Clinical Remission and Off-Treatment Remission in Pediatric Patients With Moderate-to-Severe Atopic Dermatitis Treated With Dupilumab: Open-Label Extension Study Preliminary Data

Atopic Dermatitis

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- Pediatric and adolescent patients with moderate-to-severe atopic dermatitis (AD) have a high burden of disease
- Higher disease severity and earlier onset predict disease persistence



 Early intervention with targeted therapies during infancy and childhood may have the potential to impact AD disease trajectory and associated atopic morbidities, and promote long-term remission^{1,2}



 Concerns among physicians and caregivers about the need for longterm systemic treatment may be mitigated by data supporting the possibility of disease remission





To assess the incidence of clinical remission on dupilumab and maintenance of remission after treatment discontinuation in pediatric and adolescent patients with moderate-to-severe atopic dermatitis





Baseline

16 weeks

N = 321

 $N = 294^{a}$

OLE Baseline

52 weeks

LIBERTY AD PEDS (N = 367)

- Phase 3 double-blind trial
- Children aged 6 to 11 years

Placebo + TCS

300 mg dupilumab q4w + TCS

100 mg (≤30 kg) or 200 mg (≥30 kg) dupilumab q2w + TCS

NCT03345914

LIBERTY AD PED-OLE^b

- Open-label extension study
- Children aged 6 to 17 years who completed at least 52 weeks of follow-up

300 mg dupilumab q4w + TCSc

- Clinical remission was defined as maintaining an IGA score of 0 or 1 (clear/almost clear skin) for at least 12 weeks after 40 weeks on dupilumab
- **Remission off treatment** was defined as maintaining an IGA score of 0 or 1 (clear/almost clear skin) for at least 12 weeks off treatment NCT02612454

- LIBERTY AD ADOL (N = 251)
- Phase 3 double-blind trial
- Children aged 12 to 17 years

Placebo

300 mg dupilumab q4w 200 mg (≤60 kg) or 300 mg (≥60 kg) dupilumab q2w

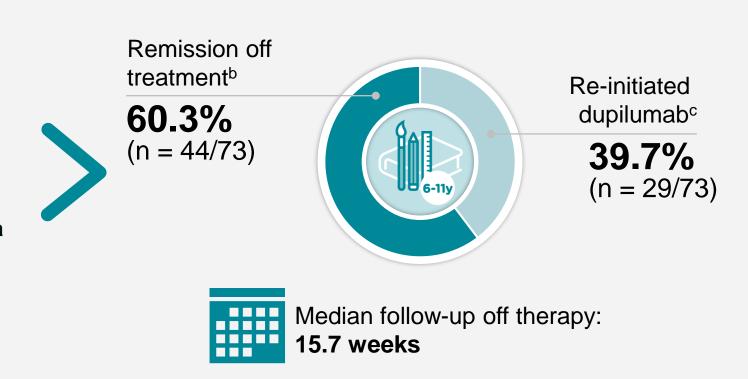
NCT03054428

- ^aAdditional patients enrolled from R688-AD-1412 (NCT02407756), and R688-AD-1607 (NCT03050151).
- ^bSome patients transitioned directly from the parent studies to the open-label extension, while others had a time lapse in between.
- ^oDupilumab dosing could be titrated to every 2 weeks if response was inadequate.
- IGA, Investigator's Global Assessment; q2w, every 2 weeks; q4w, every 4 weeks; TCS, topical corticosteroids.



Children aged 6 to 11 years achieving clinical remission on therapy and maintaining remission off treatment

28.7% (n = 73/254)
of children with severe AD treated
with dupilumab for at least 52 weeks
achieved clinical remission^a



AD, atopic dermatitis; IGA, Investigator's Global Assessment.

Cork MJ, et al. Dermatol Ther (Heidelb). 2023;13:2697-719.

^aDefined as maintenance of an IGA score of 0 or 1 (clear/almost clear) for ≥12 weeks after 40 weeks on dupilumab.

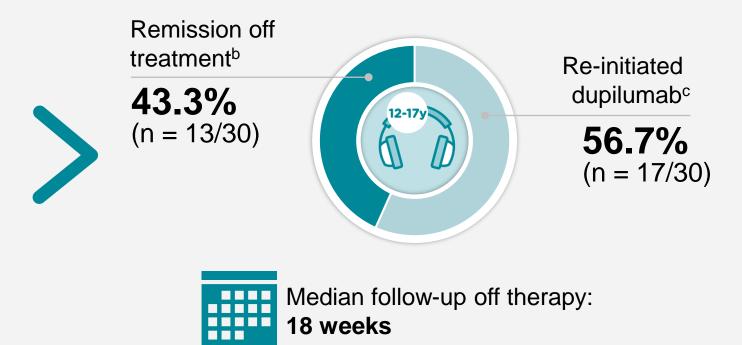
^bMaintained clear/almost clear skin for at least 12 weeks.

^cPatients who reached an IGA score ≥2 (mild disease and above) within the follow up period re-started treatment with dupilumab. In these cases, investigators were encouraged to consider treatment with topical therapy and to re-initiate dupilumab only for patients who did not respond adequately after 7 days of topical treatment.



Adolescents aged 12 to 17 years achieving clinical remission on therapy and maintaining remission off treatment

29.4% (n = 30/102) of adolescents with moderate-to-severe AD treated with dupilumab for at least 52 weeks **achieved clinical remission**^a



Blauvelt A, et al. Am J Clin Dermatol. 2022;23:365-83.

^aDefined as maintenance of an IGA score of 0 or 1 (clear/almost clear) for ≥12 weeks after 40 weeks on dupilumab.

bMaintained clear/almost clear skin for at least 12 weeks.

^cPatients who reached an IGA score ≥2 (mild disease and above) within the follow-up period re-started treatment with dupilumab. In these cases, investigators were encouraged to consider treatment with topical therapy and to re-initiate dupilumab only for patients who did not respond adequately after 7 days of topical treatment.

AD, atopic dermatitis; IGA, Investigator's Global Assessment.



- About one-third of pediatric patients achieved clinical remission on dupilumab and about half of these patients maintained remission off treatment for at least 12 weeks
- The incidence of remission off treatment is higher in younger patients