Long Term Laboratory Safety of Dupilumab in Patients Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis

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Introduction: Systemic treatments often require laboratory monitoring. Here we report 52-week laboratory safety data for dupilumab-treated children aged 6 months to 5 years with moderate-to-severe AD.

Methods: LIBERTY AD PED-OLE (NCT02612454) is an open-label extension study of children aged 6 months to <18 years with moderate-to-severe AD. This analysis includes hematologic and chemistry laboratory parameters in children aged 6 months to 5 years treated with dupilumab every 4 weeks (q4w; 200 mg: ≥5kg to <15kg; 300 mg: ≥15kg to <30kg).

Results: Of the 180 patients enrolled, 122 (67.8%) completed up to 16 weeks and 30 (16.7%) completed up to 52 weeks. Mean (SD) eosinophil counts increased slightly from baseline (1.15 × 10^9/L [1.18]) to Week 16 (1.5 × 10^9/L [1.91]), but then decreased below baseline by Week 52 (0.80 × 10^9/L [0.64]). Mean (SD) platelet counts were relatively stable with a modest decrease from baseline (388.7 × 10^9/L [102.51]) to Week 52 (356.1 × 10^9/L [107.48]). Chemistry parameters remained within

the normal reference ranges. One patient (0.6%) reported a mild case of anemia, and one patient (0.6%) reported a mild case of thrombocytopenia, which were resolving and resolved at the time of this interim analysis, respectively. Overall safety was consistent with the known dupilumab safety profile.

Conclusions: No clinically meaningful changes in hematologic and chemistry parameters were observed during 52 weeks of dupilumab treatment. As with adults, adolescents and older children, routine laboratory monitoring is unnecessary in children aged 6 months to 5 years with moderate-to-severe AD.

Keywords: pediatric, moderate-to-severe, atopic dermatitis, hematology, safety

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