Efficacy and Safety of Dupilumab in Children Aged 6–11 Years with Inadequately Controlled Severe Atopic Dermatitis: Results From an Open-Label Extension Trial up to 1 Year

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Background: Atopic dermatitis (AD), a common chronic inflammatory type 2 systemic disease, is characterized by pruritus, disruption of skin barrier function and eczematous lesions. Treatment options are limited, especially for children with moderate-to-severe AD. Dupilumab has previously demonstrated significant efficacy and an acceptable safety profile in patients with type 2 inflammatory diseases such as AD, asthma and chronic rhinosinusitis with nasal polyps. Here, we report the long-term efficacy and safety of dupilumab in patients aged 6–11 years with severe AD who enrolled in the open-label extension (OLE) study (NCT02612454).

Methods: Children aged 6–11 years with severe AD who had participated in the 16 week, double-blind, phase 3 LIBERTY AD PEDS study (NCT03345914; parent study) were enrolled into the long-term, multicentre OLE study. Patients enrolled in the OLE were treated with 300 mg dupilumab every four weeks. If treatment response was inadequate, defined as failure to achieve an Investigator's Global Assessment score of 0/1 within 16 weeks of treatment initiation, treatment could be up-titrated to 200 mg or 300 mg every 2 weeks (for patients weighing <60 kg or ≥60 kg, respectively). Patients were permitted to receive concomitant topical treatments. Data are presented as observed.

Results: The 321 patients enrolled in this OLE had a mean (standard deviation [SD]) age of 8.6 (1.7) years and a mean (SD) AD duration of 7.4 (2.2) years. Mean percentage change (SD) from parent study

baseline (PSBL) to OLE baseline in Eczema Area and Severity Index (EASI) was −62.5 (34.4). Improvements in mean percentage change from PSBL in EASI were seen at Week 16 (−79.6 [20.8]) and Week 52 (−86.0 [13.9]) of the OLE study. Relative to the PSBL, an increase in the proportion of patients achieving ≥ 50% and ≥ 75% reduction in EASI was seen from the OLE baseline (EASI-50: 230/321 [71.7%]; EASI-75: 142/321 [44.2%]) to Week 52 of OLE (EASI-50: 250/257 [97.3%]; EASI-75: 210/257 [81.7%]). Similarly, the proportion of patients achieving an Investigator's Global Assessment score of 0/1 increased from the OLE baseline (62/321 [19.3%]) to Week 52 (104/257 [40.5%]). 255 (79.4%) patients reported ≥ 1 treatment-emergent adverse events (TEAEs). The most common TEAEs were dermatitis atopic (28.7%), nasopharyngitis (17.1%) and upper respiratory tract infection (15.6%). 15 (4.7%) and 13 (4.0%) patients reported serious and severe TEAEs, respectively.

Conclusions: Dupilumab treatment resulted in substantial and sustained long-term reduction in AD signs and symptoms in patients aged 6–11 years with inadequately controlled severe AD. The long-term safety profile of dupilumab was acceptable and consistent with that previously seen in shorter term, placebo-controlled studies.

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