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

Data updates
January 2025

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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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