

Dupilumab Provides Long-Term Improvement of Sleep Loss in Children, Adolescents, and Adults With Atopic Dermatitis

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BACKGROUND

- Atopic dermatitis (AD), an immune-mediated type 2 inflammatory disease, is associated with impaired sleep quality in patients of all ages^{1,2}
- Sleep disturbance is a major factor leading to impaired quality of life, and is an important measure of disease severity³

OBJECTIVE

- To evaluate the effect of dupilumab treatment on sleep loss in children, adolescents, and adults with AD in phase 3 trials and subsequent extension trials up to 1 year

METHODS

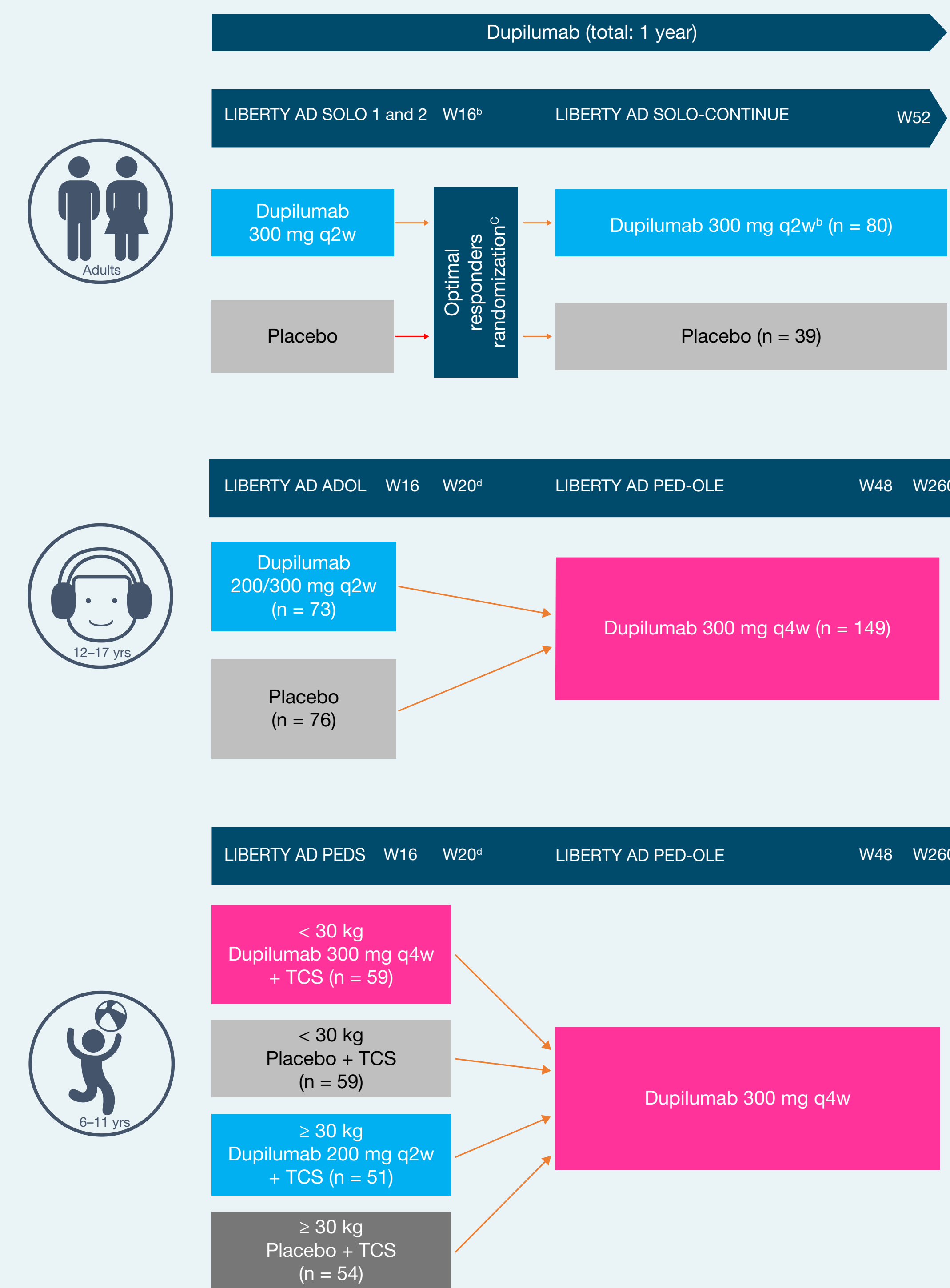
- This analysis includes data from LIBERTY AD SOLO 1 and 2 (NCT02277743, NCT02277769),⁴ SOLO-CONTINUE (NCT02395133),⁵ LIBERTY AD ADOL (NCT03054428),⁶ LIBERTY AD PEDS (NCT03345914),⁷ and LIBERTY AD PED-OLE (NCT02612454)⁸
- Intensity of sleep loss was evaluated using SCORing AD (SCORAD) sleep loss Visual Analog Scale (VAS) score, range 0 (no sleeplessness) – 10 (worst imaginable sleeplessness), over the last 3 days or nights

CONCLUSIONS

- Dupilumab treatment for up to 1 year provides sustained improvement in sleep loss as assessed by SCORAD sleep loss VAS in children with severe AD, and adolescents and adults with moderate-to-severe AD

METHODS (CONT.)

Figure 1. Analysis overview.^a



^aThis figure indicates the treatment groups used in the current analysis; the full study designs and primary analyses have already been published.⁴⁻⁸
^bDay 1 of SOLO-CONTINUE is W16 of SOLO 1 and 2. ^cOnly optimal responders (patients achieving either IGA 0/1 or EASI 75 at W16 in SOLO 1 and 2) were eligible to continue treatment in SOLO-CONTINUE. ^dFirst dose in PED-OLE was administered within 28 days of W16 of the parent study. EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; q2w, every 2 weeks; q4w, every 4 weeks; TCS, topical corticosteroids; W, week.

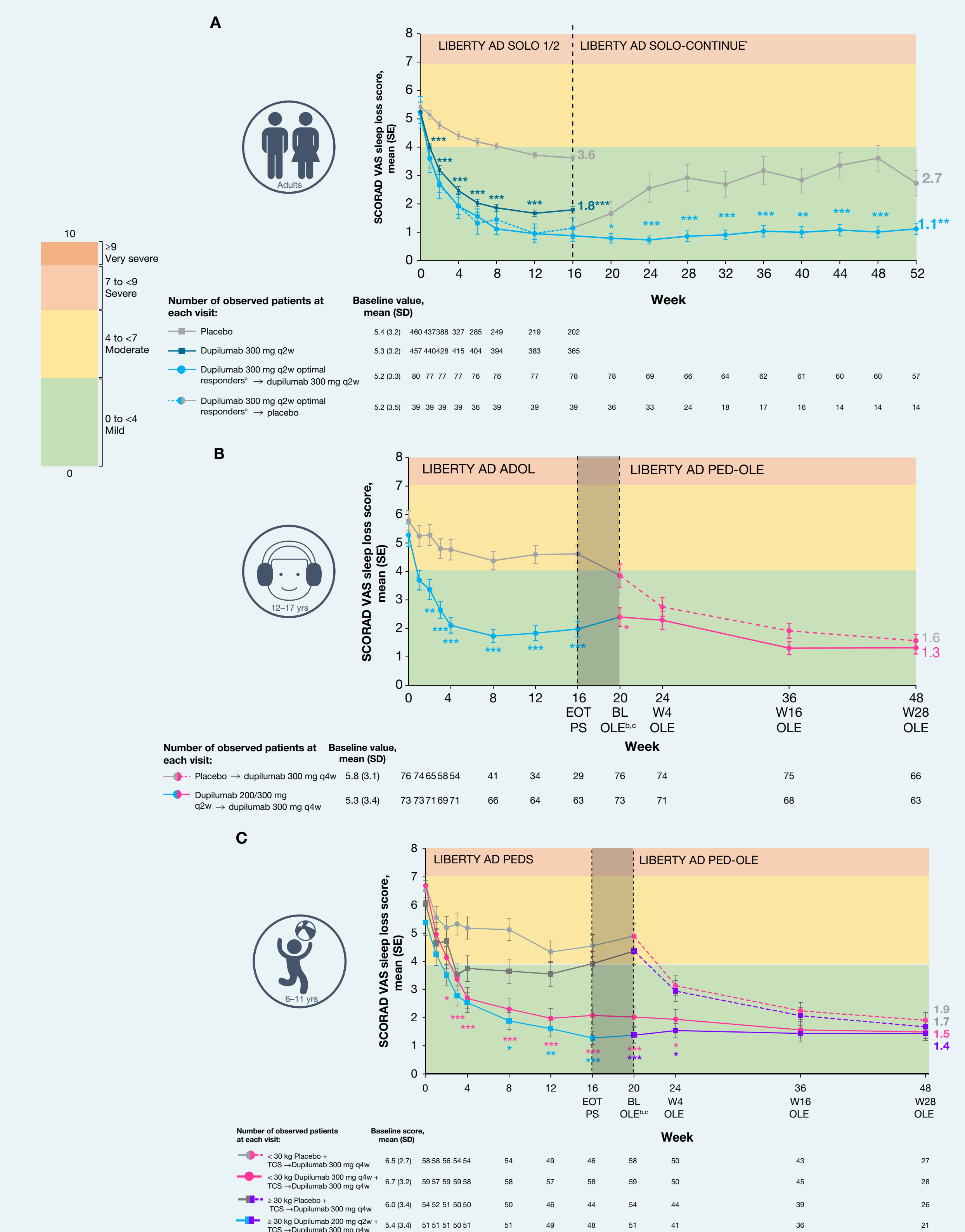
RESULTS

Safety

- Safety data were consistent with the known safety profile for dupilumab⁴⁻⁸

RESULTS (CONT.)

Figure 2. SCORAD sleep loss VAS score during dupilumab treatment for up to 1 year in (A) adults with moderate-to-severe AD who achieved an optimal response at Week 16 of SOLO 1 and 2, (B) adolescents with moderate-to-severe AD, and (C) children with severe AD.



^aOnly optimal responders (patients achieving either IGA 0/1 or EASI 75 at Week 16 in SOLO 1 and 2) were eligible to continue treatment in SOLO-CONTINUE. ^bPatients received the first dose in the PED-OLE study within 28 days after completion of the parent study. ^cThe n numbers in OLE for pediatrics reduce over time not due to drop out, but because patients did not reach the time point. Data were treated as missing after use of rescue medication or treatment discontinuation. Missing data were imputed using the multiple imputation method. BL, baseline; EOT, end of treatment; LS, least squares; PS, parent study; SD, standard deviation; SE, standard error. *P < 0.05; **P < 0.001; ***P < 0.0001.

References: 1. Ramirez FD, et al. JAMA Pediatr. 2019;173:e190025. 2. Kaaz K, et al. Acta Derm Venereol. 2019;99:175-80. 3. Chang YS, Chiang BL. J Allergy Clin Immunol. 2018;142:1033-40. 4. Simpson EL, et al. N Engl J Med. 2016;375:2335-48. 5. Worm M, et al. JAMA Dermatol. 2020;156:131-43. 6. Simpson EL, et al. JAMA Dermatol. 2020;156:44-56. 7. Paller AS, et al. J Am Acad Dermatol. 2020;83:1282-93. 8. Cork MJ, et al. Br J Dermatol. 2021;184:857-70.

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