300 mg Q4W — **6 to 11 years (n=383)** (NCT03345914) DUP dosing schedule: 30 to 60 kg 200 mg Q2W; ≥60 kg 300 mg Q2W • Concomitant use of topical AD treatments (low-potency TCS, TCI etc.) was permitted • Observed improvements in EASI scores, proportion of patients achieving EASI-75 and EASI-90, and safety were assessed at week 152
Results	• Mean **EASI** scores at parent study **baseline** to **week 152**: — 6 months to 5 years: **33.9** vs **3.7** — 6 to 11 years: **37.9** vs **3.8** • Proportion (%) of patients achieving **EASI-75** and **EASI-90** at **parent study baseline** to **week 152**: — 6 months to 5 years: **EASI-75: 29.4** vs **90.3**; **EASI-90: 14.4** vs **60.2** — 6 to 11 years: **EASI-75: 40.7** vs **89.1**; **EASI-90: 21.4** vs **61.1** • **Safety** profile – patients (%) experiencing TEAEs: — 6 months to 5 years – **any: 89.4**; **serious: 13.3**; **drug-related: 20.6 (conjunctivitis: 2.8)** — 6 to 11 years – **any: 87.7**; **serious: 11.2**; **drug-related: 24.8 (conjunctivitis: 2.6)**
Conclusions	**DUP treatment up to 3 years in children aged 6 months to 11 years with moderate-to-severe AD showed an acceptable long-term safety profile, sustained efficacy and consistent results with other age groups**

AAD, American Academy of Dermatology; AD, atopic dermatitis; DUP, dupilumab; EASI, Eczema Area and Severity Index; EASI-75, >75% improvement in EASI score; EASI-90, >90% improvement in EASI score; OLE, open-label extension; Q2/4W, every 2/4 weeks; TCS, topical corticosteroids; TCI, topical calcineurin inhibitors; TEAE, treatment emergent adverse event.

Paller AS, et al. Presented at: AAD Annual Meeting 2025, Orlando, FL, USA. 7–11 March 2025. Poster #62960.

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AAD 2025: Amlitelimab in patients aged >12 years with AD

RIVER-AD interim analysis: A 28-week OLE study of safety and efficacy of amlitelimab in patients with AD not initially achieving clinical response at week 24 of the STREAM-AD phase IIb trial	
Objective(s)	• Evaluate the safety and efficacy in participants who did not achieve clinical response (defined as reaching EASI-75 and/or IGA 0/1) at week 24 of STREAM-AD who then entered RIVER-AD, and received 28 weeks of open-label amlitelimab
Study cohort and methods	• Participants in RIVER-AD long-term extension study (NCT05492578) aged >12 years received subcutaneous amlitelimab 250 mg Q4W: — **Interim analysis at week 28** assessing EASI-75, EASI-90 and IGA 0/1
Results	• In patients **previously treated with amlitelimab in STREAM-AD** (n=91 at week 24), continued treatment in RIVER-AD improved clinical response, with clinical responder rates as follows: — **EASI-75: 81.5%; EASI-90: 44.4%; IGA 0/1: 48.1%** • In patients **previously treated with placebo in STREAM-AD** (n=38 at week 24), treatment initiation with amlitelimab in RIVER-AD improved clinical response, with clinical responder rates as follows: — **EASI-75: 80.6%; EASI-90: 52.8%; IGA 0/1: 41.7%** • Amlitelimab was well-tolerated regardless of previous dosing and treatment during 24 weeks of STREAM-AD • **Safety profile** observed up to week 28 of RIVER-AD was consistent with that previously reported in STREAM-AD parts 1 and 2 — **50.4%** of RIVER-AD participants experienced **any TEAE by week 28** — One patient experienced a TEAE leading to treatment discontinuation
Conclusions	• **Clinical improvements with an additional 28 weeks of 250 mg subcutaneous amlitelimab Q4W were seen in participants with moderate-to-severe AD who had not yet achieved clinical response (EASI-75 or IGA 0/1) by week 24 in STREAM-AD** • **Amlitelimab was well tolerated with no new safety concerns identified in this interim analysis of the ongoing RIVER-AD OLE study**

AAD, American Academy of Dermatology; AD, atopic dermatitis; DUP, dupilumab; EASI, Eczema Area and Severity Index; EASI-75, >75% improvement in EASI score; EASI-90, >90% improvement in EASI score; IGA 0/1, achieved IGA of 0 (clear) or 1 (almost clear) with >2-grade improvement; OLE, open-label extension; Q2W, every 2 weeks; TEAE, treatment emergent adverse event.

Thaçi D, et al. Presented at AAD Annual Meeting 2025, Orlando, FL, USA. 7–11 March 2025. Poster #63598.

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Treating moderate-to-severe atopic dermatitis in children and adolescents: Insights from the experts

Data updates
December 2024

Date of preparation: 16 December 2024

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Clinical trial data updates were presented at EADV 2024

	Long-term efficacy and safety of abrocitinib in adolescents with moderate-to-severe AD[1]	Remission with dupilumab in paediatrics and adolescents with moderate-to-severe AD (LIBERTY AD PED OLE)[2]
Methods	• Post hoc analysis of clinical trial data • **Adolescents** aged 12 to <18 years in: **JADE MONO-1** (NCT03349060), **JADE MONO-2** (NCT03575871), **JADE TEEN** (NCT03796676) and **JADE REGIMEN** (NCT03627767) trials who then enrolled in the phase III extension trial, **JADE EXTEND** (NCT03422822)	• Patients aged 6 to <18 years who were enrolled in the ongoing **LIBERTY AD PED OLE** (NCT02612454) (N=356) • Clinical remission was defined as maintaining IGA 0/1 for ≥12 weeks after 40 weeks on dupilumab

Results	• Efficacy cohort: **200 mg** (n=170) vs **100 mg** (n=187)
	• Comparable outcomes achieved in both dosing arms at week 112:
	  • **EASI-75: 85%** vs **83%**
	  • **EASI-90: 62%** vs **60%**
	  • **IGA 0/1: 57%** vs **57%**
	  • **Improvements** in **CDLQI, PP-NRS**, and **PtGA** scores observed by week 2 were maintained to week 112
	• Safety cohort: **200 mg** (n=289) vs **100 mg** (n=201)
	• IRs for severe TEAEs were similar across doses:
	  • **4.67** (95% CI 3.03–6.90) vs **4.98** (95% CI 3.04–7.70)
		• Clinical remission was achieved with dupilumab for:
		  • **Adolescents: 29%** (n=30/102)
		  • **Children: 29%** (n=73/254)
		• Following dupilumab discontinuation, clinical remission was maintained in:
		  • **Adolescents: 43%** (n=13/30)
		  • **Children**: **60%** (n=44/73)
		• Median time from drug withdrawal to last visit off drug was 18.0 and 15.7 weeks, respectively

Conclusions	**Abrocitinib efficacy was maintained up to 112 weeks and showed an acceptable safety profile with no new safety signals observed with up to 4.6 years' exposure**	**About half of paediatric patients experiencing sustained remission on dupilumab maintained prolonged remission off treatment. There is a higher likelihood of therapy-free remission in younger patients.**

AD, atopic dermatitis; CDLQI, Children's Dermatology Life Quality Index; CI, confidence interval; EADV, European Academy of Dermatology and Venereology; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; IR, incidence rate; OLE, open-label extension; PP-NRS, peak pruritus numeric rating scale; PtGA, Patient Global Assessment; TEAE, treatment-emergent adverse event.

1. Paller A, et al. Presented at EADV 2024 (25–28 September, Amsterdam, Netherlands). Abstract #2323;
2. Siegfried EC, et al. Presented at EADV 2024 (25–28 September, Amsterdam, Netherlands). Abstract #5487.

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Real-world data were presented at EADV 2024

	RWE for dupilumab in paediatric AD in Spain: Analysis of the adolescent cohort (READAP study)[1]	RWE for tralokinumab in adolescents with moderate-to-severe AD[2]
Baseline characteristics and methods	• National, multi-centre, retrospective analysis of medical records • **Adolescents** aged 12–17 years received **dupilumab for ≥3 months** • **98%** had received **prior systemic therapy** (cyclosporine [23%]) • **72%** had **≥1 atopic comorbidity** (asthma [57%], food allergy [51%])	• National, multi-centre, retrospective medical record analysis • **Adolescents** aged 12–17 years **naive to biologics and JAKis** • **62%** had **≥1 atopic comorbidity** (most commonly asthma) • Received **16 weeks of treatment with tralokinumab**

Results	• In 124 adolescents, changes in outcome measures from baseline at 16 and 52 weeks were:
	• Reduction in EASI from baseline: 76% vs 87%
	  • **Achieved EASI ≤7: 70%** vs **85%**
	  • **Achieved IGA 0/1: 60%** vs **75%**
	  • **Reduction of ≥4 points in PP-NRS: 54%** vs **71%**
	  • **Reduction of ≥6 points in DLQI: 67%** vs **77%**
	• **No serious AEs** related to dupilumab were reported; overall:
	  • **7%** of patients reported **conjunctivitis**
	  • **0.8%** reported **treatment-related eosinophilia**
	They did not result in treatment discontinuation
		• All patients (n=21) presented with severe disease at baseline:
		  • **EASI score: 24**
		  • **Body surface area: 34%**
		  • **IGA score: 3**
		  • **Itch-NRS: 7**
		• Substantial improvements were observed across all scales
		• **Safety** profile remained **consistently acceptable** throughout study

Conclusions	**Dupilumab rapidly achieved (by 16 weeks) and maintained (to week 52) improved eczema severity, pruritus intensity, and QoL in most patients, with an acceptable safety profile**	**Tralokinumab was well-tolerated and effective in treating adolescents with AD regardless of age, sex, AD phenotype, or ethnicity; tralokinumab may be a valuable therapeutic option for moderate-to-severe AD**

AD, atopic dermatitis; AE, adverse event; DLQI, Dermatology Life Quality Index; EADV, European Academy of Dermatology and Venereology; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; Itch-NRS, Itch-numeric rating scale; JAKi, Janus kinase inhibitor; PP-NRS, peak pruritus numeric rating scale; QoL, quality of life; RWE, real-world evidence. 1. De Lucas CR, et al. Presented at EADV 2024 (25–28 September, Amsterdam, Netherlands). Abstract #3786; 2. Noguera L, et al. Presented at EADV 2024 (25–28 September, Amsterdam, Netherlands). Abstract #4031.

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Insights on treatment goals and preferences were shared at EADV 2024

	Treatment goals and preferences in paediatric AD: Perspectives from Dutch patients and their caregivers
Methods	• A web-based survey of **Dutch children** (aged 6–11 years), **adolescents** (aged 12–17 years), **young patients** (aged 18–30 years) and **caregivers** of patients with AD

Results	• 279 respondents (28 children, 34 adolescents, 115 young adults and 102 caregivers) identified the following as most important:
	  • **Treatment goals: 'no itch', 'no lesions' and 'preventing new AD lesions'**
	  • **Treatment characteristics: 'long-term safety', high effectiveness' and 'short-term safety'**
	• **Young patients** considered **convenience of treatment** as **more important**, compared with caregivers, including:
	  • **'Easy to travel with' (p=0.005)**
	  • **'Consumes little time' (p=0.003)**
	  • **'Not sticky/greasy' (p=0.022)**
	  • **Minimal monitoring e.g. 'no/few hospital visits' (p=0.017); 'no/few blood samples needed' (p=0.058)**
	• **Caregivers** considered long- (p<0.001) and short-term (p=0.001) **safety** as **more important** compared with young patients
	• **Psychosocial goals** were considered **more important to paediatric patients**, compared with young adult patients:
	  • **'Feeling less depressed or sad' (p=0.015)**
	  • **'Not being different from peers' (p<0.001)**
	  • **'Being able to have more contact with peers' (p<0.001)**
	• **Psychosocial goals** were considered **more important in patients with moderate-to-severe AD** than in patients with mild AD
	• Gender, current treatment, presence of visible lesions and atopic comorbidities, were factors affecting differences in goals and preferences

Conclusions	**Young patients with AD and their caregivers mainly strive to clear itch and lesions with effective and safe treatment. However, perspectives differ within individuals at different stages of life. The identified differences underline the relevance of addressing individual needs and contribute to improved patient-centred care.**

AD, atopic dermatitis; EADV, European Academy of Dermatology and Venereology.
van der Rijst L, et al. Presented at EADV 2024 (25–28 September, Amsterdam, Netherlands). Abstract #4925.

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The EMA has updated the posology recommendations and safety profile information for upadacitinib in adolescents with AD

October 2024 updates to the SmPC:

Safety profile[1]

541 adolescents (aged 12 to 17 years) with AD treated in the global phase III (n=343) and supplemental studies (n=198)

Upadacitinib exposure in these adolescent cohorts
- 15 mg (n=264)
- 30 mg (n=265)

Safety profile for upadacitinib 15 mg and 30 mg in adolescents was similar to that in adults

In these adolescents with long-term exposure to upadacitinib, reported **skin papilloma** rates were:

3.4% (15 mg) vs **6.8%** (30 mg)

For more information, please refer to the SmPC[2]

Posology[1,2]

Based on results from studies M16-045 (Measure Up 1), M16-047 (AD Up) and M18-891 (Measure Up 2) Section 4.2 of the SmPC is updated to reflect:[1,2]

- ***In adolescents (12 to 17 years of age) weighing ≥30 kg,*** *a dose of* ***15 mg is recommended***
- *If the patient* ***does not respond adequately*** *to 15 mg once daily, the* ***dose can be increased to 30 mg once daily***

AD, atopic dermatitis; EMA, European Medicines Agency; SmPC, summary of product characteristics.

1. EMA. Available at: https://rb.gy/qeypfd (accessed 16 December 2024); 2. EMA. Upadacitinib SmPC. October 2024. Available at https://rb.gy/3gph7h (accessed 16 December 2024).

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